

GENOMIC HEALTH INC
Form 10-Q
November 09, 2012
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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2012

Or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: 000-51541

GENOMIC HEALTH, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

77-0552594
(I.R.S. Employer Identification No.)

301 Penobscot Drive

Redwood City, California 94063

(Address of principal executive offices) (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 NO

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES NO

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

Accelerated filer

Non-accelerated filer
(Do not check if a smaller reporting company)

Smaller reporting company

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

The number of outstanding shares of the registrant's Common Stock, \$0.0001 par value, was 30,749,914 as of October 31, 2012.

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Table of Contents**PART 1: FINANCIAL INFORMATION****Item 1. Financial Statements****GENOMIC HEALTH, INC.****Condensed Consolidated Balance Sheets****(In thousands)****(Unaudited)**

	September 30, 2012	December 31, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 57,959	\$ 32,869
Short-term marketable securities	68,251	67,605
Accounts receivable (net of allowance for doubtful accounts; 2012 - \$1,171, 2011 - \$1,206)	19,926	21,077
Prepaid expenses and other current assets	8,630	7,444
Total current assets	154,766	128,995
Long-term marketable securities	771	
Property and equipment, net	11,799	9,443
Other assets	5,837	4,560
Total assets	\$ 173,173	\$ 142,998
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 3,392	\$ 7,025
Accrued compensation	9,636	9,574
Accrued license fees	2,082	1,947
Accrued expenses and other current liabilities	8,122	5,501
Deferred revenues - current portion	800	1,849
Other current liabilities	93	243
Total current liabilities	24,125	26,139
Deferred revenues - long-term portion		211
Other liabilities	2,211	1,289
Commitments (Note 5)		
Stockholders' equity:		
Common stock	3	3
Additional paid-in capital	306,289	281,147
Accumulated other comprehensive income loss	16	(30)
Accumulated deficit	(159,471)	(165,761)
Total stockholders' equity	146,837	115,359
Total liabilities and stockholders' equity	\$ 173,173	\$ 142,998

See accompanying notes.

Table of Contents**GENOMIC HEALTH, INC.****Condensed Consolidated Statements of Income****(In thousands, except per share amounts)****(Unaudited)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Revenues:				
Product revenues	\$ 58,371	\$ 51,661	\$ 173,459	\$ 151,611
Contract revenues	277	397	1,287	1,102
Total revenues	58,648	52,058	174,746	152,713
Operating expenses:				
Cost of product revenues	9,037	9,195	27,377	26,480
Research and development	12,267	9,611	35,775	29,582
Selling and marketing	21,526	20,157	69,657	61,220
General and administrative	12,107	9,696	35,518	29,904
Total operating expenses	54,937	48,659	168,327	147,186
Income from operations	3,711	3,399	6,419	5,527
Interest income	77	77	226	217
Other income (expense), net	33	(113)	(112)	(191)
Income before income taxes	3,821	3,363	6,533	5,553
Income tax expense	109	138	243	266
Net income	\$ 3,712	\$ 3,225	\$ 6,290	\$ 5,287
Basic net income per share	\$ 0.12	\$ 0.11	\$ 0.21	\$ 0.18
Diluted net income per share	\$ 0.11	\$ 0.10	\$ 0.20	\$ 0.17
Shares used in computing basic net income per share	30,580	29,491	30,233	29,311
Shares used in computing diluted net income per share	32,578	30,808	32,095	30,661

See accompanying notes.

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GENOMIC HEALTH, INC.

Condensed Consolidated Statements of Comprehensive Income

(In thousands)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Net income	\$ 3,712	\$ 3,225	\$ 6,290	\$ 5,287
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale marketable securities	18	(70)	46	(32)
Comprehensive income	\$ 3,730	\$ 3,155	\$ 6,336	\$ 5,255

See accompanying notes.

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GENOMIC HEALTH, INC.

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2012	2011
Operating activities		
Net income	\$ 6,290	\$ 5,287
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	3,974	5,506
Stock-based compensation	10,807	8,805
Gain on disposal of property and equipment	(3)	(7)
Share of loss of equity method investee	98	119
Changes in assets and liabilities:		
Accounts receivable	1,151	(8,340)
Prepaid expenses and other assets	(1,269)	(32)
Accounts payable	(3,633)	(1,246)
Accrued compensation	62	1,081
Accrued expenses and other liabilities	3,046	588
Deferred revenues	(818)	(1,033)
Net cash provided by operating activities	19,705	10,728
Investing activities		
Purchases of property and equipment	(6,170)	(4,541)
Purchases of marketable securities	(61,496)	(89,482)
Maturities of marketable securities	60,125	85,972
Purchase of other investments	(1,409)	(2,300)
Net cash used in investing activities	(8,950)	(10,351)
Financing activities		
Net proceeds from issuance of common stock under stock plans	14,335	6,721
Net cash provided by financing activities	14,335	6,721
Net increase in cash and cash equivalents	25,090	7,098
Cash and cash equivalents at the beginning of the period	32,869	31,183
Cash and cash equivalents at the end of the period	\$ 57,959	\$ 38,281
Supplemental disclosure of cash flow information		
Cash paid for income taxes	\$ 75	\$ 73

See accompanying notes.

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GENOMIC HEALTH, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2012

(Unaudited)

Note 1. Organization and Summary of Significant Accounting Policies

The Company

Genomic Health, Inc. (the Company) is a global health company that provides actionable genomic information to personalize genomic health 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 *Oncotype 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 *Oncotype DX* colon cancer test, which is used to predict the likelihood of colon cancer recurrence in patients with stage II disease. In late December 2011, the Company made *Oncotype 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 extended its offering of the *Oncotype DX* colon cancer test to certain patients with stage III disease.

Principles of Consolidation

The condensed consolidated financial statements include all the accounts of the Company and its wholly-owned subsidiaries. The Company has three wholly-owned subsidiaries. Genomic Health International Sarl, a company incorporated and registered in Switzerland, Genomic Health International Holdings, LLC, a Delaware company, and *Oncotype Laboratories, Inc.*, an inactive Delaware corporation. Genomic Health International Holdings, LLC has three wholly-owned subsidiaries: Genomic Health U.K., Ltd., Genomic Health Germany GmbH and Genomic Health Canada. The functional currency for the Company's wholly-owned subsidiaries incorporated outside of 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 (U.S. GAAP). The condensed consolidated balance sheet as of September 30, 2012, the condensed consolidated statements of income for the three and nine months ended September 30, 2012 and 2011, the condensed consolidated statements of comprehensive income for the three and nine months ended September 30, 2012 and 2011, and the condensed consolidated statements of cash flows for the nine months ended September 30, 2012 and 2011 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

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periods presented. The condensed consolidated balance sheet at December 31, 2011 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 amounts reported 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, 2011.

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 *Oncotype 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 an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectibility 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 *Oncotype DX* test. In the absence of such arrangements, the Company considers that criterion (1) is satisfied when consistent payment patterns have been established from a third-party payor 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. Determinations 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 collectibility of those fees under any contract or arrangement. When evaluating collectibility, 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 enters into exclusive distribution agreements for the sale of its tests in various countries outside of the United States. In these 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 \$541,000 and \$562,000 at September 30, 2012 and December 31, 2011, respectively.

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

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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 income. 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 as of September 30, 2012 and December 31, 2011 was \$1.2 million and \$1.2 million, respectively. Write-offs for doubtful accounts of \$972,000 and \$2.6 million were recorded against the allowance during the three and nine months ended September 30, 2012, respectively, and write-offs of \$797,000 and \$2.3 million were recorded during the three and nine months ended September 30, 2011, respectively. Bad debt expense was \$998,000 and \$2.6 million for the three and nine months ended September 30, 2012, respectively, and \$939,000 and \$2.5 million for the three and nine months ended September 30, 2011, respectively.

Research and Development Expenses

Research and development expenses consist 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 the costs associated with these arrangements as research and development expenses. The Company records accruals for estimated study costs consisting 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 representing 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 accounted for under the cost method are subject to impairment evaluation on a quarterly basis. The fair value of a cost method investment is not estimated if there are no identified events or changes in circumstances that may have a significant adverse effect on the fair value of the investment. 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. No impairment with respect to the Company's investments in privately held companies was recognized through September 30, 2012.

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. During the quarter ended June 30, 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. Therefore, the net carrying value of this investment of \$643,000 is reflected at cost at September 30, 2012.

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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 second financing, the Company's initial redeemable preferred stock investment was reclassified 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 new investment is considered to be an equity security. 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 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, reflected at cost, was \$3.3 million and \$2.3 million at September 30, 2012 and December 31, 2011, respectively.

The Company's investments in privately held companies were \$3.9 million and \$2.6 million at September 30, 2012 and December 31, 2011, respectively, and were included in other assets on the Company's condensed consolidated balance sheets.

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In June 2011, the Financial Accounting Standards Board (FASB) issued authoritative guidance requiring companies to present items of net income, items of other comprehensive income and total comprehensive income in one continuous statement or two consecutive statements. This guidance eliminates the option for companies to present other comprehensive income in the statement of stockholders' equity. This guidance is effective for the Company for interim and annual periods beginning January 1, 2012. In December 2011, FASB released an update that deferred a portion of the new accounting requirements for comprehensive income. As this guidance provides only presentation requirements, the adoption of this guidance does not impact the Company's financial condition or results of operations. The Company adopted this standard in January 2012, as reflected by the inclusion of the Condensed Consolidated Statements of Comprehensive Income as part of its Condensed Consolidated Financial Statements.

In June 2011, the FASB issued amendments to authoritative guidance for measuring fair value when required or permitted by other accounting standards. The amendments are intended to result in common fair value measurement and disclosure requirements under GAAP and International Financial Reporting Standards. Some of the amendments clarify the FASB's intent about the application of existing fair value measurement requirements. Other amendments change a particular principle or requirement for measuring fair value or for disclosing information about fair value measurements. This amended guidance, which the Company does not expect to have a material impact on its financial condition and results of operations, is effective for the Company for interim and annual periods beginning January 1, 2012. The Company adopted this standard in January 2012, as reflected in Note 3, Fair Value Measurements, of its Condensed Consolidated Financial Statements.

Note 2. Net Income Per Share

Basic net income per share is calculated by dividing net income for the period by the weighted-average number of common shares outstanding for the period without consideration of potential common shares. Diluted net income per share is calculated by dividing net income 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 which are considered to be potential common shares and are anti-dilutive are not included in the calculation of diluted net income per share because their effect is anti-dilutive.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
	(In thousands)			
Numerator:				
Net income	\$ 3,712	\$ 3,225	\$ 6,290	\$ 5,287
Denominator:				
Weighted-average shares of common stock outstanding used in the calculation of basic net income per share	30,580	29,491	30,233	29,311
Effect of dilutive securities:				
Options to purchase common stock	1,844	1,267	1,758	1,318
Restricted stock units	154	50	104	32

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Weighted-average shares of common stock
outstanding used in the calculation of diluted

	32,578		30,808		32,095		30,661
Basic net income per share	\$ 0.12	\$	0.11	\$	0.21	\$	0.18
Diluted net income per share	\$ 0.11	\$	0.10	\$	0.20	\$	0.17

Options to purchase approximately 87,000 and 116,000 weighted average shares of the Company's common stock that were outstanding during the three and nine months ended September 30, 2012, respectively, were not included in the computation of diluted net income per share because their effect was anti-dilutive. Options to purchase approximately 156,000 and 147,000 weighted average shares of the Company's common stock that were outstanding during the three and nine months ended September 30, 2011, respectively, were not included in the computation of diluted net income per share because their effect was anti-dilutive.

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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.

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 September 30, 2012 and December 31, 2011, respectively. The following tables set forth the Company's financial instruments that were measured at fair value on a recurring basis at September 30, 2012 and December 31, 2011 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 September 30, 2012
(In thousands)				
As of September 30, 2012:				
Assets				
Money market deposits	\$ 6,731	\$	\$	\$ 6,731
U.S. Treasury securities	1,284			1,284
Debt securities of U.S. government-sponsored entities		767		767
Commercial paper		26,263		26,263
Corporate debt securities		40,708		40,708
Total	\$ 8,015	\$ 67,738	\$	\$ 75,753

	Actively Quoted Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	Balance at December 31, 2011
(In thousands)				

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As of December 31, 2011:

Assets

Money market deposits	\$	7,377	\$	\$	\$	7,377
Debt securities of U.S. government-sponsored entities				19,350		19,350
Commercial paper				19,999		19,999
Corporate debt securities				29,005		29,005
Total	\$	7,377	\$	68,354	\$	75,731

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 and 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 and nine months ended September 30, 2012 and 2011, respectively.

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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:

	Amortized Cost	September 30, 2012		Estimated Fair Value
		Unrealized Gains	Unrealized Losses	
U.S. Treasury securities	\$ 1,283	\$ 1	\$	\$ 1,284
Debt securities of U.S. government-sponsored entities	767			767
Commercial paper	26,244	19		26,263
Corporate debt securities	40,712	7	(11)	40,708
Total	\$ 69,006	\$ 27	\$ (11)	\$ 69,022

	Amortized Cost	December 31, 2011		Estimated Fair Value
		Unrealized Gains	Unrealized Losses	
Debt securities of U.S. government-sponsored entities	\$ 19,351	\$ 2	\$ (2)	\$ 19,351
Commercial paper	19,232	17		19,249
Corporate debt securities	29,052	5	(52)	29,005
Total	\$ 67,635	\$ 24	\$ (54)	\$ 67,605

The Company had no realized gains or losses on available-for-sale marketable securities for the three and nine months ended September 30, 2012 and 2011, respectively.

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

	September 30, 2012		December 31, 2011	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
Due in one year or less	\$ 68,236	\$ 68,251	\$ 67,635	\$ 67,605
Due in more than one year but less than five years	770	771		
Total	\$ 69,006	\$ 69,022	\$ 67,635	\$ 67,605

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 \$370,000 and \$1.4 million for the three and nine months ended September 30, 2012, respectively, and \$451,000 and \$2.2 million for the three and nine months ended September 30, 2011, respectively, relating to services provided in connection

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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.

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 *Oncotype 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 \$2.0 million and \$6.0 million for the three and nine months ended September 30, 2012, respectively, and \$2.9 million and \$7.8 million for the three and nine months ended September 30, 2011, respectively, which were included in cost of product revenues. A reduction in license fees for the quarter ended September 30, 2012 compared to the quarter ended September 30, 2011 resulted from the execution of an amendment to a license agreement that reduced the rate paid on polymerase chain reaction based product revenues recorded after July 1, 2011.

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At September 30, 2012, fixed future annual payments, exclusive of royalty payments, relating to the launch and commercialization of the *Oncotype DX* colon cancer test totaled \$1.4 million and are payable as follows:

	Fixed Future Annual Payments (In thousands)
Payment Due:	
January 2013	\$ 450
January 2014	450
January 2015	450
Total	\$ 1,350

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 an 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 represents a substantive milestone and the Company will recognize the \$1.5 million payment upon completion. 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. The Company did not recognize any revenue related to substantive milestones under this agreement during the three and nine months ended September 30, 2012 and 2011, respectively.

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 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. Upon execution of the lease amendment, the Company agreed to pay a \$317,000 cash security deposit, which is included in other assets on the condensed consolidated balance sheets, in exchange for the release of a \$500,000 letter of credit held as security under the original lease. The letter of credit was released in January 2011.

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In January 2007, the Company entered into a non-cancelable lease for an additional 48,000 square feet of laboratory and office space in Redwood City. In November 2010, the Company executed an amendment to extend the term of the lease through March 2018, with an option to extend the term of 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 connection with this lease, the Company paid a \$151,000 cash security deposit, which is included in other assets on the condensed consolidated balance sheets.

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 currently occupies in Redwood City. 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 which are being amortized on a straight-line basis over the life of the lease. In connection with this lease, the Company paid a \$183,000 cash security deposit, which is included in other assets on the condensed consolidated balance sheets.

In May 2010, the Company's Swiss 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. In connection with this lease, the Company paid a CHF 100,800 cash security deposit, which is included in other assets on the condensed consolidated balance sheets.

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Future non-cancelable commitments under these operating leases at September 30, 2012 were as follows:

Years Ending December 31,	Annual Payments (In thousands)
2012 (remainder of year)	\$ 716
2013	2,930
2014	3,013
2015	3,030
2016	3,070
2017 and thereafter	5,229
Total minimum payments	\$ 17,988

Note 6. Stock-Based Compensation

The Company recorded stock-based compensation expense of \$3.4 million and \$10.8 million for the three and nine months ended September 30, 2012, respectively, and \$2.9 million and \$8.8 million of stock-based compensation expense for the three and nine months ended September 30, 2011, respectively. Employee stock-based compensation expense includes expense related to stock option grants, restricted stock unit (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.

Stock Option Grants

The Company granted options to purchase 41,500 and 608,000 shares of common stock to employees and outside directors during the three and nine months ended September 30, 2012, respectively, and options to purchase 12,000 and 560,900 shares of common stock to employees and outside directors during the three and nine months ended September 30, 2011, respectively. For the three and nine months ended September 30, 2012, the Company issued 303,577 and 835,865 shares of common stock in connection with the exercise of stock options with a weighted-average exercise price of \$17.96 and \$16.53 per share, respectively. For the three and nine months ended September 30, 2011, the Company issued 89,273 and 514,819 shares of common stock in connection with the exercise of stock options with a weighted-average exercise price of \$12.60 and \$12.88 per share, respectively.

Restricted Stock Units

During the three and nine months ended September 30, 2012, the Company awarded 31,550 and 415,566 RSUs, respectively, with a grant-date fair value of \$1.1 million and \$12.3 million, respectively. During the three and nine months ended September 30, 2011, the Company awarded 16,920 and 328,468 RSUs to employees with a grant date fair value equal to \$466,000 and \$7.7 million, respectively. 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 and nine months ended September 30, 2012, the Company

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issued 2,819 and 64,909 shares of common stock, respectively, in connection with the vesting of RSUs with a weighted-average grant date fair value of \$22.80 and \$23.29 per share, respectively. No shares were issued in connection with the vesting of RSUs for either of the three or nine months ended September 30, 2011.

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 and nine months ended September 30, 2012, the Company issued 1,196 and 4,072 shares of restricted stock, respectively, to outside directors, with a grant date fair value of \$40,000 and \$120,000, respectively, and a weighted-average grant date fair value of \$33.40 and \$29.41 per share, respectively. During the three and nine months ended September 30, 2011, the Company issued 1,432 and 3,462 shares of restricted stock, respectively, to outside directors, with a grant date fair value of \$40,000 and \$93,000, respectively, and a weighted-average grant date fair value of \$27.78 and \$26.82 per share, respectively.

Employee Stock Purchase Plan

During the nine months ended September 30, 2012, 69,856 shares were issued under the ESPP. No shares were issued under the ESPP during the three months ended September 30, 2012 or the three and nine months ended September 30, 2011. A total of

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1,250,000 shares of common stock have been reserved for issuance under the ESPP, of which 1,180,144 shares were available for issuance as of September 30, 2012. As of September 30, 2012, there was \$163,000 of unrecognized compensation expense related to the ESPP, which is expected to be recognized over an estimated weighted-average period of two months.

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 unexercised 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 September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Expected volatility:				
Stock options	45%	46%	46%	47%
ESPP	38%	%	43%	%
Risk-free interest rate:				
Stock options	1.43%	1.44%	1.23%	2.28%
ESPP	0.12%	%	0.08%	%
Expected life in years:				
Stock options	6.68	5.41	6.98	6.18
ESPP	0.50		0.50	
Weighted-average fair value:				
Stock options	\$ 18.40	\$ 11.56	\$ 14.51	\$ 11.19
ESPP	\$ 8.12	\$	\$ 7.59	\$

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 September 30, 2012, the majority of the Company's product revenues have been derived from sales of one product, the *Oncotype DX* breast cancer test.

The following table summarizes total revenues from customers, payors 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

Nine Months Ended

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	September 30,		September 30,	
	2012	2011	2012	2011
	(in thousands)			
United States	\$ 50,564	\$ 46,966	\$ 155,798	\$ 138,853
Outside of the United States	8,084	5,092	18,948	13,860
Total revenues	\$ 58,648	\$ 52,058	\$ 174,746	\$ 152,713

Medicare payments for the three and nine months ended September 30, 2012 accounted for approximately 21% and 23%, respectively, of the Company's product revenues compared to 22% and 21% for the three and nine months ended September 30, 2011, respectively. There were no other customers or payors who individually accounted for 10% or more of product revenues.

Note 8. Income Taxes

The Company recorded income tax expense of \$109,000 and \$243,000 for the three and nine months ended September 30, 2012, respectively, which was computed using the discrete (or cut-off) method and was principally comprised of federal alternative minimum tax, state income taxes and foreign taxes. The Company recorded income tax expense of \$138,000 and \$266,000 for the three and nine months ended September 30, 2011, respectively, which was computed using the same method and was principally comprised of California alternative minimum tax, other state income taxes and foreign taxes. The difference in income tax expense

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between the provision and the statutory rate of the Company's income before income taxes and provision actually recorded was primarily due to the impact of nondeductible stock-based compensation expenses offset by the utilization of net operating loss carryforwards.

Based on all available objective evidence, the Company believes that it is more likely than not that the net deferred tax assets will not be fully realized. Accordingly, the Company recorded a valuation allowance against all of its net deferred tax assets for the three and nine months ended September 30, 2012 and 2011, respectively. The Company will continue to maintain a full valuation allowance on its deferred tax assets until there is sufficient evidence to support the reversal of all or some portion of this valuation allowance.

The Company had \$839,000 of unrecognized tax benefits as of September 30, 2012 and December 31, 2011, respectively. The Company does not anticipate a material change to its unrecognized tax benefits over the next twelve months. 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 income. All tax years from 2000 forward remain subject to future examination by federal, state and foreign tax authorities.

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 breast cancer; the factors that may impact our financial results; our ability to achieve sustained profitability; our ability to recognize revenues other than on a cash basis; 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; our expectations regarding our international expansion and opportunities, and our expectations regarding revenues from international sales; our intent to enter into additional foreign distribution arrangements; the factors we believe to be driving 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; plans for, and the timeframe for the development or commercial launch of, future tests or enhancements to address different patient populations of breast or colon cancer, other types of cancer or specific cancer treatments and, specifically our expected launch of a test for prostate cancer in 2013; the factors that we believe will drive 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 and the success of those relationships; whether any tests will result from our collaborations; the applicability of clinical results to actual outcomes; our estimates and assumptions with respect to disease incidence or potential market opportunities; the occurrence, timing, outcome or success of clinical trials or studies; our plans with respect to additional development or clinical studies; our expectations regarding timing of the announcement or publication of research results; our expectations regarding the timing and occurrence of future product launches; 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 benefits; our expectations regarding our future technologies, including next generation sequencing, 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

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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; how we intend to spend our existing cash and how long we expect our existing cash to last; our anticipated cash needs and our estimates regarding our capital requirements and our needs 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 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; the impact of seasonal fluctuations and economic conditions on our business; our belief that we have taken reasonable steps to protect our intellectual property; our strategies regarding filing additional patent applications to strengthen our intellectual property rights; 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

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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 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.

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 health company that provides actionable genomic information to personalize genomic health 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. In January 2004, we launched our first *Oncotype 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 *Oncotype 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 *Oncotype DX* available for patients with ductal carcinoma in situ, or DCIS, a pre-invasive form of breast cancer. In June 2012, we extended our offering of the *Oncotype DX* colon cancer test to patients with stage III disease treated with oxaliplatin-containing adjuvant therapy. Effective July 1, 2012, the list price of our *Oncotype DX* breast cancer test increased from \$4,175 to \$4,290 and the list price of our *Oncotype DX* colon cancer test increased from \$3,280 to \$3,640. The majority of our historical revenues have been derived from the sale of *Oncotype DX* breast cancer tests ordered by physicians in the United States. As discussed in greater detail below, we currently intend to launch a test for prostate cancer in 2013.

For the three and nine months ended September 30, 2012, more than 18,030 and 55,690 *Oncotype DX* test reports were delivered for use in treatment planning, respectively, compared to more than 16,890 and 49,520 reports delivered for the three and nine months ended September 30, 2011, respectively. All of our tests are conducted at our clinical reference laboratory in Redwood City, California. Our clinical reference laboratory processing capacity is currently approximately 22,000 tests per calendar quarter. As test processing for our *Oncotype DX* breast and colon cancer tests is essentially the same, except that the tests use different RNA extraction methods and analyze different genes, we believe that we currently have sufficient capacity to process both of our tests. In connection with the planned 2013 launch of our prostate cancer test, we will be expanding our clinical laboratory processing capacity.

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We depend upon third-party payors 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 and consultants in several countries, including Canada, Germany, Ireland, Japan, Sweden, Switzerland and the United Kingdom. Additionally, we have entered into exclusive distribution agreements for the sale of our tests with 20 distributors covering more than 80 countries outside of the United States. To date, we have lead executives with responsibilities for the Americas, Europe and Asia to support our international efforts.

We expect that international sales of our *Oncotype 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 *Oncotype 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 Canada, France, Germany, Greece, Ireland, Israel, Spain, the United Kingdom and Venezuela, as well as certain countries in Africa and the Middle East. We expect that it will take several years to establish broad coverage and reimbursement for our *Oncotype DX* breast and colon 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 *Oncotype DX* breast cancer test. We believe increased demand for our *Oncotype DX* breast cancer test to date in 2012, when compared to the same periods in 2011, 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 *Oncotype DX* colon cancer test or any future products we may develop, patient enrollment in *Oncotype DX* clinical studies and the number of clinical trials in process by cooperative groups or makers of other tests conducting experience studies. For the quarter ended September 30, 2012, we experienced a decrease in sequential quarterly demand for our breast cancer test. We believe this decrease was partially due to the typical seasonal variations in test levels combined with lower patient volumes overall.

Most national and regional third-party payors in the United States, along with the designated national Medicare contractor for our tests, have issued positive coverage determinations for our *Oncotype DX* breast cancer test for patients with node negative, or N-, estrogen receptor positive, or 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). Effective July 15, 2011, this coverage was extended to include 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 *Oncotype 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 late December 2011, we made *Oncotype DX* available for patients with DCIS, a pre-invasive form of breast cancer. The launch of *Oncotype DX* for DCIS patients was based upon presented positive results from a clinical validation study of *Oncotype 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 *Oncotype DX* DCIS Score derived from our 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. 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.

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Oncotype DX Colon Cancer Test

We expect to continue to focus substantial resources on pursuing global adoption of and reimbursement for our *Oncotype 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 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 *Oncotype 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*. In September 2012, at the European Society for Medical Oncology Congress, we presented the positive results from the landmark randomized NSABP C-07 clinical trial, our third large validation study, including prediction of risk of recurrence, disease-free survival and overall survival in stage II and stage III colon cancer patients. 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 national Medicare contractor for our tests established a formal coverage policy for our *Oncotype DX* colon cancer test for patients with stage II colon cancer. 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 *Oncotype 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 *Oncotype 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 January 2012, we presented positive results of our first clinical decision study of the *Oncotype DX* colon cancer test that shows that the Recurrence Score result has a significant impact on treatment recommendations for stage II colon cancer patients. Additionally, we plan to continue conducting development studies to evaluate our *Oncotype DX* colon cancer test and to predict chemotherapy benefit in stage II and stage III colon cancer patients treated with oxaliplatin. Based on the positive results of an independent validation study, in June 2012 we began offering the *Oncotype DX* colon cancer test for use in patients with stage III disease treated with oxaliplatin-containing adjuvant therapy. 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. We plan to utilize these results and initiate a validation study in 2013.

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 *Oncotype 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.

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In September 2012, we announced positive topline 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 are completing the necessary work in our clinical reference laboratory in order to proceed with a worldwide commercial launch of our prostate cancer test in 2013.

We expect to incur additional expenses related to the planned commercial launch of our prostate cancer test, such as infrastructure costs, information technology costs, and selling and marketing costs. Based upon our experience in obtaining adoption and reimbursement for our *Oncotype 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 our launch.

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Product Pipeline for Other Cancers

We are continuing work under our collaboration agreement with Pfizer Inc. for the development of a genomic test to estimate the risk of recurrence following surgery for patients with stage I-III renal carcinoma, clear cell type that has not spread to other parts of the body. Based on results from our first renal gene identification study, which demonstrated a strong correlation between gene expression and recurrence risk in this patient population, we plan to move forward with a clinical validation study and to continue to evaluate a potential renal cancer product depending upon results of validation studies for specific therapies.

Technology

In our *Oncotype DX* platform we utilize existing technologies, such as RT-PCR, and information technologies and optimize and integrate them into new processes. We are also incorporating new technologies, such as high-throughput next generation sequencing, or NGS, in our research and development laboratory. NGS technologies parallelize the sequencing process, producing millions of sequences at once. These technologies are intended to provide DNA and RNA sequence information in greater amounts and 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 technological source of new biomarkers in the future. We expect to continue to develop the capabilities of various technologies to create new products.

Economic Environment

Continuing concerns over prolonged high unemployment levels, the availability and cost of credit, the U.S. mortgage market, the U.S. real estate market, Federal budget negotiations, proposed regulatory changes and taxation issues, inflation, deflation, energy costs and geopolitical issues have contributed to increased volatility and uncertain expectations both for the U.S. and for global economies. These factors, combined with uncertainties in business and consumer confidence, a volatile stock market, the European sovereign debt crisis, continued concerns regarding the stability of the Euro currency and some European Union member countries and slowing growth in China, have precipitated an economic slowdown and expectations of slower global economic growth and possibly another recession going forward. 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 investments, 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 growth in tests delivered and revenues generated during the three and nine months ended September 30, 2012. 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 PPACA, enacted in March 2010, makes changes that are expected to significantly impact the pharmaceutical and medical device industries and clinical laboratories. The PPACA 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 will have to pay sales tax in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices. Although there are some exceptions to the tax, because the Food and Drug Administration, or FDA, maintains that clinical laboratory tests that are developed and validated by a laboratory for its own use, referred to as LDTs, such as our *Oncotype DX* breast and colon cancer tests, are medical devices, this tax may apply to some or all of our current products and products in development. The American Clinical Laboratory Association has requested confirmation that laboratory services, such as those offered by us, are not subject to the device tax. We cannot assure you that those efforts will be successful.

The PPACA also mandates a reduction in payments for clinical laboratory services paid under the Medicare Clinical Laboratory Fee Schedule, or CLFS, of 1.75% for the years 2011 through 2015 and a productivity adjustment to the CLFS. In addition, the PPACA establishes a board that is charged with reducing the per capita rate of growth in Medicare spending. We are monitoring the impact of the PPACA 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.

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In February 2012, Congress passed the Middle Class Tax Relief and Job Creation Act of 2012 which in part reduced the potential future cost-based increases to the Medicare CLFS by 2%. Overall, the expected total fee cut to the CLFS for 2013 is estimated to be 2.95% not considering a potential further reduction of 2% anticipated from automatic expense reductions under the Budget Control Act of 2011 unless Congress acts before January 1, 2013 to avert or modify the automatic cuts. The Centers for Medicare and Medicaid Services, CMS, sought public input through the notice and comment period for the proposed Medicare Physician Fee Schedule, on whether all new AMA Molecular Diagnostic codes be placed on either the Medicare Physician Fee Schedule, which would likely require a 20% patient co-payment for such services, or remain on the Clinical Laboratory Fee Schedule. On November 1, 2012, CMS issued a final rule on the Physician Fee Schedule which stated that these new codes would be placed on the CLFS. On August 31, 2012, CMS also issued a preliminary determination for the 2013 CLFS which proposed not to recognize Multi-Analyte codes with Algorithmic Analyses, or MAAA, and questioned whether algorithm-based tests are covered benefits for Medicare beneficiaries. However, in its final determination released on November 6, 2012, CMS deleted the statement about not covering algorithmic analysis, and stated that laboratories performing MAAA tests for Medicare beneficiaries should continue to bill for these tests in 2013 as they are currently billed under the CLFS. Our current Medicare reimbursement determination was set by a local coverage decision and not set nationally by CMS. These or any future changes in covered benefit determination, proposed fees or mandated reductions in payments may apply to some or all of our clinical laboratory tests delivered to Medicare beneficiaries.

Critical Accounting Policies

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.

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 an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectibility 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 agreements. When evaluating collectibility, 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.

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We enter into exclusive distribution agreements for the sale of one or more of our *Oncotype 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 agreement 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 September 30, 2012, 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 \$40 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

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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 \$541,000 and \$562,000 at September 30, 2012 and December 31, 2011, 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 September 30, 2012 and December 31, 2011, our allowance for doubtful accounts was \$1.2 million. See *Liquidity and Capital Resources* for additional information, including a summary of accounts receivable aging by payor mix.

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 and colon 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.

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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 September 30, 2012 and December 31, 2011. 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 valuation allowance.

Results of Operations

Three and Nine Months Ended September 30, 2012 and 2011

We recorded net income of \$3.7 million and \$6.3 million for the three and nine months ended September 30, 2012, respectively, compared to net income of \$3.2 million and \$5.3 million for the three and nine months ended September 30, 2011, respectively. On a basic per share basis, net income was \$0.12 and \$0.21 for the three and nine months ended September 30, 2012, respectively, compared to net income of \$0.11 and \$0.18 for the three and nine months ended September 30, 2011, respectively. On a diluted per share basis, net income was \$0.11 and \$0.20 for the three and nine months ended September 30, 2012, respectively, compared to net income of \$0.10 and \$0.17 for the three and nine months ended September 30, 2011, respectively. 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 September 30, 2012, substantially all of our product revenues have been derived from the sale of our *Oncotype DX* breast cancer test. Payors are billed upon generation and delivery of a test report 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 collectibility is reasonably assured. Contract revenues are derived from studies conducted with biopharmaceutical and pharmaceutical companies and are recorded as contractual obligations are completed.

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	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2012	2011	2012	2011
	(In thousands)			
Product revenues	\$ 58,371	\$ 51,661	\$ 173,459	\$ 151,611
Contract revenues	277	397	1,287	1,102
Total revenues	\$ 58,648	\$ 52,058	\$ 174,746	\$ 152,713
Period over period dollar increase in product revenues	\$ 6,710		\$ 21,848	
Period over period percentage increase in product revenues	13%		14%	

The increase in product revenues for the three and nine months ended September 30, 2012 compared to the three and nine months ended September 30, 2011 resulted, in part, from 59% and 37% period over period increases in international revenue, respectively, and increased adoption, as evidenced by 7% and 12% period over period increases in test volume, respectively, as well as increased payments from Medicare, during the first nine months of 2012. These payments from Medicare were for colon tests performed prior to the establishment of reimbursement coverage. Approximately \$36.4 million, or 62%, and \$113.5 million, or 65%, of product revenues for the three and nine months ended September 30, 2012, respectively, were recorded on an accrual basis and recognized at the time the test results were delivered, compared to \$36.2 million, or 70%, and \$101.7 million, or 67%, for the three and nine months ended September 30, 2011, respectively. For both periods, the balance of product revenues was recognized upon cash

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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 and nine months ended September 30, 2012 were \$12.3 million, or 21%, and \$39.5 million, or 23%, of product revenues, respectively, compared to \$11.2 million, or 22%, and \$31.9 million, or 21%, of product revenues for the three and nine months ended September 30, 2011, respectively. There were no other third-party payors representing product revenues of 10% or more for those periods. International product revenues increased to \$8.1 million, or 14%, and \$18.9 million, or 11%, of product revenues for the three and nine months ended September 30, 2012, respectively, from \$5.1 million, or 10%, and \$13.9 million, or 9%, of product revenues for the three and nine months ended September 30, 2011, respectively.

Contract revenues were \$277,000 and \$1.3 million for the three and nine months ended September 30, 2012, respectively, compared to \$397,000 and \$1.1 million for the three and nine months ended September 30, 2011, respectively. Contract revenues represented studies assessing our gene expression technology or collaborative work in gene selection and protocol design with pharmaceutical partners. The increase in contract revenues for the nine months ended September 30, 2012 compared to 2011 was due to ongoing activities related to our collaboration with Pfizer Inc. as well as new activities with other collaboration partners. We expect that our contract revenues will fluctuate based on the number and timing of studies being conducted.

Cost of Product Revenues

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2012	2011	2012	2011
	(In thousands)			
Tissue sample processing costs	\$ 6,929	\$ 6,213	\$ 21,086	\$ 18,462
Stock-based compensation	100	79	309	253
Total tissue sample processing costs	7,029	6,292	21,395	18,715
License fees	2,008	2,903	5,982	7,765
Total cost of product revenues	\$ 9,037	\$ 9,195	\$ 27,377	\$ 26,480
Period over period dollar increase (decrease)	\$ (158)		\$ 897	
Period over period percentage increase (decrease)	(2)%		3%	

Cost of product revenues represents the cost of materials, direct labor, equipment and infrastructure expenses associated with processing tissue samples (including histopathology, anatomical pathology, extraction, RT-PCR, quality control analyses and shipping charges to transport tissue samples) and license fees. Infrastructure expenses include allocated information technology and facility occupancy 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 *Oncotype 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 change in license fees does not correlate exactly to the percentage change 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.

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Tissue sample processing costs increased \$716,000, or 12%, for the three months ended September 30, 2012 compared to the three months ended September 30, 2011. Tissue sample processing costs increased \$2.6 million, or 14%, for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011. These increases were primarily due to increases in test volume. The decreases in license fees for the three and nine months ended September 30, 2012 compared to the three and nine months ended September 30, 2011 of \$895,000, or 31% and \$1.8 million, or 23%, resulted from an amendment in 2011 to a license agreement that reduces the rate paid on PCR-based product revenues recorded after July 1, 2011. License fees for the three and nine months ended September 30, 2011 were reduced by an \$800,000 payment under a legal settlement related to the abandonment of a patent. We expect the cost of product revenues to increase in future periods to the extent we process more tests.

Table of Contents*Research and Development Expenses*

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2012	2011	2012	2011
	(In thousands)			
Personnel-related expenses	\$ 6,240	\$ 5,027	\$ 18,325	\$ 15,261
Stock-based compensation	961	734	2,821	2,266
Reagents and laboratory supplies	696	526	2,209	1,685
Collaboration expenses	370	451	1,388	2,242
Allocated information technology, facilities and other costs	3,037	1,975	7,998	5,383
Other expenses	963	898	3,034	2,745
Total research and development expenses	\$ 12,267	\$ 9,611	\$ 35,775	\$ 29,582
Period over period dollar increase	\$ 2,656		\$ 6,193	
Period over period percentage increase	28%		21%	

Research and development expenses represent costs incurred to develop our technology and carry out clinical studies and include personnel-related expenses, reagents and supplies used in research and development laboratory work, contract services, allocated information technology and facility occupancy costs, and other expenses. Research and development expenses also include costs related to activities performed under contracts with biopharmaceutical and pharmaceutical companies.

The \$2.7 million, or 28%, increase in research and development expenses for the three months ended September 30, 2012 compared to the three months ended September 30, 2011 included a \$1.2 million increase in personnel-related expenses, a \$1.1 million increase in allocated information technology, facilities and other costs, a \$227,000 increase in stock-based compensation expense, a \$170,000 increase in reagents and laboratory supplies expense, and a \$65,000 increase in other expenses, partially offset by a \$81,000 decrease in collaboration expenses. The \$1.2 million increase in personnel-related expenses was primarily attributable to increases in salaries and benefits due to increased headcount to support projects related to our product pipeline and ongoing work in NGS. The increase in allocated information technology, facilities and other costs is primarily due to increased project work from our various information technology groups, allocated based on specific departmental projects.

The \$6.2 million, or 21%, increase in research and development expenses for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 included a \$3.1 million increase in personnel-related expenses, a \$2.6 million increase in allocated information technology, facilities and other costs, a \$555,000 increase in stock-based compensation expense, a \$524,000 increase in reagents and laboratory supplies expense, and a \$289,000 increase in other expenses, partially offset by a \$854,000 decrease in collaboration expenses. The increase in personnel-related expenses was primarily attributable to increases in salaries and benefits due to increased headcount to support projects related to our product pipeline and ongoing work in NGS. The increase in allocated information technology, facilities and other costs is primarily due to increased project work from our various information technology groups, allocated based on specific departmental projects. The decrease in collaboration expenses is primarily due to a higher level of work performed by our collaborators in 2011 related to a variety of studies covering breast, colon and prostate cancers.

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

Table of Contents*Selling and Marketing Expenses*

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2012	2011	2012	2011
	(In thousands)			
Personnel-related expenses	\$ 11,503	\$ 10,701	\$ 36,000	\$ 32,262
Stock-based compensation	1,006	791	2,987	2,388
Promotional and marketing materials	2,947	3,409	10,598	9,702
Travel, meetings and seminars	2,616	2,010	8,413	6,991
Allocated information technology, facilities and other costs	2,752	2,571	9,414	7,692
Other expenses	702	675	2,245	2,185
Total selling and marketing expenses	\$ 21,526	\$ 20,157	\$ 69,657	\$ 61,220
Period over period dollar increase	\$ 1,369		\$ 8,437	
Period over period percentage increase	7%		14%	

Our selling and marketing expenses consist primarily of personnel-related expenses, education and promotional expenses and allocated information technology and facility occupancy costs and other expenses. These expenses include the costs of educating physicians, laboratory personnel and other healthcare professionals regarding our genomic technologies, how our *Oncotype 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 *Oncotype DX* tests. Our sales force compensation includes annual salaries and eligibility for quarterly commissions based on the achievement of predetermined sales goals.

The \$1.4 million, or 7%, increase in selling and marketing expenses for the three months ended September 30, 2012 compared to the three months ended September 30, 2011 was due to a \$802,000 increase in personnel-related expenses, a \$606,000 increase in travel, meetings and seminars expenses primarily related to our international expansion efforts, a \$215,000 increase in stock-based compensation expense and a \$181,000 increase in allocated information technology, facilities and other costs, partially offset by a \$462,000 decrease in promotional and marketing materials. Of the \$802,000 increase in personnel-related expenses, \$1.1 million was attributable to increases in salaries, benefits and related expenses due primarily to increased headcount, partially offset by lower commissions and bonus payments of \$256,000. The increase in allocated information technology, facilities and other costs is primarily due to increased work from our various information technology groups, allocated based on specific departmental projects.

The \$8.4 million, or 14%, increase in selling and marketing expenses for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 was due to a \$3.7 million increase in personnel-related expenses, a \$1.7 million increase in allocated information technology, facilities and other costs, a \$1.4 million increase in travel, meetings and seminars expenses primarily related to our international expansion efforts, a \$896,000 increase in promotional and marketing materials related to the expansion of our international commercial business and our domestic DCIS product launch in December 2011, and a \$599,000 increase in stock-based compensation expense. The \$3.7 million increase in personnel-related expenses was attributable to increases in salaries, benefits and related expenses due primarily to increased headcount to support our domestic and international expansion. The increase in allocated information technology, facilities and other costs is primarily due to increased project work from our various information technology groups, 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 *Oncotype DX* colon cancer test, continued investment in our global commercial infrastructure and growing our sales

force, as well as costs associated with the planned commercial launch of our prostate cancer test in 2013.

Table of Contents*General and Administrative Expenses*

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2012	2011	2012	2011
	(In thousands)			
Personnel-related expenses	\$ 8,825	\$ 6,607	\$ 25,322	\$ 19,397
Stock-based compensation	1,334	1,304	4,691	3,898
Occupancy and equipment expenses	3,700	3,635	11,921	10,754
Billing and collection fees	2,353	1,682	6,514	5,049
Bad debt expense	998	939	2,571	2,545
Professional fees and other expenses	1,867	1,226	5,698	4,827
Information technology, facilities and other cost allocations	(6,970)	(5,697)	(21,199)	(16,566)
Total general and administrative expenses	\$ 12,107	\$ 9,696	\$ 35,518	\$ 29,904
Period over period dollar increase	\$ 2,411		\$ 5,614	
Period over period percentage increase	25%		19%	

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 \$2.4 million, or 25%, increase in general and administrative expenses for the three months ended September 30, 2012 compared to the three months ended September 30, 2011 included a \$2.2 million increase in personnel-related expenses, a \$671,000 increase in billing and collection fees, a \$641,000 increase in professional fees and other expenses, a \$59,000 increase in bad debt expense and a \$30,000 increase in stock-based compensation expense, partially offset by a \$1.3 million increase in information technology, facilities and other costs allocated to other functional areas. Of the \$2.2 million increase in personnel-related expenses, \$1.3 million was attributable to salaries and benefits expenses due primarily to increased headcount as well as annual increases, and \$954,000 was attributable to higher consulting expenses to support the growth of our business.

The \$5.6 million, or 19%, increase in general and administrative expenses for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 included a \$5.9 million increase in personnel-related expenses, a \$1.5 million increase in billing and collection fees, a \$1.1 million increase in occupancy and equipment expenses, a \$871,000 increase in professional fees and other expenses, and a \$793,000 increase in stock-based compensation expense, partially offset by a \$4.6 million increase in information technology, facilities and other costs allocated to other functional areas. Of the \$5.9 million increase in personnel-related expenses, \$3.3 million was attributable to salaries and benefits expenses due primarily to increased headcount as well as annual increases, \$2.2 million was attributable to higher consulting expenses to support the growth of our business and \$361,000 was attributable to higher bonus payments.

We expect general and administrative expenses to increase in future periods as we hire additional personnel 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. We expect billing and collections fees and bad debt expense in total will continue to be approximately 5% of product revenues for at least the next year or more.

Interest Income

Interest income was \$77,000 and \$226,000 for the three and nine months ended September 30, 2012, respectively, compared to \$77,000 and \$217,000 for the three and nine months ended September 30, 2011, respectively. We expect interest income will remain nominal if the current low interest rate environment continues.

Other Income (Expense), Net

Other income (expense), net was \$33,000 and \$(112,000) for the three and nine months ended September 30, 2012, respectively, compared to other expense, net of \$(113,000) and \$(191,000) for the three months and ended September 30, 2011, respectively. The increase in other income, net and the decrease in other (expense), net for the three and nine months ended September 30, 2012 compared to the three and nine months ended September 30, 2011 were due primarily to increases in net foreign exchange gains of \$112,000 and \$63,000, respectively. 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.

Table of Contents*Income Tax Expense*

Income tax expense was \$109,000 and \$243,000 for the three and nine months ended September 30, 2012, respectively, compared to \$138,000 and \$266,000 for the three and nine months ended September 30, 2011, respectively. Income tax expense for both periods was principally comprised of federal alternative minimum tax, 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 nine months ended September 30, 2012 and 2011, 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.

Liquidity and Capital Resources

As of September 30, 2012, we had an accumulated deficit of \$159.5 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.

	2012	(In thousands)	2011
As of September 30:			
Cash, cash equivalents and marketable securities	\$ 126,981		\$ 87,394
Working capital	130,641		85,917
For the nine months ended September 30:			
Cash provided by (used in):			
Operating activities	19,705		10,728
Investing activities	(8,950)		(10,351)
Financing activities	14,335		6,721
Capital expenditures (included in investing activities above)	(6,170)		(4,541)

Sources of Liquidity

At September 30, 2012, we had cash, cash equivalents and marketable securities of \$127.0 million compared to \$87.4 million at September 30, 2011. The \$39.6 million increase was attributable to increased cash collections from sales of our tests, payments from collaborators and cash received from the exercise of stock options, which were partially offset by investments in the growth of our business, including research and development, international expansion and strategic investments in privately held companies. In accordance with our investment policy, available cash is invested in short-term, low-risk, investment-grade debt instruments. Our cash and short-term investments 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 marketable securities and cash received in payment for our tests.

Accounts Receivable

At September 30, 2012 and December 31, 2011, \$19.9 million, or 12%, and \$21.1 million, or 15%, respectively, of our total assets consisted of accounts receivable. The \$1.2 million decrease in accounts receivable from December 31, 2011 to September 30, 2012 resulted from acceleration in payments from Medicare, as indicated in the tables below, combined with the seasonal decrease in tests delivered. 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 September 30, 2012 and December 31, 2011, our weighted average DSOs were 68 days and 63 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 September 30, 2012 and December 31, 2011:

	Total	% of Total	Current	September 30, 2012				
				31-60 Days	61-90 Days	91-120 Days	121 to 180 Days	Over 180 Days
(In thousands)								
Managed care and other	\$ 16,351	78%	\$ 7,312	\$ 3,010	\$ 1,721	\$ 1,155	\$ 1,408	\$ 1,745
Medicare	4,746	22	3,907	123	38	37	75	566
Total	21,097	100%	\$ 11,219	\$ 3,133	\$ 1,759	\$ 1,192	\$ 1,483	\$ 2,311
Allowance for doubtful accounts	(1,171)							
Net accounts receivable	\$ 19,926							

	Total	% of Total	Current	December 31, 2011				
				31-60 Days	61-90 Days	91-120 Days	121 to 180 Days	Over 180 Days
(In thousands)								
Managed care and other	\$ 16,644	75%	\$ 7,785	\$ 2,615	\$ 1,616	\$ 1,243	\$ 1,364	\$ 2,021
Medicare	5,639	25	3,974	358	286	404	396	221
Total	22,283	100%	\$ 11,759	\$ 2,973	\$ 1,902	\$ 1,647	\$ 1,760	\$ 2,242
Allowance for doubtful accounts	(1,206)							
Net accounts receivable	\$ 21,077							

Cash Flows

Net cash provided by operating activities was \$19.7 million for the nine months ended September 30, 2012, compared to \$10.7 million for the nine months ended September 30, 2011. Net cash provided by operating activities includes net income adjusted for certain non-cash items and changes in assets and liabilities. Net cash provided by operating activities for the nine months ended September 30, 2012 reflected net income of \$6.3 million, adjusted for \$14.8 million of stock-based compensation and depreciation and amortization expense, a \$3.0 million increase in accrued expenses and other liabilities and a \$1.2 million decrease in accounts receivable, partially offset by a \$3.6 million decrease in accounts payable, a \$1.3 million decrease in prepaid expenses and other liabilities and a \$818,000 decrease in deferred revenues. Net cash provided by operating activities for the nine months ended September 30, 2011 reflected net income of \$5.3 million, adjusted for \$14.3 million of stock-based compensation and depreciation and amortization expense, partially offset by an \$8.3 million increase in accounts receivable, a \$1.2 million decrease in accounts payable and a \$1.1 million increase in accrued compensation.

Net cash used in investing activities was \$9.0 million for the nine months ended September 30, 2012, compared to \$10.4 million for the nine months ended September 30, 2011. Our investing activities have consisted predominately of purchases and maturities of marketable securities and capital expenditures. Net cash provided by investing activities for the nine months ended September 30, 2012 included \$1.4 million in net

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purchases of marketable securities, \$6.2 million in capital expenditures and \$1.4 million of investments in privately held companies. Net cash used in investing activities for the nine months ended September 30, 2011 included \$4.5 million in capital expenditures, \$3.5 million in net purchases of marketable securities and a \$2.3 million investment in a privately held company.

Net cash provided by financing activities was \$14.3 million for the nine months ended September 30, 2012, compared to \$6.7 million for the nine months ended September 30, 2011. Our financing activities have historically consisted primarily of sales of our equity securities. Net cash provided by financing activities for the nine months ended September 30, 2012 included \$15.5 million in proceeds from the issuance of our common stock upon the exercise of stock options and upon the semi-annual ESPP stock purchase, partially offset by cash paid for tax withholdings in the amount of \$1.2 million related to net share settlements of restricted stock units and awards. Net cash provided by financing activities for the nine months ended September 30, 2011 included \$6.7 million in proceeds from the issuance of our common stock upon the exercise of stock options.

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The following table summarizes our significant contractual obligations as of September 30, 2012 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 (In thousands)	3-5 Years	More than 5 Years
Non-cancelable operating lease obligations	\$ 17,988	\$ 2,909	\$ 6,030	\$ 6,186	\$ 2,863

Our non-cancelable operating lease obligations are for laboratory and office space. In September 2005, we entered into a non-cancelable lease for 48,000 square feet of laboratory and office space in Redwood City, California. In November 2010, we executed an amendment to extend the term of the lease through March 2019, with an option to extend the terms of the lease for an additional five years. In January 2007, we 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, we executed an amendment to extend the term of the lease through March 2018, with an option to extend the terms of the lease for an additional five years. In October 2009, we entered into a non-cancelable lease for an additional 30,500 square feet of office space in a nearby location. This lease expires in March 2018, with an option to extend the terms of the lease for an additional five years. In May 2010, we entered into a non-cancelable lease for 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 *Oncotype DX* colon cancer test. We made payments under this agreement of \$300,000, \$200,000 and \$150,000 in 2012, 2011 and 2010, respectively. As of September 30, 2012, future annual payments under this agreement totaled \$1.35 million, of which \$450,000 is due in each of the years 2013, 2014 and 2015. However, because this agreement 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 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 had positive operating cash flow for the nine months ended September 30, 2012 and the year ended December 31, 2011. We currently anticipate that our cash, cash equivalents and short-term investments, together with payments for our *Oncotype 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 research and development efforts, our efforts to expand adoption of and reimbursement for our *Oncotype DX* colon cancer and DCIS tests, development of our *Oncotype DX* prostate cancer test and our international expansion efforts. We expect to spend over \$20 million over the next 12 months for planned laboratory equipment, information technology expansion and facilities expansion. In addition, we

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continue to evaluate appropriate timing to implement new enterprise software affecting a broad range of business processes and functional areas, including order fulfillment, sample processing, customer service and supply chain management. We may also use cash to acquire or invest in complementary businesses, technologies, services or products, including increases to our existing investments in privately-held companies. We expect that our cash, cash equivalents and short-term investments will be 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 outside of the United States.

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 *Oncotype DX* colon and DCIS cancer 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.

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

- the rate of progress in establishing 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 *Oncotype DX* breast and colon cancer tests;
- the rate of progress and cost of selling and marketing activities associated with expanding adoption of and reimbursement for our *Oncotype DX* colon cancer test and *Oncotype DX* DCIS test;
- the rate of progress and cost of research and development activities associated with products in research and development focused on cancers other than breast and colon 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;
- the cost of acquiring or investing in complementary businesses or assets;
- costs related to future product launches, including our planned launch of a test for prostate cancer;
- 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;
- the cost 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 September 30, 2012, we had no material off-balance sheet arrangements.

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Recently Issued Accounting Pronouncements

In June 2011, the Financial Accounting Standards Board (FASB) issued authoritative guidance requiring companies to present items of net income, items of other comprehensive income and total comprehensive income in one continuous statement or two consecutive statements. This guidance eliminates the option for companies to present other comprehensive income in the statement of stockholders' equity. This guidance is effective for interim and annual periods beginning January 1, 2012. In December 2011, FASB released an update that deferred a portion of the new accounting requirements for comprehensive income. As this guidance provides only presentation requirements, the adoption of this guidance does not impact our financial condition or results of operations. We adopted this standard in January 2012, as reflected by the inclusion of the Condensed Consolidated Statements of Comprehensive Income as part of our Condensed Consolidated Financial Statements.

In June 2011, the FASB issued amendments to authoritative guidance for measuring fair value when required or permitted by other accounting standards. The amendments are intended to result in common fair value measurement and disclosure requirements under GAAP and International Financial Reporting Standards. Some of the amendments clarify the FASB's intent about the application of existing fair value measurement requirements. Other amendments change a particular principle or requirement for measuring fair value or for disclosing information about fair value measurements. This amended guidance, which we do not expect to have a material impact on our financial condition and results of operations, is effective for interim and annual periods beginning January 1, 2012. We adopted this standard in January 2012, as reflected in Note 3, Fair Value Measurements, of our Condensed Consolidated Financial Statements.

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 consist 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.

Our cash, cash equivalents and marketable securities, totaling \$127.0 million at September 30, 2012, did not include 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 September 30, 2012, 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 translation gains of \$30,000 and losses of \$17,000 for the three and nine months ended September 30, 2012, respectively, compared to net foreign exchange transaction losses of \$83,000 and \$80,000 for the three and nine months ended September 30, 2011, respectively. The functional currency of our wholly-owned foreign 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

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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 conditions.

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.

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 September 30, 2012, we had an accumulated deficit of \$159.5 million. We expect to continue to invest in our product pipeline, including our current *Oncotype DX* tests and future products, and in our global commercial infrastructure, our laboratory operations and next generation sequencing development. For the three and nine months ended September 30, 2012, our research and development expenses were \$12.3 million and \$35.8 million, respectively, and our selling and marketing expenses were \$21.5 million and \$69.7 million, respectively. We expect our expense levels to continue to increase for the foreseeable future as we seek to expand the clinical utility of our *Oncotype DX* breast cancer test, drive adoption of and reimbursement for our *Oncotype DX* colon cancer test, develop and commercialize new tests, including our planned *Oncotype DX* prostate cancer test, and increase our international markets. As a result, we will need to generate significant 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, the availability and cost of credit, the U.S. mortgage market, the U.S. real estate market, Federal budget deficits and related proposals, proposed regulatory changes and taxation issues, inflation, deflation, energy costs and geopolitical issues have contributed to increased volatility and uncertain expectations for both the U.S. and global economies. These factors,

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combined with uncertainties in business and consumer confidence, a volatile stock market, the European sovereign debt crisis and continued concerns regarding the stability of the Euro currency and some European Union member countries, and slowing economic growth in China, have precipitated an economic slowdown and expectations of slower global economic growth and possibly another recession going forward. These economic conditions continued to impact growth in tests delivered and revenues generated during the three and nine months ended September 30, 2012. 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.

Healthcare policy and reimbursement 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 PPACA, enacted in March 2010, makes changes that are expected to significantly impact the pharmaceutical and medical device industries and clinical laboratories. Beginning in 2013, each medical device manufacturer will have to pay a sales tax in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices. Although there are some exceptions to the tax, because the Food and Drug Administration, or FDA, maintains that clinical laboratory tests that are developed and validated by a laboratory for its own use, referred to as LDTs, such as our *Oncotype DX* breast and colon cancer tests, are medical devices, this tax may apply to some or all of our current products and products in development. The American Clinical Laboratory Association has requested confirmation that laboratory services, such as those offered by us, are not subject to the device tax. We cannot assure you that those efforts will be successful. The PPACA also mandates a reduction in payments for clinical laboratory services paid under the

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Medicare Clinical Laboratory Fee Schedule, or CLFS, of 1.75% for the years 2011 through 2015 and a productivity adjustment to the Clinical Laboratory Fee Schedule.

Other significant measures contained in the PPACA include, for example, coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures, initiatives to revise Medicare payment methodologies, such as bundling of payments across the continuum of care by providers and physicians, and initiatives to promote quality indicators in payment methodologies. The PPACA also includes significant new fraud and abuse measures, including required disclosures of financial arrangements with physician customers, lower thresholds for violations and increasing potential penalties for such violations. In addition, the PPACA establishes an Independent Payment Advisory Board, or IPAB, to reduce the per capita rate of growth in Medicare spending. The IPAB has broad discretion to propose policies to reduce expenditures, which may have a negative impact on payment rates for services. 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 PPACA 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.

In addition to the PPACA, the effect of which cannot presently be fully quantified given its recent enactment, various healthcare reform proposals have also emerged from federal and state governments. For example, in February 2012, Congress passed the Middle Class Tax Relief and Job Creation Act of 2012 which in part reduced the potential future cost-based increases to the Medicare Clinical Laboratory Fee Schedule by 2%. Overall the expected total fee cut to the CLFS for 2013 is estimated to be 2.95% not considering a potential further reduction of 2% anticipated from automatic expense reductions under the Budget Control Act of 2011 unless Congress acts before January 1, 2013 to avert or modify the automatic cuts. The Centers for Medicare and Medicaid Services, CMS, sought public input through the notice and comment period for the Proposed Medicare Physician Fee Schedule, on whether all new AMA Molecular Diagnostic codes be placed on either the Medicare Physician Fee Schedule, which would likely require a 20% patient co-payment for such services, or remain on the CLFS. On November 1, 2012, CMS issued a final rule on the Physician Fee Schedule which described that these new codes would be placed on the CLFS. On August 31, 2012, CMS also issued a preliminary determination for the 2013 CLFS which proposed not to recognize Multi-Analyte codes with Algorithmic Analyses, or MAAA, and questioned whether algorithm-based tests are covered benefits for Medicare beneficiaries. However, in its final determination released on November 6, 2012, CMS deleted the statement about not covering algorithmic analysis, and stated that laboratories performing MAAA tests for Medicare beneficiaries should continue to bill for these tests in 2013 as they are currently billed under the CLFS. Our current Medicare reimbursement determination was set by a local coverage decision and not set nationally by CMS. These or any future changes in covered benefit determination, proposed fees or mandated reductions in payments may apply to some or all of our clinical laboratory tests delivered to Medicare beneficiaries.

Changes in healthcare policy, such as the creation of broad test utilization limits for diagnostic products in general or requirements that Medicare patients pay for portions of clinical laboratory tests or services received, could substantially impact the sales of our tests, decrease revenues, increase costs and divert management's attention from our business.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which we may do business, or the effect any future legislation or regulation will have on us. The taxes imposed by the new federal legislation, 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 *Oncotype* 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.

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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 June 2011, the FDA issued draft guidance regarding Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only. In addition, during 2011 the FDA also issued other draft guidance documents which may impact our tests or our future tests, including draft guidance regarding Mobile Medical Applications which is directed at patient management tools. Neither of these guidance documents has been finalized. In October 2011, the FDA published a list of planned guidance documents that the agency stated it plans to focus on in its fiscal year 2012, including three 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.

If we were required to conduct additional clinical trials to continue to sell our breast and colon cancer tests or to launch our prostate cancer test or any other tests we may develop, those trials could lead to delays or failure to obtain necessary regulatory approval, which could cause significant delays in commercializing any future products and interruption in sales of our current tests and harm our ability to achieve sustained profitability.

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. If we are required to conduct pre-market clinical trials, whether using prospectively acquired samples or archival samples, delays in the commencement or completion of clinical testing could significantly increase our test development costs and delay commercialization of any future tests, including our test for prostate cancer currently in development, 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

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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.

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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 Oncotype 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 Oncotype 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 Oncotype DX breast cancer test, the test has received negative assessments in the past and this test and our other 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 Oncotype DX breast cancer test did not meet the panel's technology criteria for clinical effectiveness and appropriateness for usage in patients with N+ disease. The National Institute for Health and Clinical Excellence, the special health authority for the National Health Service in England, also recently issued a draft guidance that did not support any breast cancer treatment decision-making test.

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 Oncotype DX breast cancer test for N-, ER+ patients from most

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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.

Following the reporting of clinical studies to support the use of our *Oncotype DX* breast cancer test in patients with N+, ER+ disease and in patients with DCIS, we experienced an increase in usage for N+ patients and expect to experience increasing usage for DCIS patients. We may not be able to obtain reimbursement coverage for our test for breast cancer patients with N+, ER+ disease or DCIS that is similar to the coverage we have obtained for early stage N-, ER+ patients.

We have obtained limited reimbursement from private third-party payors in the United States for our *Oncotype DX* colon cancer test launched in January 2010. We expect to focus substantial resources on obtaining adoption of and reimbursement coverage for this test. Until further clinical data is presented, 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 colon cancer test. However, we cannot predict whether, under what circumstances, or at what payment levels payors will reimburse for our test. If we fail to establish broad adoption of and reimbursement for our colon cancer test, our reputation could be harmed and our future prospects and our business could suffer.

If we are unable to obtain or maintain reimbursement from private payors such as Blue Cross Blue Shield family and 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.

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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 *Oncotype 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. 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 with a particular payor if our agreement with a distributor is terminated or expires or a distributor fails to pay us for other reasons. Reimbursement of distributors for our tests may also be negatively affected by the financial instability of, and austerity measures implemented by, several countries in the European Union.

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 of clinical laboratory services. From time to time, Congress has considered and implemented changes to the Medicare fee schedules in conjunction with budgetary legislation, and pricing and payment terms, including the possible requirement of a patient co-payment for Medicare beneficiaries for tests covered by Medicare, are subject to change at any time. Reductions in the reimbursement rate of payors may occur in the future. Reductions in the prices at which our tests are reimbursed could have a negative impact on our revenues.

There is no specific Current Procedural Terminology, or CPT, procedure code or group of codes to report the *Oncotype DX* breast or colon cancer tests. The tests are reported under a non-specific, unlisted procedure code, which is subject to manual review of each claim. With regard to Medicare's initial reimbursement of our *Oncotype DX* breast cancer test, we were informed that, under the local coverage determination made by the designated Medicare Administrative Contractor, or MAC, claims are to be paid as laboratory services consistent with the average allowed reimbursement rate for claims that were billed and processed to completion as of September 30, 2005. Effective September 18, 2012, the designated MAC established a formal coverage policy for our *Oncotype DX* colon cancer test for patients with stage II colon cancer. These reimbursement rates remain in effect as of the date of this report, but are subject to review and adjustment. A Healthcare Common Procedure Coding System, or HCPCS, code has been issued effective January 1, 2006 for the *Oncotype DX* breast cancer test that some private third-party payors may accept on claims for the test. However, Medicare will not accept this HCPCS code. The American Medical Association, which has the copyright on the CPT coding system, has established a work group to develop a new coding framework for non-infectious disease molecular pathology testing and recommend new codes to the panel, which determines new and revised codes and descriptors. It is possible that this process will result in a new code or codes to report and bill for our *Oncotype DX* tests, and could result in our tests being priced on the physician fee schedule rather than the clinical laboratory fee schedule and that such coding changes may result in higher or lower reimbursement of our tests. Whether or not we obtain a specific CPT code for our tests, there can be no assurance that an adequate payment rate will continue to be assigned to the tests, which could have a negative impact on our revenues.

Additionally, on a five year rotational basis, Medicare requests bids for its regional MAC services. In 2008, we were notified of the transition from our initial MAC, NHIC, to Palmetto, GBA as a result of this bidding process. Palmetto GBA has issued coverage and payment determinations on our *Oncotype DX* tests since that transition. In September 2012, Medicare notified us that the next successor MAC for our

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region was Noridian Administrative Services, or Noridian. Two contractors, including Palmetto GBA, have filed appeals of the Noridian MAC award. We expect to transition to a new contractor or receive an update on these appeals during 2013. A change in the MAC processing the Medicare claims for our *Oncotype DX* tests could impact the coverage or payment rate for our tests.

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 *Oncotype 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

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this rule represent a de minimus percentage of our total breast cancer 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. 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 *Oncotype* 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 23% and 21% of our product revenues for the three and nine months ended September 30, 2012, respectively, and 22% and 21% of our product revenues for the three and nine months ended September 30, 2011, respectively. Accounts receivable on behalf of patients covered by Medicare represented 24% of our net accounts receivable at September 30, 2012 and 27% of our net accounts receivable at September, 30, 2011. While there were no other third-party payors with product revenues representing 10% or more 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 colon 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 actions 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 substantially all of our revenues from sales of one test, our *Oncotype* 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 of and reimbursement for this test have been established. We have similar expectations for revenue related to our *Oncotype* DX DCIS test, which was launched in December 2011. We are in various stages of research and development for other tests that we may offer, such as our planned prostate cancer test, as well as for enhancements to our existing tests. We may not be able to successfully commercialize a prostate cancer test or tests for other cancers or diseases. If we are unable to increase sales of our test for invasive breast cancer, establish significant levels of adoption of and reimbursement for our colon cancer and DCIS tests, or successfully develop and commercialize a prostate cancer test and 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.

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Although we are required to hold a certificate of accreditation 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).

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, and any such regulation may require review of our

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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. Any such regulations, restrictions or licensing requirements may limit our ability to distribute our tests 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 by both the federal government and the states in which we conduct our business, 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, which applies 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 of the tests we are currently developing.

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 and colon cancer with the sensitivity and specificity necessary to be clinically and commercially useful or that our colon cancer test will result in a commercially successful product. 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; and

- 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.

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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. 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 planned 2013 launch of 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. For example, we recently began to implement a plan to migrate from our existing quantitative polymerase chain reaction, or qPCR, equipment to new equipment. We cannot assure you that this transition 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.

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If medical practitioners do not order our *Oncotype 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, 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 *Oncotype DX* breast cancer test in clinical guidelines for treatment of invasive 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.

Our *Oncotype DX* colon cancer test predicts recurrence but, unlike our test for invasive breast cancer, does not predict chemotherapy benefit. We will need to educate physicians, patients and payors about the benefits and cost-effectiveness of our colon cancer test and to establish reimbursement arrangements for this test with payors. We may need to hire additional commercial, 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 our colon cancer test. 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.

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

Some patients may decide not to use our Oncotype 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 loss of healthcare coverage, delayed medical checkups or 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 can measure 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.

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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 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.

As of September 30, 2012, we had 29 issued patents in the United States and 36 issued patents outside of the United States covering genes and methods that are components of the *Oncotype DX* breast and colon cancer tests or research methods and platform technologies. For patents granted by the European Patent Office, we have validated these patents in what we believe are key European Union countries. In addition, we have a number of pending patent applications in the United States and in other countries. 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, or any foreign patent office will protect our technology. 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.

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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 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. A suit brought by multiple plaintiffs, including the American Civil Liberties Union, or ACLU, against Myriad Genetics, or Myriad, and the USPTO, could impact biotechnology patents. That case involves certain of Myriad's U.S. patents related to the breast cancer susceptibility genes BRCA1 and BRCA2. The Federal Circuit issued a written decision on July 29, 2011 that reversed the U.S. District Court for the Southern District of New York holding instead that the breast cancer genes are patentable subject matter. Subsequently, on March 20, 2012, the Supreme Court issued a decision in *Mayo Collaborative v. Prometheus Laboratories*, or Prometheus, a case involving patent claims directed to optimizing the amount of drug administered to a specific patient. According to that decision, Prometheus' claims failed to add enough inventive content to the underlying correlations to allow the processes they describe to qualify as patent-eligible processes that apply natural laws. The Supreme Court subsequently granted *certiorari* in the Myriad case, vacated the judgment, and remanded the case back to the Federal Circuit for further consideration in light of their decision in the Prometheus case. The Federal Circuit heard oral arguments on July 20, 2012, and issued a decision on August 16, 2012. The Federal Circuit reaffirmed its earlier decision and held that composition of matter claims directed to isolated nucleic acids are patent-eligible subject matter, but that method claims consisting of only abstract mental processes are not patent-eligible. On September 25, 2012, the ACLU filed a petition for a *writ of certiorari* asking the Supreme Court to review the Federal Circuit's decision. It is unknown whether the Myriad case will be reviewed by the Supreme Court, and if so, whether any decision therefrom will have an impact on gene patents generally or the ability of biotechnology companies to obtain or enforce gene patents in the future.

On July 3, 2012, 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. The guidance indicates that claims directed to a law of nature, a natural phenomenon, or an abstract idea that do not meet the eligibility requirements should be rejected as non-statutory subject matter. We cannot assure you that our patent portfolio will not be negatively impacted by the decision described above, rulings in other cases or changes in guidance or procedures issued by the USPTO.

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. This study will examine the impact that independent second opinion testing has on providing medical care to patients; the effect that providing independent second opinion genetic diagnostic testing would have on the existing patent and license holders of an exclusive genetic test; the impact of current practices on testing results and performance; and the role of insurance coverage on the provision of genetic diagnostic tests. The USPTO was directed to report the findings of the study to Congress and provide recommendations for establishing the availability of independent confirming genetic diagnostic test activity by June 16, 2012. 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.

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 in the past 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 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 or colon cancer, including public companies such as GE Healthcare, a business unit of General Electric Company, Hologic, Inc., Novartis AG, Myriad Genetics, Inc., 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 Life Technologies Corporation and Illumina, Inc., both of which have recently 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. 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 may 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 *Oncotype 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 in the United States, tumor biopsies removed from patients are 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.

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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.

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

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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 a 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 geneticists, 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 close relationships with medical oncologists, 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.

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 *Oncotype 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

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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 establishing 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, anti-corruption regulations and other governmental approvals, permits and licenses;

- 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;

- 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;

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- 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 sales and distributors activities that may fall within the purview of the Foreign Corrupt Practice Act, 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.

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 September 30, 2012, we have entered into exclusive distribution agreements for the sale of our tests with 20 distributors covering more than 80 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

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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 *Oncotype DX* tests and enhancements to those tests;
- fund commercialization of a test for prostate cancer and 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;
- expand our research and development activities;
- acquire, license or invest in technologies, including next generation sequencing;
- 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 reimbursement arrangements with domestic and international third-party payors;
- the cost of expanding our commercial and laboratory operations, including our selling and marketing efforts;

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- the rate of progress and cost of research and development activities associated with expansion of our *Oncotype DX* breast and colon cancer tests;
- the rate of progress and cost of selling and marketing activities associated with establishing adoption of and reimbursement for our *Oncotype DX* colon cancer test and *Oncotype DX* DCIS test;
- cost related to launching our planned prostate cancer test and future product launches;
- the rate of progress and cost of research and development activities associated with products in research and early development focused on cancers other than breast cancer and colon 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;
- 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;
- the cost 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 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 our company.

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.

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Security breaches, loss of data and other disruptions could compromise sensitive information related to our business 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. The secure processing, storage, maintenance and transmission of this information is critical 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 replacements 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.

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.

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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.

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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 Oncotype 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.

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 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).
101.INS*	XBRL Instance Document
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.

* In accordance with Rule 406T of Regulation S-T, the information furnished in these exhibits will not be deemed filed for purposes of Section 18 of the Exchange Act. Such exhibits will not be deemed to be incorporated by reference into any filing under the Securities Act or 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: November 9, 2012

By: /s/ Kimberly J. Popovits
Kimberly J. Popovits
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 9, 2012

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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