GENOMIC HEALTH INC
Form 10-Q
August 08, 2011
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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2011

Or

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

For the transition period from to

Commission File Number: 000-51541

GENOMIC HEALTH, INC.

(Exact name of registrant as specified in its charter)

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

301 Penobscot Drive

Redwood City, California 94063

(Address of principal executive offices, including Zip Code)

(650) 556-9300

(Registrant s telephone number, including area code)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

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

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

The number of outstanding shares of the registrant s Common Stock, $0.0001 par value, was 29,492,177 as of July 29, 2011.

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PART 1: FINANCIAL INFORMATION

Item 1. Financial Statements

GENOMIC HEALTH, INC.

Condensed Consolidated Balance Sheets

(In thousands)

(Unaudited)

	June 30, 2011	December 31, 2010
ASSETS		
Current assets:		
Cash and cash equivalents	$ 23,750	$ 31,183
Short-term marketable securities	37,252	45,635
Accounts receivable (net of allowance for doubtful accounts; 2011 - $799, 2010 - $680)	19,369	14,306
Prepaid expenses and other current assets	6,980	6,541
Total current assets	87,351	97,665
Long-term marketable securities	19,914	
Property and equipment, net	9,591	10,345
Restricted cash	121	608
Other assets	4,395	2,243
Total assets	$ 121,372	$ 110,861
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,895	$ 3,968
Accrued compensation	8,244	7,352
Accrued license fees	2,716	3,126
Accrued expenses and other current liabilities	5,203	5,584
Deferred revenues current portion	1,441	1,295
Other current liabilities		243
Total current liabilities	19,499	21,568
Deferred revenues long-term portion	737	1,526
Other liabilities	1,471	1,657
Commitments (Note 6)		
Stockholders equity:		
Common stock	3	3
Additional paid-in capital	271,179	259,724
Accumulated other comprehensive loss	28	(10)
Accumulated deficit	(171,545)	(173,607)
Total stockholders equity	99,665	86,110
Total liabilities and stockholders equity	$ 121,372	$ 110,861

See accompanying notes.

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GENOMIC HEALTH, INC.

Condensed Consolidated Statements of Operations

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Revenues:				
Product revenues	$ 50,493	$ 42,514	$ 99,951	$ 82,779
Contract revenues	353	925	705	1,888
Total revenues	50,846	43,439	100,656	84,667
Operating expenses:				
Cost of product revenues	8,226	8,107	17,285	17,073
Research and development	9,879	7,980	19,971	15,773
Selling and marketing	20,529	17,517	41,064	35,532
General and administrative	9,852	8,752	20,208	17,079
Total operating expenses	48,486	42,356	98,528	85,457
Income (loss) from operations	2,360	1,083	2,128	(790)
Interest income	75	54	140	119
Other income (expense), net	(28)	(21)	(78)	1
Income (loss) before income taxes	2,407	1,116	2,190	(670)
Income tax expense	59	251	128	396
Net income (loss)	$ 2,348	$ 865	$ 2,062	$ (1,066)
Basic net income (loss) per share	$ 0.08	$ 0.03	$ 0.07	$ (0.04)
Diluted net income (loss) per share	$ 0.08	$ 0.03	$ 0.07	$ (0.04)
Shares used in computing basic net income (loss) per share	29,332	28,794	29,219	28,759
Shares used in computing diluted net income (loss) per share	30,870	29,627	30,591	28,759

See accompanying notes.

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GENOMIC HEALTH, INC.

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Six Months Ended June 30,	
	2011	**2010**
Operating activities		
Net income (loss)	$ 2,062	$ (1,066)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	3,707	3,461
Stock-based compensation	5,898	5,406
Gain on disposal of property and equipment		(45)
Share of loss of equity method investee	72	
Changes in assets and liabilities:		
Accounts receivable	(5,063)	(1,189)
Prepaid expenses and other assets	46	(288)
Accounts payable	(2,073)	1,921
Accrued compensation	892	(1,355)
Accrued expenses and other liabilities	(1,254)	(884)
Deferred revenues	(643)	
Net cash provided by operating activities	3,644	5,961
Investing activities		
Purchases of property and equipment	(2,841)	(2,329)
Purchases of marketable securities	(67,565)	(36,224)
Maturities of marketable securities	56,072	37,870
Purchase of other investments	(2,300)	
Net cash used in investing activities	(16,634)	(683)
Financing activities		
Principal payments of notes payable		(120)
Proceeds from issuance of common stock under stock plans	5,557	934
Net cash provided by financing activities	5,557	814
Net increase (decrease) in cash and cash equivalents	(7,433)	6,092
Cash and cash equivalents at the beginning of the period	31,183	9,082
Cash and cash equivalents at the end of the period	$ 23,750	$ 15,174
Cash paid for interest	$	$ 10
Cash paid for income taxes	$ 73	$ 546

See accompanying notes.

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GENOMIC HEALTH, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2011

(Unaudited)

Note 1. Organization and Summary of Significant Accounting Policies

The Company

Genomic Health, Inc. (the Company) is a molecular diagnostics company focused 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. The Company was incorporated in Delaware in August 2000. The Company s first product, the Onco*type* DX breast cancer test, was launched in 2004 and is used for early stage breast cancer patients to predict the likelihood of breast cancer recurrence and the likelihood of chemotherapy benefit. In January 2010, the Company launched its second product, the Onco*type* DX colon cancer test, which is used to predict the likelihood of colon cancer recurrence in patients with stage II disease.

Principles of Consolidation

The accompanying interim period 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, which was established in Switzerland in 2009, and Genomic Health International Holdings, LLC, which was established in Delaware in 2010, support the Company s international sales and marketing efforts. Oncotype Laboratories, Inc., which was established in Delaware in 2003, is inactive. Genomic Health International Holdings, LLC has two wholly-owned subsidiaries, Genomic Health U.K., Ltd. and Genomic Health Germany GmbH, which were established in 2011. 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 (GAAP). The condensed consolidated balance sheet as of June 30, 2011, condensed consolidated statements of operations for the three and six months ended June 30, 2011 and 2010 and condensed consolidated statements of cash flows for the six months ended June 30, 2011 and 2010 are unaudited, but include all adjustments, consisting only of normal recurring adjustments, which the Company considers necessary for a fair presentation of its financial position, operating results and cash flows for the periods presented. The condensed consolidated balance sheet at December 31, 2010 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, 2010.

Revenue Recognition

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

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The Company s product revenues for tests performed are recognized when the following revenue recognition criteria are met: (1) persuasive evidence that an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) 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 Onco*type* DX test. In the absence of such arrangements, the Company considers that criterion (1) is satisfied when a third-party payor pays the Company for the test performed. Criterion (2) is satisfied when the Company performs the test and generates and delivers to the physician, or makes available on its web portal, a patient report. Determination of criteria (3) and (4) is 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 agreement. 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.

As of June 30, 2011, the Company had agreements with 16 distributors in various countries outside of the United States. A distributor provides certain marketing and administrative services to the Company within its territory. As a condition of these agreements, the distributor 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 international distributors. Product revenues for tests performed are recognized on an accrual basis when the following revenue recognition criteria are met: (1) persuasive evidence that an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectibility is reasonably assured. 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 $581,000 and $659,000 at June 30, 2011 and December 31, 2010, 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

The Company accrues an allowance for doubtful accounts against its accounts receivable based on estimates consistent with historical payment experience. Bad debt expense is included in general and administrative expense on the Company s condensed consolidated statements of operations. Accounts receivable are written off against the allowance when the appeals process is exhausted, when an unfavorable coverage decision is received or when there is other substantive evidence that the account will not be paid. The Company s allowance for doubtful accounts as of June 30, 2011 and December 31, 2010 was $799,000 and $680,000, respectively. Write-offs for doubtful accounts of $714,000 and $1,487,000 were recorded against the allowance during the three and six months ended June 30, 2011, respectively, and write-offs of $534,000 and $944,000 were recorded during the three and six months ended June 30, 2010, respectively. Bad debt expense was $736,000 and $1.6 million for the three and six months ended June 30, 2011, respectively, and $632,000 and $1.1 million for the three and six months ended June 30, 2010, respectively.

Research and Development Expenses

Research and development expenses are comprised of costs incurred to develop technology and carry out clinical studies and include: salaries and benefits, reagents and supplies used in research and development laboratory work, infrastructure expenses,

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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.

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

Income Taxes

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

The Company accounts for uncertain income tax positions using a benefit recognition model with a two-step approach, a more-likely-than-not recognition criterion and a measurement attribute that measures the position as the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate settlement, in accordance with the accounting guidance for uncertain tax positions. If it is not more likely than not that the benefit will be sustained on its technical merits, no benefit is recorded. Uncertain tax positions that relate only to timing of when an item is included on a tax return are considered to have met the recognition threshold. The Company recognizes accrued interest and penalties related to unrecognized tax benefits in income tax expense when and if incurred. See Note 8, Income Tax, for additional disclosures 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 51% 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 in privately held companies determined to be debt securities are accounted for as available-for-sale or held-to-maturity securities, in accordance with accounting guidance for investments.

In 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. The investment was recorded at cost and is 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. The carrying value of this investment was $2.3 million at June 30, 2011, and no impairment was recognized during the three and six months ended June 30, 2011.

The Company s investments in privately held companies were $2.7 million and $500,000 at June 30, 2011 and December 31, 2010, respectively, and were included in other assets on the Company s consolidated balance sheets.

Recent 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 after December 15, 2011. As this guidance provides only presentation requirements, the adoption of this guidance will not impact the Company s financial condition or results of operations.

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

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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, for which the Company is currently assessing the impact on its financial condition and results of operations, is effective for interim and annual periods beginning after December 15, 2011.

Note 2. Net Income (Loss) Per Share

Basic net income (loss) per share is calculated by dividing net income (loss) for the period by the weighted-average number of common shares outstanding for the period without consideration of potential common shares. Diluted net income (loss) per share is calculated by dividing net income (loss) by the weighted-average number of common shares outstanding for the period and dilutive potential common shares for the period determined using the treasury-stock method. The following table is a reconciliation of the numerator and denominator used in the calculation of basic and diluted net income (loss) per share:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
	(In thousands)			
Numerator:				
Net income (loss)	$ 2,348	$ 865	2,062	$ (1,066)
Denominator:				
Weighted-average shares of common stock outstanding used in the calculation of basic net income (loss) per share	29,332	28,794	29,219	28,759
Effect of dilutive securities:				
Options to purchase common stock	1,494	833	1,349	
Restricted stock units	44		23	
Weighted-average shares of common stock outstanding used in the calculation of diluted net income (loss) per share	30,870	29,627	30,591	28,759

Options to purchase approximately 676,000 and 1.1 million weighted-average shares of the Company s common stock were outstanding during the three and six months ended June 30, 2011, respectively, but are not included in the computation of diluted net income per share because the options exercise prices were greater than the average market price of the Company s common stock during these periods; therefore, their effect is anti-dilutive. Options to purchase approximately 4.2 million weighted-average shares of the Company s common stock were outstanding during the three months ended June 30, 2010, but are not included in the computation of diluted net income per share because the options exercise prices were greater than the average market price of the Company s common stock during these periods; therefore, their effect is anti-dilutive.

Options to purchase 5.6 million shares of the Company s common stock were outstanding as of June 30, 2010, but are not included in the computation of diluted net loss per share for the six months ended June 30, 2010 because their effect is anti-dilutive.

Comprehensive Income (Loss)

The Company currently reports comprehensive income (loss) and its components as part of total stockholders equity.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
	(In thousands)			
Net income (loss)	$ 2,348	$ 865	$ 2,062	$ (1,066)
Change in unrealized gain (loss) on marketable securities available for sale	39	7	38	(6)
Comprehensive income (loss)	$ 2,387	$ 872	$ 2,100	$ (1,072)

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Note 3. Fair Value Measurements

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

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

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

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 June 30, 2011 and December 31, 2010, respectively. The following tables set forth the Company s financial instruments that were measured at fair value on a recurring basis at June 30, 2011 and December 31, 2010 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 June 30, 2011
		(In thousands)		
As of June 30, 2011:				
Assets				
Money market deposits	$ 6,779	$	$	$ 6,779
U.S. Treasury securities	3,775			3,775
Debt securities of U.S. government-sponsored entities		23,925		23,925
Commercial paper		15,748(1)		15,748(1)
Corporate debt securities		15,467		15,467
Total	$ 10,554	$ 55,140	$	$ 65,694

	Actively Quoted Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	Balance at December 31, 2010
		(In thousands)		

As of December 31, 2010:				
Assets				
Money market deposits	$ 9,956	$	$	$ 9,956
U.S. Treasury securities	3,818			3,818
Debt securities of U.S. government-sponsored entities		20,819		20,819
Commercial paper		11,869		11,869
Corporate debt securities		9,129		9,129
Total	$ 13,774	$ 41,817	$	$ 55,591

(1) Includes commercial paper with a fair value of $1.7 million that matures within three months of June 30, 2011 and was classified as cash equivalents on the condensed consolidated balance sheet as of June 30, 2011.

The Company s debt securities of U.S. government-sponsored entities, commercial paper and corporate bonds are classified as Level 2 as they are valued using multi-dimensional relational pricing models that use observable market inputs, including benchmark yields, reported trades, broker-dealer quotes, issuer spreads, benchmark securities, bids, offers and reference data. Not all inputs listed are available for use in the evaluation process on any given day for each security evaluation. In addition, market indicators, industry and economic events are monitored and may serve as a trigger to acquire further corroborating market data. There were no transfers between Level 1 and Level 2 categories during the three and six months ended June 30, 2011 and 2010.

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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:

	June 30, 2011			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
	(In thousands)			
U.S. Treasury securities	$ 3,773	$ 2	$	$ 3,775
Debt securities of U.S. government-sponsored entities	23,911	15	(1)	23,925
Commercial paper	13,984	15		13,999
Corporate debt securities	15,470	1	(4)	15,467
Total	$ 57,138	$ 33	$ (5)	$ 57,166

	December 31, 2010			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
	(In thousands)			
U.S. Treasury securities	$ 3,818	$	$	$ 3,818
Debt securities of U.S. government-sponsored entities	20,825	1	(7)	20,819
Commercial paper	11,868	2	(1)	11,869
Corporate debt securities	9,134		(5)	9,129
Total	$ 45,645	$ 3	$ (13)	$ 45,635

The Company had no realized gains or losses on available-for-sale marketable securities during the three and six months ended June 30, 2011 and 2010, respectively.

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

	June 30, 2011		December 31, 2010	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
	(In thousands)			
Due in one year or less	$ 37,238	$ 37,252	$ 45,645	$ 45,635
Due in more than one year but less than five years	19,900	19,914		
Total	$ 57,138	$ 57,166	$ 45,645	$ 45,635

Note 4. 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 milestones under this arrangement during the three and six months ended June 30, 2011 and 2010, respectively.

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Note 5. 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 expense of $900,000 and $1.8 million for the three and six months ended June 30, 2011, respectively, and $567,000 and $1.2 million for the three and six months ended June 30, 2010, respectively, relating to services provided in connection with these agreements. In addition to these expenses, some of the agreements contain provisions for royalties from inventions resulting from these collaborations. The Company has specified options and rights relating to joint inventions arising out of the collaborations.

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 laboratory tests for the Onco*type* DX tests. While certain agreements contain provisions for fixed annual payments, license fees are generally calculated as a percentage of product revenues, with rates that vary by agreement and may be tiered, and payments that may be capped at annual minimum or maximum amounts. The Company recognized costs recorded under these agreements totaling $2.1 million and $4.9 million for the three and six months ended June 30, 2011, respectively, and $2.1 million and $5.0 million for the three and six months ended June 30, 2010, respectively, which were included in cost of product revenues. License fees for the three and six months ended June 30, 2011 were reduced by an $800,000 payment from Incyte under a legal settlement related to the abandonment of a patent.

At June 30, 2011, future fixed annual payments, exclusive of royalty payments, relating to the launch and commercialization of the Onco*type* DX colon cancer test totaled $1.7 million and are payable as follows:

		Fixed Future Annual Payments (In thousands)
Payment Due:		
January 2012	$	300
January 2013		450
January 2014		450
January 2015		450
Total	$	1,650

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

Note 6. Commitments

Lease Obligations

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

In January 2007, the Company entered into a non-cancelable lease for an additional 48,000 square feet of laboratory and office space. In November 2010, the Company executed an amendment to extend the term of the lease through March 2018, with an option for the Company to extend the 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. The lease expires in March 2018, with an option for the Company to extend the term of the lease for an additional five years. The agreement includes lease incentive obligations of $307,000 that are being amortized on a straight-line basis over the life of the lease. In 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.

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In May 2010, the Company s European subsidiary entered into a non-cancelable lease for approximately 2,500 square feet of office space in Geneva, Switzerland. The lease expires in May 2015. In connection with this lease, the Company paid a CHF 100,800 cash security deposit, which is classified as restricted cash on the condensed consolidated balance sheets.

Future non-cancelable commitments under these operating leases at June 30, 2011 were as follows:

		Annual Payments (In thousands)
Years Ending December 31,		
2011(remainder of year)	$	1,228
2012		2,782
2013		2,915
2014		2,999
2015		3,024
2016 and thereafter		7,030
Total minimum payments	$	19,978

Note 7. Stock-Based Compensation

The Company recorded $3.0 million and $5.9 million of employee stock-based compensation expense for the three and six months ended June 30, 2011, respectively, and $2.8 million and $5.4 million of employee stock-based compensation expense for the three and six months ended June 30, 2010, respectively, including expense for stock option grants and restricted stock awards. Employee stock-based compensation expense was calculated based on options and awards 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. Employee stock-based compensation expense includes expense related to awards to outside directors of the Company.

Restricted Stock

During the three and six months ended June 30, 2011, the Company awarded 23,740 and 311,548 restricted stock units to employees with a grant-date fair value equal to $621,000 and $7.2 million, respectively. Each restricted stock unit entitles the recipient to receive one share of the Company s common stock upon vesting. Restricted stock units 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 six months ended June 30, 2011, the Company awarded 2,030 shares of restricted stock with a grant date fair value equal to $53,000 to outside directors serving on the Company s board. Restricted stock awards to directors were in lieu of fees paid for director service and vested immediately on the award date. The Company did not award any restricted stock to employees or outside directors during the three and six months ended June 30, 2010.

Stock Option Grants

The Company granted options to purchase 69,500 and 548,900 shares of common stock to employees and outside directors during the three and six months ended June 30, 2011, respectively. The Company granted options to purchase 100,850 and 1.2 million shares of common stock to employees during the three and six months ended June 30, 2010, respectively. The Company values its stock option grants using the Black-Scholes option valuation model. Option valuation models require the input of highly subjective assumptions that can vary over time. The Company s assumptions regarding expected volatility are based on the historical volatility of the Company s common stock. The expected life of options granted is estimated based on historical option exercise data and assumptions related to unsettled options. The risk-free interest rate is estimated using published rates for U.S. Treasury securities with a remaining term approximating the expected life of the options granted. The Company uses a dividend yield of zero as it has never paid cash dividends and does not anticipate paying cash dividends in the foreseeable future. The weighted-average fair values and assumptions used in calculating such values during each fiscal year are as follows:

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	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Expected volatility	46%	50%	47%	53%
Risk-free interest rate	1.97%	2.18%	2.30%	2.56%
Expected life of options in years	5.71	5.86	6.20	5.86
Weighted-average fair value	$ 11.65	$ 6.89	$ 11.18	$ 8.75

For the three and six months ended June 30, 2011, the Company issued 189,187 and 425,546 shares of common stock in connection with the exercise of stock options with a weighted-average exercise price of $12.66 and $12.94 per share, respectively. For the three and six months ended June 30, 2010, the Company issued 38,108 and 132,619 shares of common stock in connection with the exercise of stock options with a weighted-average exercise price of $4.34 and $7.05 per share, respectively.

Employee Stock Purchase Plan

At the annual meeting of stockholders held on June 9, 2011, the Company s stockholders approved the Genomic Health, Inc. Employee Stock Purchase Plan (ESPP), as adopted by the Company s board of directors. The ESPP provides eligible employees with an opportunity to purchase common stock from the Company and to pay for their purchases through payroll deductions. A total of 1,250,000 shares of common stock were reserved for issuance under the ESPP. The ESPP is expected to be implemented through a series of offerings of purchase rights to eligible employees beginning December 1, 2011. Under the ESPP, the Compensation Committee of the Company s board of directors may specify offerings with a duration of not more than 27 months, and may specify shorter purchase periods within each offering. During each purchase period, payroll deductions will accumulate, without interest. On the last day of the purchase period, accumulated payroll deductions will be used to purchase common stock for employees participating in the offering. The purchase price will be specified pursuant to the offering, but cannot, under the terms of the ESPP, be less than 85% of the fair market value per share of the Company s common stock on either the last trading day preceding the offering date or on the purchase date, whichever is less.

The Company s board of directors has determined that the purchase periods initially shall have a duration of six months and that the purchase price will be 85% of the fair market value per share of the Company s common stock on either the last trading day preceding the offering date or the purchase date, whichever is less. The length of the purchase period applicable to U.S. employees and the purchase price may not be changed without the approval of the independent board members of the Company s board of directors.

Note 8. Income Tax

The Company recorded income tax expense of $59,000 and $128,000 for the three and six months ended June 30, 2011, respectively, which was computed using the discrete (or cut-off) method and was principally comprised of state income taxes and foreign taxes. The Company recorded income tax expense of $251,000 and $396,000 for the three and six months ended June 30, 2010, respectively, which was computed using the discrete (or cut-off) method and was principally comprised of California alternative minimum tax, other state income taxes and foreign taxes. The difference of income tax expense between the provision and the statutory rate of the Company s loss before income taxes and provision actually recorded was primarily due to the impact of nondeductible stock-based compensation expenses. No federal tax provision was recorded due to the utilization of net operating loss carryforwards for federal and alternative minimum tax purposes.

The Company is required to reduce its deferred tax assets by a valuation allowance if it is more likely than not that some or all of its deferred tax assets will not be realized. Management 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 the valuation allowance, if any, the Company assesses the likelihood that it will be able to recover its deferred tax assets using historical levels of income, estimates of future income and tax planning strategies. As a result of historical cumulative losses, the Company determined that, based on all available evidence, there was substantial uncertainty as to whether it will recover recorded net deferred taxes in future periods. Accordingly, the Company recorded a valuation allowance against all of its net deferred tax assets at both June 30, 2011 and December 31, 2010. The Company intends to continue maintaining a full valuation allowance on its deferred tax assets until there is sufficient evidence to support the reversal of all or some portion of these allowances. Should the actual timing differences differ from the Company s estimates, the amount of its valuation allowance could be materially impacted.

The Company had $768,000 of unrecognized tax benefits as of June 30, 2011 and December 31, 2010. 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.

The Company recognizes accrued interest and penalties related to unrecognized tax benefits as part of its income tax provision in its consolidated statements of operations. All tax years from 2000 forward remain subject to future examination by federal, state and foreign tax authorities.

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

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. When used in this report, the words expects, anticipates, intends, estimates, plans, believes, and similar expressions are intended to identify forward-looking statements. These are statements that relate to future periods and include statements about our expectation that, for the foreseeable future, a significant amount of our revenues will be derived from Oncotype DX for breast cancer; the factors that may impact our financial results; the extent of our net losses and 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; the amount of future revenues that we may derive from Medicare patients or categories of patients; 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 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; 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 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; 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; 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 the ability of our technology to continue to increase throughput; our expectations regarding our future technologies and their potential benefits; our belief that multi-gene analysis provides better analytical information; our beliefs regarding the benefits of genomic analysis in various patient populations; our expectations regarding clinical development processes future tests may follow; our beliefs regarding the benefits of individual gene reporting; our expectation that our research and development, general and administrative and sales and marketing expenses will increase and our anticipated uses of those funds; our beliefs regarding future levels of bad debt expense and billing and collection fees; our expectations regarding capital expenditures; our ability to comply with the requirements of being a public company; 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 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 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 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 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 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

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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 and Recurrence 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 molecular diagnostic company focused 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. In January 2004, we launched our first Onco*type* DX test, which is used to predict the likelihood of cancer recurrence and the likelihood of chemotherapy benefit in early stage breast cancer patients. In January 2010, we launched our second Onco*type* DX test, which is used to predict the likelihood of cancer recurrence in stage II colon cancer patients. Effective July 1, 2011, the list price of our Onco*type* DX breast cancer test increased from $4,075 to $4,175 and the list price of our Onco*type* DX colon cancer test increased from $3,200 to $3,280. The majority of our historical revenues have been derived from the sale of Onco*type* DX breast cancer tests ordered by physicians in the United States.

For the three and six months ended June 30, 2011, more than 16,390 and 32,630 Onco*type* DX test reports were delivered for use in treatment planning, respectively, compared to more than 14,050 and 27,360 reports delivered for the three and six months ended June 30, 2010, 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 20,000 tests per calendar quarter. As test processing for our Onco*type* 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.

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 also 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. Our initial commercialization efforts in markets outside of the United States have focused on offering products predominately on a patient self-pay basis and, over time, seeking coverage from public health systems and private insurance on a country by country basis. We have sales representatives as well as distributors in certain countries outside of the United States. We may decide to work directly on our own in certain countries while continuing to utilize distributors in other countries. We have subsidiaries in Europe and have lead executives with assignments in the Americas, Europe and Asia to support our international efforts.

We expect that international sales of our Onco*type* DX tests will be heavily dependent on the availability of reimbursement. 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. We expect that it will take several years to establish broad coverage and reimbursement for our tests in countries outside of the United States, and we do not expect international product revenues to comprise more than 10% of our total revenues for the remainder of the year.

Oncotype DX Breast Cancer Test

We expect to continue to focus substantial resources on pursuing global adoption of and reimbursement for our Onco*type* DX breast cancer test. We believe increased demand for our Onco*type* DX breast cancer test resulted from our ongoing commercial efforts, 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. However, this increased demand is not necessarily indicative of future growth rates, and we cannot assure you that this level of increased demand can be sustained or that publication of articles, future appearances or presentations at medical conferences or increased commercial efforts will have a similar impact on demand for our breast cancer test in the future. Sequential quarterly demand for our breast cancer test may also be impacted by other factors, including the economic environment and continued high unemployment levels, seasonal variations that have historically impacted physician office visits, our shift in commercial focus to our Onco*type* DX colon cancer test or any future products we may develop, patient enrollment in Onco*type* DX clinical studies and the number of clinical trials in process by cooperative groups or makers of other tests conducting experience studies.

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

As of June 30, 2011, we had distribution agreements for our Onco*type* DX breast cancer test with 16 distributors in countries outside of the United States**,** and have established reimbursement arrangements for this test with several public and private payors and hospitals. We have obtained initial coverage for our breast cancer test for certain patient populations in Canada, Germany, Greece, Ireland, Israel, Mexico, Spain, Venezuela and the United Kingdom and have completed or initiated multiple international studies intended to support the adoption of our breast cancer test outside of the United States. In March 2011, at the St. Gallen International Breast Conference, we presented results of nine studies from seven countries demonstrating chemotherapy reduction and overall cost effectiveness when Onco*type* DX is used. In June 2011, *Annals of Oncology* published results from a decision impact study of the Onco*type* DX breast cancer test in Spain demonstrating a more than 30% change in chemotherapy treatment recommendations, consistent with previously reported results in the United States, Germany, the United Kingdom and Israel. In July 2011, updated St. Gallen Breast Cancer Expert Panel guidelines including Onco*type* DX for prognosis and prediction of chemotherapy benefit were published online by the *Annals of Oncology*. However, we expect that it may take several years to establish coverage with public and private payors outside of the United States and we may not be able to obtain such reimbursement.

Oncotype DX Colon Cancer Test

We expect to continue to focus substantial resources on pursuing global adoption of and reimbursement for our Onco*type* DX colon cancer test. We believe the key factors that will drive adoption of this test include publication of peer-reviewed articles on the QUASAR colon cancer clinical validation study and other studies we sponsored, conducted or collaborated on that support the use of and reimbursement for the test, clinical presentations at major symposia and our ongoing commercial efforts. In June 2011, the QUASAR clinical validation study was accepted for publication by the *Journal of Clinical Oncology*. We are working with 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. We may need to hire additional commercial, scientific, technical and other personnel to support this process.

We have obtained limited reimbursement coverage for our Onco*type* DX colon cancer test from third-party payors. As a 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 are also working with public and private payors and health plans to secure coverage for our Onco*type* DX colon cancer test based upon clinical evidence showing the utility of the test. We believe it may take several years to achieve reimbursement with a majority of third-party payors for our colon cancer test. However, we cannot predict whether, at what rate, or under what circumstances, payors will reimburse for this test. Based upon our experience in obtaining adoption of and reimbursement for our Onco*type* DX breast cancer test, we do not expect product revenues from our colon cancer test to comprise more than 10% of our total revenues for at least the next year or more.

In June 2011, at the American Society of Clinical Oncology, or ASCO, Annual Meeting, a second large validation study confirming that the Onco*type* DX colon cancer test independently predicts individualized recurrence risk for stage II colon cancer was presented. We are currently enrolling patients in our first treatment decision impact study of our colon cancer test, and we are planning additional studies to support the clinical utility and assess the treatment impact and health economic benefit of our colon cancer test. Additionally, we plan to continue conducting early development studies to evaluate our Onco*type* DX colon cancer test for treatment planning in stage III disease, and we are also conducting studies to investigate our colon cancer test s ability to predict chemotherapy benefit in stage II and stage III colon cancer patients treated with oxaliplatin.

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Product Pipeline

We are investigating the utility of Onco*type* DX in patients with ductal carcinoma in situ, or DCIS, breast cancer, which generally refers to a pre-invasive tumor with reduced risk of recurrence. We plan to evaluate the use of the Onco*type* DX 21-gene breast cancer panel and also seek to identify other genes that may be used for treatment planning in DCIS. In May 2011, we announced positive preliminary results from our DCIS clinical validation study. The study met its primary endpoint by demonstrating that a pre-specified Onco*type* DX DCIS Score can 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. Based on these preliminary results, we plan to make the Onco*type* DX DCIS Score available to patients and physicians worldwide by the end of 2011.

In February 2011, at the American Society of Clinical Oncology Genitourinary Cancer Symposium and the United States and Canadian Academy of Pathology meeting, we presented positive full results from our prostate gene identification study. The study, which applied the same reverse transcription polymerase chain reaction, or RT-PCR, technology used in our Onco*type* DX breast and colon cancer tests, identified 295 genes strongly associated with clinical recurrence of prostate cancer following radical prostatectomy. Based on these results, we announced that we are moving forward with full clinical development for a prostate cancer test and plan to conduct multiple additional studies.

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 are planning a renal cancer clinical validation study.

Technology

We are developing high-throughput, next generation sequencing, or NGS, to be our primary technology for future gene discovery. 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 of transcriptome profiling 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.

Economic Environment

Continuing concerns over prolonged high unemployment levels across the United States, the availability and cost of credit, the U.S. mortgage market, the U.S. real estate market, Federal budget proposals, proposed regulatory changes, inflation, deflation, taxation issues, energy costs and geopolitical issues have contributed to increased volatility and uncertain expectations for the U.S. economy. These factors, combined with uncertainties in business and consumer confidence, uncertainty related to the impact of the recent downgrade of the United States credit rating and a volatile stock market, have precipitated an economic slowdown and expectations of slower global economic growth and possibly another recession going forward. We periodically evaluate the impact of this 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. From time to time, we 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 months and six ended June 30, 2011. 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, the volume of tests delivered could continue to be negatively impacted and we could, in turn, experience lower revenues.

U.S. Healthcare Legislation

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. Though there are some exceptions to the tax, because the FDA maintains that clinical laboratory tests that are developed and validated by a laboratory for its own use, or LDTs, such as our

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Onco*type* DX breast and colon cancer tests, are medical devices, it may apply to some or all of our current products and products in development. The PPACA also mandates a reduction in payments for clinical laboratory services paid under the Medicare Clinical Laboratory Fee Schedule, and a productivity adjustment to the Clinical Laboratory Fee Schedule. In addition, the PPACA establishes a board that is charged with reducing the per capita rate of growth in Medicare spending. These or any future proposed or mandated reductions in payments may apply to some or all of our clinical laboratory tests delivered to Medicare beneficiaries**.**

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.

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 that 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.

As of June 30, 2011, we had agreements with 16 distributors in various countries outside of the United States The distributor provides us with certain marketing and administrative services within its territory. As a condition of these agreements, the distributor 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 international

distributors. Product revenues for tests performed are recognized on an accrual basis when the following revenue recognition criteria are met: (1) persuasive evidence that an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectibility is reasonably assured. 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 June 30, 2011, 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 $33 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 $581,000 and $659,000 at June 30, 2011 and December 31, 2010, 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 June 30, 2011 and December 31, 2010, our allowance for doubtful accounts was $799,000 and $680,000, respectively. 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 negotiations, 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

Compensation expense related to restricted stock unit awards is based on the market value of the Company s common stock at the date of grant and is recognized as expense ratably over the requisite service period. Compensation expense related to stock option grants is estimated at the date of grant based on the fair value of the award using the Black-Scholes option valuation model and is recognized as expense 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. Expected forfeiture rates for both restricted stock unit awards and stock option grants are based on historical data, and compensation expense is adjusted for actual results.

We review our valuation assumptions on an ongoing basis, and, as a result, our assumptions used to value stock awards granted in future periods may change. See Note 7, 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.

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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, we determined that, based on all available evidence, there was substantial uncertainty as to our ability to realize recorded net deferred taxes in future periods. Accordingly, we recorded a valuation allowance against all of our net deferred tax assets at both June 30, 2011 and December 31, 2010.

Results of Operations

Three and Six Months Ended June 30, 2011 and 2010

We recorded net income of $2.3 million and $2.1 million for the three and six months ended June 30, 2011, respectively, compared to net income of $865,000 for the three months ended June 30, 2010 and a net loss of $1.1 million for the six months ended June 30, 2010. On a basic and diluted per share basis, net income was $0.08 and $0.07 for the three and six months ended June 30, 2011, respectively, compared to net income of $0.03 for the three months ended June 30, 2010 and a net loss was $0.04 for the six months ended June 30, 2010. Net income for the three and six months ended June 30, 2011 included an $800,000 payment from Incyte under a legal settlement related to the abandonment of a patent. 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 June 30, 2011, the majority of product revenues have been derived from the sale of our Onco*type* DX breast cancer test. Payors are billed upon generation and delivery of a patient 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.

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2011	2010	2011	2010
	(In thousands)			
Product revenues	$ 50,493	$ 42,514	$ 99,951	$ 82,779
Contract revenues	353	925	705	1,888
Total revenues	$ 50,846	$ 43,439	$ 100,656	$ 84,667

Period over period dollar increase in product revenues	$	7,979	$	17,172
Period over period percentage increase in product revenues		19%		21%

The increase in product revenues for both the three and six month comparative periods resulted from increased adoption, as evidenced by 17% and 19% period over period increases in test volume, respectively. We also experienced expanded reimbursement coverage and an increase in revenues recorded on an accrual basis. Approximately 66% of product revenues for both the three and six months ended June 30, 2011, respectively, were recorded on an accrual basis and recognized at the time the test results were delivered, compared to approximately 53% for both the three and six months ended June 30, 2010. For all periods presented, the balance of product revenues was recognized upon cash collection as payments were received. The timing of recognition of revenues related to third-party payments may cause fluctuations in product revenues from period to period.

Product revenues related to Medicare patients were $10.3 million, or 20%, and $20.7 million, or 21%, of product revenues for the three and six months ended June 30, 2011, respectively, compared to $8.4 million, or 20%, and $16.7 million, or 20%, of product revenues for the three and six months ended June 30, 2010, respectively. There were no other third-party payors comprising product revenues of 10% or more for those periods. International product revenues were $4.8 million, or 9%, and $8.8 million, or 9%, of

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product revenues for the three and six months ended June 20, 2011, respectively, compared to $2.2 million, or 5%, and $4.0 million, or 5%, of product revenues for the three and six months ended June 30, 2010, respectively.

Contract revenues were $353,000 and $705,000 for the three and six months ended June 30, 2011, respectively, compared to $925,000 and $1.9 million for the three and six months ended June 30, 2010, respectively. Contract revenues represented studies assessing our gene expression technology or collaborative work in gene selection and protocol design with our pharmaceutical partners. The decrease in contract revenues for 2011 compared to 2010 was due to the level of ongoing activities related to our collaboration with Pfizer Inc. We have entered into other short-term contract research arrangements that are not material to our financial condition or results of operations. We expect that our contract revenues will continue to fluctuate based on the number and timing of studies being conducted.

Cost of Product Revenues

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2011	2010	2011	2010
	(In thousands)			
Tissue sample processing costs	$ 6,071	$ 5,930	$ 12,249	$ 11,883
Stock-based compensation	85	96	175	189
Total tissue sample processing costs	6,156	6,026	12,424	12,072
License fees	2,070	2,081	4,861	5,001
Total cost of product revenues	$ 8,226	$ 8,107	$ 17,285	$ 17,073
Period over period dollar increase	$ 119		$ 212	
Period over period percentage increase	1%		1%	

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, including royalties. Infrastructure expenses include allocated information technology and facility occupancy costs. Costs associated with performing our test are recorded as tests are processed. Costs recorded for tissue sample processing represent the cost of all the tests processed during the period regardless of whether revenue was recognized with respect to that test. Royalties for licensed technology calculated as a percentage of product revenues and fixed annual payments relating to the launch and commercialization of Onco*type* DX tests are recorded as license fees in cost of product revenues at the time product revenues are recognized or in accordance with other contractual obligations. While license fees are generally calculated as a percentage of product revenues, the percentage increase in license fees does not correlate exactly to the percentage increase in product revenues because certain agreements contain provisions for fixed annual payments and other agreements have tiered rates and payments that may be capped at annual minimum or maximum amounts. License fees represent a significant component of our cost of product revenues and are expected to remain so for the foreseeable future.

Tissue sample processing costs increased $141,000 or 2%, for the three months ended June 30, 2011 compared to the three months ended June 30, 2010. Tissue sample processing costs increased $366,000, or 3%, for the six months ended June 30, 2011 compared to the six months ended June 30, 2010. These increases were due to increases in test volume offset by cost controls and efficiency gains. License fees for the three and six months ended June 30, 2011 were reduced by an $800,000 payment from Incyte under a legal settlement related to the abandonment of a patent. We expect the cost of product revenues to return to historical levels and to increase in future periods in proportion with increased product revenues as long as the license agreements remain unchanged and the patents underlying those agreements remain effective.

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Research and Development Expenses

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2011	2010	2011	2010
	(In thousands)			
Personnel-related expenses	$ 5,087	$ 3,965	$ 10,233	$ 8,058
Stock-based compensation	769	759	1,532	1,466
Reagents and laboratory supplies	465	478	1,159	820
Collaboration expenses	900	567	1,791	1,163
Allocated information technology, facilities and other costs	1,740	1,296	3,408	2,605
Other expenses	918	915	1,848	1,661
Total research and development expenses	$ 9,879	$ 7,980	$ 19,971	$ 15,773
Period over period dollar increase	$ 1,899		$ 4,198	
Period over period percentage increase	24%		27%	

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 $1.9 million, or 24%, increase in research and development expenses for the three months ended June 30, 2011 compared to the three months ended June 30, 2010 included a $1.1 million increase in personnel-related expenses, a $444,000 increase in allocated information technology, facilities and other costs, and a $333,000 increase in collaboration expenses. The $4.2 million, or 27%, increase in research and development expenses for the six months ended June 30, 2011 compared to the six months ended June 30, 2010 included a $2.2 million increase in personnel-related expenses, an $803,000 increase in allocated information technology, facilities and other costs, a $628,000 increase in collaboration expenses, and a $339,000 increase in reagents and laboratory supplies expense. The increases in personnel-related expenses were primarily attributable to increases in salaries and benefits due to increased headcount to support projects related to our pipeline and ongoing work in NGS. We expect our research and development expenses to increase in future periods due to the initiation of additional studies related to our colon test and increased investment in NGS and our product pipeline for breast, colon, renal, prostate and other cancers.

Selling and Marketing Expenses

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2011	2010	2011	2010
	(In thousands)			
Personnel-related expenses	$ 10,646	$ 8,464	$ 21,561	$ 17,359
Stock-based compensation	804	831	1,597	1,658
Promotional and marketing materials	3,422	3,510	6,293	7,056
Travel, meetings and seminars	2,226	1,933	4,981	4,112
	2,621	2,166	5,121	4,039

Allocated information technology, facilities and other costs				
Other expenses	810	613	1,511	1,308
Total sales and marketing expenses	$ 20,529	$ 17,517	$ 41,064	$ 35,532
Period over period dollar increase	$ 3,012		$ 5,532	
Period over period percentage increase	17%		16%	

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

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The $3.0 million, or 17%, increase in selling and marketing expenses for the three months ended June 30, 2011 compared to the three months ended June 30, 2010 was attributable to both U.S. and international operations support and included a $2.2 million increase in personnel-related expenses, a $455,000 increase in allocated information technology, facilities and other costs, and a $293,000 increase in travel, meetings and seminars expenses. Of the $2.2 million increase in personnel-related expenses, $1.4 million was attributable to increases in salaries, benefits and related expenses due primarily to increased headcount, $564,000 was attributable to higher commissions and bonus payments, and $179,000 was attributable to higher consulting expenses.

The $5.5 million, or 16%, increase in selling and marketing expenses for the six months ended June 30, 2011 compared to the six months ended June 30, 2010 was attributable to both U.S. and international operations support and included a $4.2 million increase in personnel-related expenses, a $1.1 million increase in allocated information technology, facilities and other costs, and a $869,000 increase in travel, meetings and seminars expenses, partially offset by a $763,000 decrease in promotional and marketing materials related to our colon product launch in January 2010. Of the $4.2 million increase in personnel-related expenses, $2.5 million was attributable to increases in salaries, benefits and related expenses due primarily to increased headcount, $1.2 million was attributable to higher commissions and bonus payments, and $527,000 was attributable to higher consulting expenses

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 Onco*type* DX colon cancer test and continued investment in our global commercial infrastructure.

General and Administrative Expenses

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2011	2010	2011	2010
	(In thousands)			
Personnel-related expenses	$ 6,362	$ 5,304	$ 12,790	$ 10,527
Stock-based compensation	1,322	1,092	2,594	2,092
Occupancy and equipment expenses	3,550	3,141	7,119	6,197
Billing and collection fees	1,620	1,735	3,366	3,261
Bad debt expense	736	632	1,606	1,111
Professional fees and other expenses	1,692	1,605	3,602	3,105
Information technology, facilities and other cost allocations	(5,430)	(4,757)	(10,869)	(9,214)
Total general and administrative expenses	$ 9,852	$ 8,752	$ 20,208	$ 17,079
Period over period dollar increase	$ 1,100		$ 3,129	
Period over period percentage increase	13%		18%	

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

The $1.1 million, or 13%, increase in general and administrative expenses for the three months ended June 30, 2011 compared to the three months ended June 30, 2010 included a $1.1 million increase in personnel-related expenses, a $409,000 increase in occupancy and equipment expenses, and a $230,000 increase in stock-based compensation expense, partially offset by a $673,000 increase in information technology, facilities and other costs allocated to other functional areas. Of the $1.1 million increase in personnel-related expenses, $882,000 was attributable to annual increases in salaries and benefits expenses and $176,000 was attributable to higher consulting expenses to support the growth of our business.

The $3.1 million, or 18%, increase in general and administrative expenses for the six months ended June 30, 2011 compared to the six months ended June 30, 2010 included a $2.3 million increase in personnel-related expenses, a $922,000 increase in occupancy and equipment expenses, a $497,000 increase in professional fees and other expenses, a $495,000 increase in bad debt expense, and a $502,000 increase in stock-based compensation expense, partially offset by a $1.7 million increase in information technology, facilities and other costs allocated to other functional areas. Of the $2.2 million increase in personnel-related expenses, $1.7 million was attributable to annual increases in salaries and benefits expenses and $528,000 was attributable to higher consulting expenses to support the growth of our business.

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We expect general and administrative expenses to increase in future periods as we hire additional staff and incur other expenses to support the growth of our business, and to the extent we spend more on billing and collection fees and bad debt expenses. We expect billing and collection fees and bad debt expenses in total will continue to be approximately 5% of product revenues for at least the next year or more.

Interest Income

Interest income was $75,000 and $140,000 for the three and six months ended June 30, 2011, respectively, compared to $54,000 and $119,000 for the three and six months ended June 30, 2010, respectively. The period over period increases were due primarily to increases in the balances of our marketable securities portfolio. We expect our interest income will remain nominal if the current low interest rate environment continues.

Other Income (Expense), Net

Other expense was $28,000 and $78,000 for the three and six months ended June 30, 2011, respectively, compared to other expense of $21,000 and other income of $1,000 for the three and six months ended June 30, 2010, respectively. The period over period variances were due primarily to losses of $43,000 and $72,000 on an investment in a private company accounted for using the equity method during the three and six months ended June 30, 2011, respectively, partially offset by net foreign currency transaction gains. Other income for the six months ended June 30, 2010 also included $45,000 in gains on disposals of equipment. We expect other income (expense) to continue to fluctuate based on the performance of an investment accounted for under the equity method and fluctuations in exchange rates that impact our foreign exchange transaction gains and losses.

Income Tax Expense

Income tax expense was $59,000 and $128,000 for the three and six months ended June 30, 2011, respectively, compared to $251,000 and $396,000 for the three and six months ended June 30, 2010, respectively. Income tax expense for all periods was principally comprised of state income taxes and foreign taxes and was computed using the discrete, or cut-off , method.

As a result of historical losses since inception and based on all available evidence, we continue to believe that there is substantial uncertainty as to whether we will recover recorded net deferred taxes in future periods. We intend to maintain a full valuation allowance on our deferred tax assets until sufficient evidence exists to support the reversal of all or some portion of these allowances. Accordingly, we maintained a full valuation allowance on our net deferred tax assets at both June 30, 2011 and December 31, 2010.

Liquidity and Capital Resources

As of June 30, 2011, we had an accumulated deficit of $171.5 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.

	2011	2010	$ Change
		(In thousands)	
As of June 30:			
Cash, cash equivalents and marketable securities	$ 80,916	$ 61,888	$ 19,028
Working capital	67,852	61,937	5,915
For the six months ended June 30:			
Cash provided by (used in):			
Operating activities	3,644	5,961	(2,317)
Investing activities	(16,634)	(683)	(15,951)
Financing activities	5,557	814	4,743
Capital expenditures (included in investing activities above)	$ (2,841)	$ (2,329)	$ (512)

Sources of Liquidity

At June 30, 2011, we had cash, cash equivalents and marketable securities of $80.9 million compared to $61.9 million at June 30, 2010. The $19.0 million increase was attributable to increased cash collections from sales of our tests, payments from collaborators, cash received from the exercise of employee stock options and cash received from a legal settlement, which were partially offset by

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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 low-risk, investment-grade debt instruments. Our cash and marketable securities are held in a variety of interest-bearing instruments including money market accounts, U.S. Treasury securities, debt obligations of U.S. government-sponsored entities, and high-grade commercial paper and corporate bonds.

Historically we have financed our operations primarily through sales of our equity securities and cash received in payment for our tests. Purchases of equipment and leasehold improvements have been partially financed through capital equipment financing arrangements. Our notes payable under these arrangements were paid in full as of November 2010.

Accounts Receivable

At June 30, 2011 and December 31, 2010, $19.4 million, or 16%, and $14.3 million, or 13%, respectively, of our total assets consisted of accounts receivable. The $5.1 million increase in accounts receivable was primarily attributable to additional payors moving from cash basis to accrual basis. 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 June 30, 2011 and December 31, 2010, our weighted average DSOs were 58 days and 47 days, respectively. The timing of our billing and cash collections causes fluctuations in our monthly DSOs and accounts receivable.

The following tables summarize accounts receivable by payor mix at June 30, 2011 and December 31, 2010:

	June 30, 2011							
	Total	% of Total	Current	31-60 Days	61-90 Days	91-120 Days	121 to 180 Days	Over 180 Days
				(In thousands)				
Managed care and other	$ 14,869	74%	$ 7,437	$ 2,449	$ 1,643	$ 1,283	$ 864	$ 1,193
Medicare	5,299	26	4,116	793	69	34	65	222
Total	20,168	100%	$ 11,553	$ 3,242	$ 1,712	$ 1,317	$ 929	$ 1,415
Allowance for doubtful accounts	(799)							
Net accounts receivable	$ 19,369							

	December 31, 2010							
	Total	% of Total	Current	31-60 Days	61-90 Days	91-120 Days	121 to 180 Days	Over 180 Days
				(In thousands)				
Managed care and other	$ 9,725	65%	$ 5,367	$ 1,598	$ 706	$ 525	$ 579	$ 950
Medicare	5,261	35	4,070	666	73	110	103	239
Total	14,986	100%	$ 9,437	$ 2,264	$ 779	$ 635	$ 682	$ 1,189
Allowance for doubtful accounts	(680)							
Net accounts receivable	$ 14,306							

Cash Flows

Net cash provided by operating activities was $3.6 million for the six months ended June 30, 2011 compared to $6.0 million for the six months ended June 30, 2010. Net cash provided by operating activities includes net loss adjusted for certain non-cash items and changes in assets and liabilities. Net cash provided by operating activities for the six months ended June 30, 2011 reflected net income of $2.1 million, adjusted for $9.6 million of stock-based compensation and depreciation and amortization expense, partially offset by a $5.1 million increase in accounts receivable, a $2.1 million decrease in accounts payable and a $1.3 million decrease in accrued expenses and other liabilities. Net cash provided by operating activities for the six months ended June 30, 2010, reflected a net loss of $1.1 million, adjusted for $8.9 million of stock-based compensation and depreciation and amortization expense, and a $1.9 million increase in accounts payable, partially offset by a $1.2 million increase in accounts receivable, a $1.4 million decrease in accrued compensation expense and an $884,000 decrease in accrued expenses and other liabilities.

Net cash used in investing activities was $16.6 million for the six months ended June 30, 2011 compared to $683,000 for the six months ended June 30, 2010. Our investing activities have consisted predominately of purchases and maturities of marketable securities and capital expenditures. Net cash used in investing activities for the six months ended June 30, 2011 included $11.5 million in net purchases of marketable securities, a $2.3 million investment in a privately held company and $2.8 million in capital expenditures. Net cash used in investing activities for the six months ended June 30, 2010 included $2.3 million in capital expenditures, partially offset by $1.6 million in net purchases of marketable securities.

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Net cash provided by financing activities was $5.6 million for the six months ended June 30, 2011 compared to $814,000 for the six months ended June 30, 2010. Our financing activities have historically included sales of our equity securities and payments on our capital equipment financing arrangements. Net cash provided by financing activities for the six months ended June 30, 2011 included $5.6 million in proceeds from the issuance of our common stock upon the exercise of employee stock options. Net cash provided by financing activities for the six months ended June 30, 2010 included $934,000 in proceeds from the issuance of our common stock upon the exercise of employee stock options, partially offset by $120,000 in principal payments on our debt.

Contractual Obligations

The following table summarizes our significant contractual obligations as of June 30, 2011 and the effect those obligations are expected to have on our liquidity and cash flows in future periods:

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
			(In thousands)		
Non-cancelable operating lease obligations	$ 19,978	$ 2,586	$ 5,831	$ 6,057	$ 5,504

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. This lease, as amended, expires in March 2019. In January 2007, we entered into a non-cancelable lease for 48,000 square feet of additional laboratory and office space in a nearby location. This lease, as amended, expires in March 2018. In October 2009, we entered into a non-cancelable lease an additional 30,500 square feet of office space in a nearby location. This lease, as amended, expires in March 2018. In May 2010, we entered into a non-cancelable lease for 2,500 square feet of office space in Geneva, Switzerland. This lease expires in May 2015.

We are required to make a series of fixed annual payments under one of our collaboration agreements beginning with the January 2010 launch of our Onco*type* DX colon cancer test. We made payments under this agreement of $150,000 in 2010 and $200,000 in 2011. As of June 30, 2011, future annual payments under this agreement totaled $1.7 million, of which $300,000 is due in 2012 and $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 achieved positive operating cash flow for the six months ended June 30, 2011 and the year ended December 31, 2010. We currently anticipate that our cash, cash equivalents and marketable securities, together with cash flows from operations, 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, establishment of adoption of and reimbursement for our Onco*type* DX colon cancer test, and our international expansion efforts. We expect to spend approximately $7 million over the next 12 months for planned laboratory equipment, information technology expansion and facilities expansion. We may also use cash to acquire or fund additional investments in complementary businesses, technologies, services or products. We expect that our cash, cash equivalents and marketable securities 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 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 establish adoption of and reimbursement for our Onco*type* DX colon cancer test or the development of future products will be successful or that we will be able to raise sufficient additional

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funds to see these activities through to a successful result. It may take years to move any one of a number of product candidates in research through development and validation to commercialization.

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

- the rate of progress in establishing reimbursement arrangements with domestic and international third-party payors;
- the cost of expanding our commercial and laboratory operations, including our selling and marketing efforts;
- the rate of progress and cost of research and development activities associated with expansion of our Onco*type* DX breast and colon cancer tests;
- the rate of progress and cost of selling and marketing activities associated with establishing adoption of and reimbursement for our Onco*type* DX colon cancer 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;
- costs related to future product launches;
- the cost of acquiring or achieving access to tissue samples and technologies;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the effect of competing technological and market developments;
- costs related to international expansion;

- 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 June 30, 2011, we had no material off-balance sheet arrangements.

Recent Accounting Pronouncements

In June 2011, the Financial Accounting Standards Board, or 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

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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 after December 15, 2011. As this guidance provides only presentation requirements, the adoption of this guidance will not impact our financial condition or results of operations.

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 in 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, for which we are currently assessing the impact on its financial condition and results of operations, is effective for interim and annual periods beginning after December 15, 2011.

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 low-risk, investment-grade debt instruments. Our investments in marketable securities, which are comprised primarily of money market funds, obligations of U.S. Government agencies and government-sponsored entities, commercial paper and corporate bonds, are subject to default, changes in credit rating and changes in market value. These investments are subject to interest rate risk and will decrease in value if market interest rates increase.

Our cash, cash equivalents and marketable securities, totaling $80.9 million at June 30, 2011, did not include any auction preferred stock, auction rate securities or mortgage-backed investments. We currently do not hedge interest rate exposure, and we do not have any foreign currency or other derivative financial instruments. The securities in our investment portfolio are classified as available for sale and are subject to minimal interest rate risk. To date, we have not experienced a loss of principal on any of our marketable securities. 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 June 30, 2011, 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 volatility in foreign currency exchange rates or changes in economic conditions in foreign markets will affect our financial results. We recognized net foreign exchange transaction gains of $22,000 and $2,000 for the three and six months ended June 30, 2011, respectively, compared to net foreign exchange transaction losses of $20,000 and $35,000 for the three and six months ended June 30, 2010, respectively. The functional currency of our wholly-owned subsidiaries incorporated outside of the United States is the U.S. dollar, so we are not currently subject to gains and losses from foreign currency translation of the subsidiary financial statements. We currently do not hedge foreign currency exchange rate exposure. Although the impact of currency fluctuations on our financial results has been

immaterial in the past, there can be no guarantee that the impact of currency fluctuations related to our international activities will not be material in the future.

ITEM 4. CONTROLS AND PROCEDURES.

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

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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 June 30, 2011, we had an accumulated deficit of $171.5 million. We expect to continue to invest in our product pipeline, including our current Onco*type* DX tests and future products, our global commercial infrastructure and our laboratory operations. For the three and six months ended June 30, 2011, our research and development expenses were $9.9 million and $20.0 million, respectively, and our sales and marketing expenses were $20.5 million and $41.1 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 Onco*type* DX breast cancer test, drive adoption of and reimbursement for our Onco*type* DX colon cancer test and develop new tests. 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 across the United States, the availability and cost of credit, the U.S. mortgage market, the U.S. real estate market, Federal budget proposals, proposed regulatory changes, inflation, deflation, taxation issues, energy costs and geopolitical issues have contributed to increased volatility and uncertain expectations for the U.S. economy. These factors, combined with uncertainties in business and consumer confidence, uncertainty related to the impact of the recent downgrade of the United States credit rating and a volatile stock market, have precipitated an economic slowdown and expectations of slower 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 six months ended June 30, 2011. If the economic environment does not improve or deteriorates, our business, including our patient population, our suppliers and our third-party payors, could be negatively affected, resulting in a negative impact on our product revenues.

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

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, collectively, the 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, because the FDA maintains that clinical laboratory tests that are developed and validated by a laboratory for its own use, or LDTs, such as our Onco*type* DX breast and colon cancer tests, are medical devices, this tax may apply to some or all of our current products and products in development. The PPACA also mandates a reduction in payments for clinical laboratory services paid under the Medicare Clinical Laboratory Fee Schedule of 1.75% for the years 2011 through 2015. This adjustment is in addition to a productivity adjustment to the Medicare Clinical Laboratory Fee Schedule. These or other reductions in payments may apply to some or all of our clinical laboratory test services furnished to Medicare beneficiaries.

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, lowering the government s thresholds

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to find 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, including clinical laboratory services. IPAB proposals may impact payments for clinical laboratory services beginning in 2016 and for hospital services beginning in 2020.

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 at the state level. Changes in healthcare policy, such as changes in the FDA regulatory policy for LDTs, the creation of broad test utilization limits for diagnostic products in general or requirements that Medicare patients pay for portions of clinical laboratory tests or services received, could substantially impact the sales of our tests, increase costs and divert management s attention from our business. Such co-payments by Medicare beneficiaries for laboratory services were discussed as a possible cost savings for the Medicare program and may be enacted in the future. In addition, sales of our tests outside of the United States make us subject to foreign regulatory requirements, which may also change over time.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level, or the effect any future legislation or regulation will have on us. The taxes imposed by the new federal legislation and the expansion in government s 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, possibly materially.

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

At various times since 2006, the FDA has issued guidance documents or announced draft guidance regarding initiatives that may require varying levels of FDA oversight of our tests. 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. 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 in the current Congress as well. It is possible that legislation will be enacted into law or guidance could be issued by the FDA which may result in increased regulatory burdens for us to continue to offer our tests or to develop and introduce new tests.

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

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

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In June 2011 the FDA issued draft guidance regarding Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only. This draft guidance has not been finalized and is subject to public comment. We cannot predict the ultimate form of any such guidance and the potential impact on our tests or 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 vendors 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 prior to continuing to sell our breast and colon cancer tests 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 research organizations to perform the trials properly. If these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality, completeness or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, our clinical trials may have to be extended, delayed or terminated. Many of these factors would be beyond our control. We may not be able to enter into replacement arrangements without undue delays or considerable expenditures. If there are delays in testing or approvals as a result of the failure to perform by third parties, our research and development costs would increase, and we may not be able to obtain regulatory clearance or approval for our tests. In addition, we may not be able to establish or maintain relationships with these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market our tests, or to achieve sustained profitability.

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

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

- not experimental or investigational,

- medically necessary,
- appropriate for the specific patient,
- cost-effective,
- supported by peer-reviewed publications, and
- included in clinical practice guidelines.

There is uncertainty concerning third-party payor reimbursement of any test incorporating new technology, including tests developed using our Onco*type* DX platform. Several entities conduct technology assessments of new medical tests and devices and provide the results of their assessments for informational purposes to other parties. These assessments may be used by third-party payors and health care providers as grounds to deny coverage for a test or procedure. Although there are a number of favorable assessments of our Onco*type* DX breast cancer test, the test has received negative assessments in the past and our tests may receive

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negative assessments in the future. For example, in April 2010, the Medical Advisory Panel of the Blue Cross and Blue Shield Association s Technology Evaluation Center, a technology assessment group, published its conclusion that the existing clinical data in support of our Onco*type* DX breast cancer test did not meet the panel s technology criteria for clinical effectiveness and appropriateness for usage in patients with N+ disease.

Since each payor makes its own decision as to whether to establish a policy to reimburse our test, seeking these approvals is a time-consuming and costly process. To date, we have positive coverage determinations for our Onco*type* DX breast cancer test for N-, ER+ patients from most third-party payors in the United States through contracts, agreements or policy decisions. We cannot be certain that coverage for this test will be provided in the future by additional third-party payors or that existing contracts, agreements or policy decisions or reimbursement levels will remain in place or be fulfilled within existing terms and provisions.

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

We have obtained limited reimbursement coverage from third-party payors in the United States for our Onco*type* DX colon cancer test launched in January 2010. We expect to focus substantial resources on obtaining adoption of and reimbursement coverage for this test. Because it is new, our Onco*type* DX 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. 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 Onco*type* DX 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 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 contract implementation steps, documentation requirements and other issues, which could cause our revenues to fluctuate from period to period.

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

The majority of our international product revenues are currently generated by patient self-pay and third party reimbursement for our Onco*type* DX breast cancer test and through clinical collaborations. 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 in certain countries 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.

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 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 total revenues. In addition, insurers, including managed care organizations as well as government payors such as Medicare and Medicaid, have increased their efforts to control the cost, utilization and delivery of healthcare services. These measures have resulted in reduced payment rates and decreased utilization for the clinical laboratory industry. 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 Onco*type* 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 current reimbursement of our Onco*type* DX breast cancer test, we were informed that, under the local coverage determination, claims are to be paid consistent with the average allowed reimbursement rate for claims that were billed and processed to completion as of September 30, 2005. This reimbursement rate remains in effect as of the date of this report, but is

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subject to review and adjustment. A Healthcare Common Procedure Coding System, or HCPCS, code has been issued effective January 1, 2006 for the Onco*type* 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 Onco*type* 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.

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

Under current Medicare billing rules, claims for our Onco*type* DX breast cancer 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 a written agreement in place with these hospitals to purchase these tests, we may not be paid for our tests or may have to pursue payment from the hospital on a case-by-case basis. We believe patients coming under this rule represent approximately 1% of our total breast cancer testing population. We believe these billing rules may lead to confusion regarding whether Medicare provides adequate reimbursement for our breast cancer test, and could discourage Medicare patients from using our test. If we obtain Medicare reimbursement coverage for our Onco*type* DX colon cancer test in the future, these billing rules would also apply to those tests performed for hospital inpatients ordered less than 14 days from discharge. We have no assurance that Medicare will reverse or revise the billing rule to allow us to bill for tests subject to the 14 day billing rule or that Congress will require Medicare to do so at some point in the future, and we also cannot ensure that hospitals will agree to arrangements to pay us for Onco*type* DX tests performed on patients falling under these rules.

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

Reimbursement on behalf of patients covered by Medicare represented 8% of our product revenues for both the three and six months ended June 30, 2011, respectively, and 8% and 9% of our product revenues for the three and six months ended June 30, 2010, respectively. 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, we may become more dependent on Medicare reimbursement in the future. It is possible that Medicare or other third-party payors that provide reimbursement for our tests may suspend, revoke or discontinue coverage at any time, may require co-payments from patients, or may reduce the reimbursement rates payable to us. Any such action could have a negative impact on our revenues.

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

For the near future, we expect to derive substantially all of our revenues from sales of one test, our Onco*type* DX breast cancer test. We have been selling this test since January 2004. While we launched our test for colon cancer in January 2010, we do not expect to recognize significant

revenues from this test until adoption of and reimbursement for this test have been established. We are in various stages of research and development for other tests that we may offer as well as for enhancements to our existing tests. We may not be able to successfully commercialize tests for other cancers or diseases. If we are unable to increase sales of our breast cancer test, establish adoption of and reimbursement for our colon cancer test, or successfully develop and commercialize other tests or enhancements, our revenues and our ability to achieve sustained profitability would be impaired.

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

We are subject to CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating 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

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Pathologists, or CAP. To renew this certificate, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of our clinical reference laboratory.

Although we are required to hold a certificate of accreditation 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.

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; and

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

We have adopted policies and procedures designed to comply with these laws, including policies and procedures relating to financial arrangements between us and physicians who refer patients to us. 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 may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these 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 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. For example, we are conducting development studies in breast, colon, prostate, renal cell and lung cancers. There can be no assurance that our technologies will be capable of reliably predicting the recurrence or drug response of cancers other than breast and colon cancer with the sensitivity

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and specificity necessary to be clinically and commercially useful. 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.

This 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, we will need to bring new equipment on-line, implement new systems, technology, controls and procedures and hire personnel with different qualifications. Failure to implement necessary procedures 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 our test results, or that we will be successful in responding to the growing complexity of our testing operations. If we encounter difficulty meeting market demand or quality standards for our tests, our reputation could be harmed and our future prospects and our business could suffer.

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

If medical practitioners do not order our Onco*type* DX tests or any future tests developed by us, we will likely not be able to create 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 Onco*type* DX breast cancer test in clinical guidelines, 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

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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 Onco*type* DX colon cancer test predicts recurrence but, unlike our breast cancer test, 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 reimbursement for our colon cancer test, our reputation could be harmed and our business could suffer.

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

Some patients may decide not to use our Onco*type* DX tests due to their price, all or part of which may be payable directly by the patient if the applicable payor denies reimbursement in full or in part. Even if medical practitioners recommend that their patients use our tests, patients may still decide not to use our tests, either because they do not want to be made aware of the likelihood of recurrence or they wish to pursue a particular course of therapy regardless of test results. Additionally, the current economic environment could continue to negatively impact patients, resulting in loss of healthcare coverage, delayed medical checkups or inability to pay for relatively expensive 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 that we use to analyze genes for possible inclusion in our tests and that we use 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. 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 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 reportedly permit measurement of gene expression in fixed paraffin-embedded tissue specimens. New chemotherapeutic or biologic strategies are being developed that may increase survival time and reduce toxic side effects. There have also been advances in methods used to analyze very large amounts of genomic information, including next-generation sequencing. These advances require us to

continuously develop our technology, develop new products and enhance existing products to keep pace with evolving standards of care. Our tests could become obsolete unless we continually innovate and expand our products to demonstrate recurrence and treatment benefit in patients treated with new therapies. New treatment therapies typically have only a few years of clinical data associated with them, which limits our ability to perform clinical studies and correlate sets of genes to a new treatment s effectiveness. If we are unable to demonstrate the applicability of our tests to new treatments, sales of our test could decline, which would harm our revenues.

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

Our ability to compete and to achieve sustained profitability is impacted by our ability to protect our proprietary discoveries and technologies. We currently rely on a combination of 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 June 30, 2011, we had 15 issued patents in the United States and 18 issued patents internationally covering genes and methods that are components of the Onco*type* DX breast cancer test, 23 of which were issued jointly to us and our collaborators and five of which were assigned to us by a collaborator. In addition, we have a number of pending patent applications in the United States

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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, 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.

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.

On October 30, 2008, the Court of Appeals for the Federal Circuit issued a decision that methods or processes cannot be patented unless they are tied to a machine or involve a physical transformation. The U.S. Supreme Court reversed that decision in 2010, finding that the machine or transformation test is not the only test for determining patent eligibility. The Court, however, declined to specify how and when processes are patentable. In response, the USPTO issued an Interim Guidance for Determining Subject Matter Eligibility for Process Claim dated July 27, 2010. 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.

A suit brought by multiple plaintiffs, including the American Civil Liberties Union, or ACLU, against Myriad Genetics and the USPTO, could also impact biotechnology patents. That case involves certain of Myriad s U.S. patents related to the breast cancer susceptibility genes BRCA1 and BRCA2. Related European patents were canceled in 2004 by the European Patent Office after opposition, and a similar challenge is pending in Australia. The plaintiffs in the Myriad case filed motions for summary judgment in the Southern District of New York requesting that the court, among other things, find that the breast cancer genes are not patentable subject matter. We joined other diagnostic companies in filing an *amici* brief in this case. The U.S. District Court for the Southern District of New York filed an opinion on this case on March 20, 2010, finding that Myriad s BRCA sequence and sequence related claims are unpatentable under the Federal Circuit machine or transformation test. Myriad appealed the decision before the Federal Circuit, which has been instructed by the Supreme Court to use broader patentability principles. The Federal Circuit issued a written decision on July 29, 2011. In that decision, the Federal Circuit reversed the District Court s ruling that Myriad s composition claims to isolated DNA molecules cover unpatentable subject matter. However, the Federal Court affirmed the District Court s decision that Myriad s method claims directed to simply comparing or analyzing DNA sequences without a transformation step are not patentable. It is possible that the ACLU will appeal the case to the Supreme Court and it is unknown whether or how this case will be decided if argued before the Supreme Court, whether this decision will have an indirect impact on gene patents generally, or if this decision will have a significant impact on the ability of biotechnology companies to obtain or enforce gene patents in the future.

Also, on February 5, 2010, the Secretary s Advisory Committee on Genetics, Health and Society for HHS voted to approve a report entitled Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests. That report defines patent claims on genes broadly to include claims to isolated nucleic acid molecules as well as methods of detecting particular sequences or mutations. The report also contains six recommendations, including the creation of an exemption from liability for infringement of patent claims on genes for anyone making, using, ordering, offering for sale, or selling a test developed under the patent for patient care purposes, or for anyone using the patent-protected genes in the pursuit of research. In addition, the report recommended that the Secretary should explore, identify, and implement mechanisms that will encourage more voluntary adherence to current guidelines that promote non-exclusive in-licensing of diagnostic genetic and genomic technologies. It is unclear whether these recommendations will be acted upon by the HHS, or if the recommendations would result in a change in law or process that could negatively impact our patent portfolio or 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,

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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.

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. In addition, few diagnostic methods are as expensive as our Onco*type* DX tests.

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 face competition from commercial laboratories with strong distribution networks for diagnostic tests, such as Laboratory Corporation of America Holdings and Quest Diagnostics Incorporated. 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, life science technology providers, such as Complete Genomics, Inc., Illumina, Inc. and Life Technologies Corporation, and other companies and academic and research institutions. Our competitors may invent and commercialize technology platforms that compete with ours. Additionally, projects related to cancer genomics have received increased 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 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 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.

We have changed the list price of our breast cancer test 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, less complex tests that could be viewed by physicians and payors as functionally equivalent to our tests, which could force us to lower the list prices of our tests and impact our operating margins and our ability to achieve sustained profitability. Some competitors have developed tests cleared for marketing by the FDA. There may be a marketing differentiation or perception that an FDA-cleared test is more desirable than Onco*type* DX tests, and that may discourage adoption of and reimbursement for our tests. If we are unable to compete successfully against current or future competitors, we may be unable to increase market acceptance for and sales of our tests,

which could prevent us from increasing or sustaining our revenues or achieving sustained profitability and could cause the market price of our common stock to decline.

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

Under standard clinical practice 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. Others have demonstrated their ability to 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

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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 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 extend 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 a test 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 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 and as we 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 products. 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 employees, 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 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

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period of time may result in the loss of customers or harm our reputation, and we may be unable to regain those customers in the future. Although we possess insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all.

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

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

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

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

- 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 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 and exposure to foreign currency exchange rate fluctuations;

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

- regulatory and compliance risks that relate to maintaining accurate information and control over 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 foreign sales of our Oncotype DX tests could limit or prevent us from selling our test in foreign markets and from realizing long-term international revenue growth.

As of June 30, 2011, we had agreements with 16 distributors in various countries outside of the United States for our Onco*type* DX breast cancer test, and we may enter into other similar arrangements in other countries in the future. We intend 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 test. Distributors may not commit the necessary resources to market and sell our test to the level of our expectations. If current or future distributors do not perform adequately, or we are unable to locate distributors in particular geographic areas, we may not realize long-term international revenue growth. Regulatory requirements, costs of doing business outside of the United States and the

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reimbursement process in foreign markets may also impact our revenues from international sales or impact our ability to increase international sales in the future.

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

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

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

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

We invest our cash in accordance with an established internal policy in instruments which historically have been highly liquid and carried relatively low risk. However, similar types of investments have in the past and may in the future experience losses in value or liquidity issues which differ from historical patterns. Should a portion of our marketable securities lose value or have their liquidity impaired, it could adversely affect our overall financial position by imperiling our ability to fund our operations and forcing us to seek additional financing sooner than we would otherwise. Such financing, if available, may not be available on commercially attractive terms.

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

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

- sustain commercialization of our Onco*type* DX tests and enhancements to those tests;
- fund commercialization of any future tests we may develop;
- increase our selling and marketing efforts to drive market adoption and address competitive developments;
- further expand our clinical laboratory operations;
- expand our technologies into other areas of cancer or other diseases;
- expand our research and development activities;
- acquire, license or invest in technologies;
- acquire or invest in complementary businesses or assets; and
- finance capital expenditures and general and administrative expenses.

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

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telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business and our product revenues.

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 in the event our suppliers no longer supply that equipment or those materials, or those materials do not meet our quality specifications.

We rely solely on Applied Biosystems, a division of Life Technologies Corporation, to supply some of the laboratory equipment on which we perform our tests. We periodically forecast our needs for laboratory equipment and enter into standard purchase orders with Applied Biosystems based on these forecasts. We believe that there are relatively few equipment manufacturers other than Applied Biosystems that are currently capable of supplying the equipment necessary for our Onco*type* DX platform. Even if we were to identify other suppliers, there can be no assurance that we will be able to enter into agreements with such suppliers on a timely basis on acceptable terms, if at all. If we should encounter delays or difficulties in securing from Applied Biosystems the quality and quantity of equipment we require for our tests, we may need to reconfigure our test processes, which would result in delays in commercialization or an interruption in sales. If any of these events occur, our business and operating results could be harmed. Additionally, if Applied Biosystems deems us to have become uncreditworthy, it has the right to require alternative payment terms from us, including payment in advance. We are also required to indemnify Applied Biosystems against any damages caused by any legal action or proceeding brought by a third party against Applied Biosystems for damages caused by our failure to obtain required approval with any regulatory agency.

We also rely on several sole suppliers for certain laboratory 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, or if the materials do not meet our quality specifications, delays in commercialization or an interruption in sales could occur.

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

Future growth will impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. In addition, rapid and significant growth may place strain on our administrative and operational infrastructure, including customer service and our clinical reference laboratory. Our ability to manage our operations and growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy.

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

The marketing, sale and use of our tests could lead to the filing of product liability claims if someone were to allege that our tests failed to perform as it was designed. We may also be subject to liability for errors in the test results we provide to physicians or for a misunderstanding of, or inappropriate reliance upon, the information we provide. For example, physicians sometimes order our Onco*type* DX breast cancer test for patients who do not have the same specific clinical attributes indicated on the report form as those for which the test provides clinical experience information from validation studies. It is our practice to offer medical consultation to physicians ordering our test for such patients, including

patients with ER- breast cancers. A product liability or professional liability claim could result in substantial damages and be costly and time consuming for us to defend. Although we believe that our existing product and professional liability insurance is adequate, we cannot assure you that our insurance would fully protect us from the financial impact of defending against product liability or professional liability 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 biological and hazardous materials in a manner that causes injury, we could be liable for damages.

Our activities currently require the controlled use of potentially harmful biological materials, hazardous materials and chemicals and may in the future require the use of radioactive compounds. 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.

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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 and accounting 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
10.1	Genomic Health, Inc. Employee Stock Purchase Plan.
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##	The following materials from Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, formatted in Extensible Business Reporting Language (XBRL) includes: (i) Condensed Consolidated Balance Sheets at June 30, 2011 and December 31, 2010, (ii) Condensed Consolidated Statements of Operations for the Three and Six Months Ended June 30, 2011 and 2010, (iii) Condensed Consolidated Statements of Cash Flows for the Three and Six Months Ended June 30, 2011 and 2010, and (iv) Notes to Condensed Consolidated Financial Statements.

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 of 1933 or the Exchange Act.

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SIGNATURES

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

GENOMIC HEALTH, INC.

Date: August 8, 2011	By:	/s/ Kimberly J. Popovits Kimberly J. Popovits President and Chief Executive Officer (Principal Executive Officer)
Date: August 8, 2011	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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