GENOMIC HEALTH INC
Form 10-Q
November 09, 2010

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q

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

For the quarterly period ended September 30, 2010

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 þ 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 o 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 þ	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 þ

The number of outstanding shares of the registrant s Common Stock, $0.0001 par value, was 28,857,463 as of October 29, 2010.

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PART 1: FINANCIAL INFORMATION

Item 1. Financial Statements

GENOMIC HEALTH, INC.
Condensed Consolidated Balance Sheets
(In thousands)
(Unaudited)

	September 30, 2010	December 31, 2009
ASSETS		
Current assets:		
Cash and cash equivalents	$ 23,616	$ 9,082
Short-term investments	46,095	48,366
Accounts receivable (net of allowance for doubtful accounts; 2010 - $738, 2009 - $545)	12,311	11,123
Prepaid expenses and other current assets	5,539	5,677
Total current assets	87,561	74,248
Property and equipment, net	10,524	12,865
Restricted cash	500	500
Other assets	1,568	494
Total assets	$ 100,153	$ 88,107
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 2,539	$ 1,304
Accrued compensation	6,159	6,188
Accrued license fees	2,884	3,016
Accrued expenses and other current liabilities	5,111	5,736
Deferred revenues	1,685	2,238
Note payable	43	225
Total current liabilities	18,421	18,707
Other liabilities	1,437	891
Commitments (Note 5)		
Stockholders equity:		
Common stock	2	2
Additional paid-in capital	255,575	246,383
Accumulated other comprehensive income	10	19
Accumulated deficit	(175,292)	(177,895)
Total stockholders equity	80,295	68,509
Total liabilities and stockholders equity	$ 100,153	$ 88,107

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 September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Revenues:				
Product revenues	$ 45,773	$ 38,910	$ 128,553	$ 107,529
Contract revenues	544	607	2,432	2,436
Total revenues	46,317	39,517	130,985	109,965
Operating expenses:				
Cost of product revenues	8,853	8,301	25,927	24,019
Research and development	8,180	9,120	23,953	27,007
Selling and marketing	17,336	15,313	52,868	45,719
General and administrative	8,561	7,316	25,640	22,318
Total operating expenses	42,930	40,050	128,388	119,063
Income (loss) from operations	3,387	(533)	2,597	(9,098)
Interest and other income	70	116	219	591
Interest and other expense	(2)	(22)	(31)	(109)
Income (loss) before income taxes	3,455	(439)	2,785	(8,616)
Income tax provision (benefit)	(215)	63	182	454
Net income (loss)	$ 3,670	$ (502)	$ 2,603	$ (9,070)
Basic net income (loss) per share	$ 0.13	$ (0.02)	$ 0.09	$ (0.32)
Diluted net income (loss) per share	$ 0.12	$ (0.02)	$ 0.09	$ (0.32)
Shares used in computing basic net income (loss) per share	28,832	28,579	28,784	28,539
Shares used in computing diluted net income (loss) per share	29,584	28,579	29,625	28,539

See accompanying notes.

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GENOMIC HEALTH, INC.
Condensed Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2010	**2009**
Operating activities		
Net income (loss)	$ 2,603	$ (9,070)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	5,311	4,868
Employee stock-based compensation	8,048	7,638
Non-employee stock-based compensation	15	
Gain on disposal of property and equipment	(45)	(45)
Changes in assets and liabilities:		
Accounts receivable	(1,188)	(848)
Prepaid expenses and other assets	(1,052)	(747)
Accounts payable	1,235	680
Accrued expenses and other liabilities	(79)	2,163
Accrued license fees	(132)	(273)
Accrued compensation	(29)	1,872
Deferred revenues	(553)	(1,036)
Net cash provided by operating activities	14,134	5,202
Investing activities		
Purchases of property and equipment	(2,809)	(2,417)
Purchases of short-term investments	(60,627)	(41,670)
Maturities of short-term investments	62,889	44,800
Net cash provided by (used in) investing activities	(547)	713
Financing activities		
Principal payments on notes payable	(182)	(1,507)
Proceeds from issuance of common stock under stock plans	1,129	1,140
Net cash provided by (used in) financing activities	947	(367)
Net increase in cash and cash equivalents	14,534	5,548
Cash and cash equivalents at the beginning of the period	9,082	11,171
Cash and cash equivalents at the end of the period	$ 23,616	$ 16,719
Cash paid for interest	$ 12	$ 109
Cash paid for income taxes	$ 587	$ 28

See accompanying notes.

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GENOMIC HEALTH, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2010
(Unaudited)

Note 1. Organization and Summary of Significant Accounting Policies

The Company

Genomic Health, Inc. (the Company) is a life science company focused on the global development and commercialization of genomic-based clinical diagnostic tests for cancer that allow 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 condensed consolidated financial statements include all the accounts of the Company and its wholly-owned subsidiaries. The Company has two wholly-owned subsidiaries, Genomic Health International LLC, a European subsidiary that was established in 2009 to support the Company s international sales and marketing efforts, and Onco*type* Laboratories, Inc., which was established in 2003 and is inactive. The functional currency for the Company s European subsidiary 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 September 30, 2010, condensed consolidated statements of operations for the three and nine months ended September 30, 2010 and 2009 and condensed consolidated statements of cash flows for the nine months ended September 30, 2010 and 2009 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, 2009 has been derived from audited financial statements. However, 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.

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 Onco*type* DX breast cancer tests. The Company generally bills third-party payors upon generation and delivery of a Recurrence Score 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.

The Company s 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. 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

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arrangements, the Company considers criterion (1) 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 Recurrence Score report. Determination of criteria (3) and (4) is based on management s judgments regarding whether a contractual agreement has been entered into and 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 September 30, 2010, the Company had distributor agreements in 13 countries outside of the U.S. The distributor provides certain marketing and administrative services for 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 a refund is due. Accrued refunds were $499,000 and $757,000 at September 30, 2010 and December 31, 2009, 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. As of September 30, 2010 and December 31, 2009, the Company s allowance for doubtful accounts was $738,000 and $545,000, respectively. Write-offs for doubtful accounts of $526,000 and $1.5 million were recorded against the allowance during the three and nine months ended September 30, 2010, respectively, and write-offs of $373,000 and $1.2 million were recorded during the three and nine months ended September 30, 2009, respectively. Bad debt expense was $552,000 and $1.7 million for the three and nine months ended September 30, 2010, respectively, and $382,000 and $922,000 for the three and nine months

ended September 30, 2009, respectively.

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Research and Development Expenses

Research and development expenses are comprised of the following types of costs incurred in performing research and development activities: salaries and benefits, allocated overhead and facility occupancy costs, contract services, reagents and laboratory supplies, and costs to acquire in-process research and development projects and technologies that have no alternative future use. 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 an expense as the goods are delivered or the related services are performed.

Recently Issued Accounting Pronouncements

In April 2010, the Financial Accounting Standards Board (FASB) issued authoritative guidance for applying the milestone method of revenue recognition to research and development arrangements. Under this guidance, revenue contingent upon the achievement of a milestone in its entirety may be recognized in the period in which the milestone is achieved only if the milestone meets all the criteria within the guidance to be considered substantive. This guidance is effective on a prospective basis for research and development milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. This guidance, which the Company does not expect to have a material impact on its financial condition and results of operations, will become effective for the Company on January 1, 2011.

In October 2009, FASB issued authoritative guidance that amends existing guidance for identifying separate deliverables in a revenue-generating transaction where multiple deliverables exist, and provides guidance for allocating and recognizing revenue based on those separate deliverables. The guidance is expected to result in more multiple-deliverable arrangements being separable than under current guidance and is required to be applied prospectively to new or significantly modified revenue arrangements. This guidance, which the Company does not expect to have a material impact on its financial condition and results of operations, will become effective for the Company on January 1, 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 September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
	(In thousands)		(In thousands)	
Numerator:				
Net income (loss)	$ 3,670	$ (502)	$ 2,603	$ (9,070)
Denominator:				
Weighted-average shares of common stock outstanding used in the calculation of basic net income (loss) per share	28,832	28,579	28,784	28,539
Effect of dilutive securities:				

Options to purchase common stock	752		841	
Weighted-average shares of common stock outstanding used in the calculation of diluted net income (loss) per share	29,584	28,579	29,625	28,539

Options to purchase approximately 4.2 and 4.0 million weighted-average shares of the Company s common stock were outstanding during the three and nine months ended September 30, 2010, respectively, but were not included in the computation of

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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 4.7 million shares of the Company s common stock were outstanding for the three and nine months ended September 30, 2009, but are not included in the computation of diluted net loss per share because their effect is anti-dilutive.

Comprehensive Income (Loss)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
	(In thousands)		(In thousands)	
Net income (loss)	$ 3,670	$ (502)	$ 2,603	$ (9,070)
Change in unrealized gain on available-for-sale securities	(3)	(31)	(9)	(186)
Comprehensive income (loss)	$ 3,667	$ (533)	$ 2,594	$ (9,256)

Note 3. Fair Value Measurements

The Company measures certain financial assets, including cash equivalents and available-for-sale securities, at their fair value. The fair value of these financial assets was determined based on 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 prices, 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.

The Company did not have any non-financial assets or liabilities that were measured or disclosed at fair value on a recurring basis at September 30, 2010 or December 31, 2009. 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 considers factors specific to the asset or liability. The following tables set forth the Company s financial instruments that were measured at fair value on a recurring basis at September 30, 2010 and December 31, 2009 by level within the fair value hierarchy:

	Actively Quoted Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	Balance at September 30, 2010
		(In thousands)		
As of September 30, 2010				
Assets				
Money market deposits	$ 8,714	$	$	$ 8,714
U.S. Treasury securities	1,002(1)			1,002(1)
Debt securities of U.S. government-sponsored entities		30,153		30,153

Commercial paper		11,867		11,867
Corporate bonds		4,074		4,074
Total	$ 9,716	$ 46,094	$	$ 55,810

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	Actively Quoted Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	Balance at December 31, 2009
		(In thousands)		
As of December 31, 2009				
Assets				
Money market deposits	$ 6,011	$	$	$ 6,011
U.S. Treasury securities	4,546			4,546
Debt securities of U.S. government-sponsored entities		44,820(2)		44,820(2)
Total	$ 10,557	$ 44,820	$	$ 55,377

(1) Includes a U.S. Treasury security with a fair value of $1,002,000 that matures within three months of September 30, 2010 and was classified as cash equivalents on the condensed consolidated balance sheet at September 30, 2010.

(2) Includes a debt security with a fair value of $1,000,000 that matured within three months of December 31, 2009 and was classified as cash equivalents on the condensed consolidated balance sheet at December 31, 2009.

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 nine months ended September 30, 2010 and 2009, respectively.

The following tables illustrate the Company s available-for-sale securities as of the dates indicated:

	September 30, 2010			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
		(In thousands)		
Debt securities of U.S. government-sponsored entities	$ 30,146	$ 7	$	$ 30,153
Commercial paper	11,861	6		11,867
Corporate bonds	4,078		(4)	4,074
U.S. Treasury securities	1,002			1,002
Total	$ 47,087	$ 13	$ (4)	$ 47,096

December 31, 2009

	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
		(In thousands)		
Debt securities of U.S. government-sponsored entities	$ 43,800	$ 29	$ (9)	$ 43,820
U.S. Treasury securities	4,547		(1)	4,546
Total	$ 48,347	$ 29	$ (10)	$ 48,366

The Company had no realized gains or losses on its available-for-sale securities for the three and nine months ended September 30, 2010 and 2009, respectively.

As of September 30, 2010, all of the Company s available-for-sale securities had contractual maturities of one year or less.

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Note 4. Collaboration and Commercial Technology Licensing Agreements

The Company has entered into a variety of collaboration and specimen transfer agreements relating to its development efforts. The Company recorded collaboration expenses of $351,000 and $1.5 million for the three and nine months ended September 30, 2010, respectively, and $387,000 and $1.9 million for the three and nine months ended September 30, 2009, 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 nonexclusive basis in the field of human diagnostics. Access to these licenses enables the Company to process its Onco*type* DX tests. While certain agreements contain provisions for fixed annual payments, license fees are generally calculated as a percentage of product revenues, with rates that vary by agreement and may be tiered, and payments that may be capped at annual minimum or maximum amounts. The Company recognized costs recorded under these agreements of $2.6 million and $7.6 million for the three and nine months ended September 30, 2010, respectively, and $2.7 million and $7.4 million for the three and nine months ended September 30, 2009, respectively, which were included in cost of product revenues.

At September 30, 2010, future fixed annual payments, exclusive of royalty payments, relating to the launch and commercialization of our Onco*type* DX breast and colon cancer tests totaled $2.3 million and were payable as follows:

	Onco*type* DX Breast Cancer	Onco*type* DX Colon Cancer	Total Fixed Future Annual Payments
		(In thousands)	
Payment Due:			
January 2011	$ 475	$ 200	$ 675
January 2012		300	300
January 2013		450	450
January 2014		450	450
January 2015		450	450
Total	$ 475	$ 1,850	$ 2,325

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 5. Commitments

Notes Payable

In March 2005, the Company entered into an arrangement to finance the acquisition of laboratory and office equipment, computer hardware and software and leasehold improvements. In connection with this arrangement, the Company granted the lender a security interest in the assets purchased with the borrowed amounts. The Company can prepay all, but not part of, the amounts outstanding under the arrangement so long as the Company also pays a 4% premium on the outstanding principal balance. At September 30, 2010, the outstanding notes payable balance under this arrangement was $43,000, at an annual interest rate of 11.30%, which is scheduled to be paid in full by November 2010. According to the terms of the arrangement, the Company is required to notify the lender if there is a material adverse change in its financial condition, business or operations. The Company believes it has complied with all the material covenants of the financing arrangement as of September 30, 2010.

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. The lease expires in February 2012, with an option for the Company to extend the lease for an additional five years. The agreement included lease incentive obligations of $834,000 that are being amortized

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on a straight-line basis over the life of the lease. In connection with this lease, the Company was required to secure a $500,000 letter of credit, which is classified as restricted cash on the condensed consolidated balance sheets.

In January 2007, the Company entered into a non-cancelable lease for an additional 48,000 square feet of office space in a nearby location. The lease expires in February 2012, 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 $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 commenced on April 1, 2010 and 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.

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 commenced on June 1, 2010 and has a term of five years. In connection with this lease, the Company paid an $87,000 cash security deposit, which is included in other assets on the condensed consolidated balance sheets.

Future non-cancelable commitments under these operating leases at September 30, 2010 were as follows:

	Annual Payments (In thousands)
Years Ending December 31,	
2010 (remainder of the year)	$ 585
2011	2,426
2012	1,010
2013	739
2014	757
2015 and thereafter	2,338
Total minimum payments	$ 7,855

Note 6. Stock-Based Compensation

The Company values its stock option grants using the Black-Scholes option valuation model. The Company recorded employee stock-based compensation expense of $2.7 million and $8.0 million for the three and nine months ended September 30, 2010, respectively, and $2.5 million and $7.6 million for the three and nine months ended September 30, 2009, respectively. Employee stock-based compensation expense was calculated based on 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 options granted to outside directors of the Company. The following table presents the impact of employee stock-based compensation expense on selected statements of operations line items for the periods indicated:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
	(In thousands)			

Cost of product revenues	$ 86	$ 96	$ 275	$ 277
Research and development	778	796	2,243	2,336
Selling and marketing	760	786	2,403	2,381
General and administrative	1,033	870	3,126	2,610
Total stock-based compensation expense	$ 2,657	$ 2,548	$ 8,047	$ 7,604

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As of September 30, 2010, total unrecognized compensation expense related to unvested stock options, net of estimated forfeitures, was $16.8 million. The Company expects to recognize this expense over a weighted-average period of 30 months.

Valuation Assumptions

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 Company granted options to purchase 51,300 and 1,235,598 shares of common stock to employees during the three and nine months ended September 30, 2010, respectively. The Company granted options to purchase 71,700 and 279,250 shares of common stock to employees and directors during the three and nine months ended September 30, 2009, respectively. The weighted-average fair values and the assumptions used in calculating such values for stock options granted during these periods were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Expected volatility	48%	55%	53%	55%
Risk-free interest rate	1.53%	2.67%	2.52%	2.30%
Expected life of options in years	5.09	5.86	5.78	5.86
Weighted-average fair value	$ 6.43	$ 10.53	$ 8.66	$ 12.40

Stock Options Exercised

For the three and nine months ended September 30, 2010, the Company issued 38,537 and 171,156 shares of common stock in connection with the exercise of stock options with a weighted-average exercise price of $5.04 and $6.60 per share, respectively. For the three and nine months ended September 30, 2009, the Company issued 54,716 and 149,366 shares of common stock in connection with the exercise of stock options with a weighted-average exercise price of $8.73 and $7.64 per share, respectively.

Note 7. Income Tax

The Company recorded a benefit provision for income taxes of $215,000 and a provision for income taxes of $182,000 for the three and nine months ended September 30, 2010, respectively, and a provision for income taxes of $63,000 and $454,000 for the three and nine months ending September 30, 2009, respectively. The benefit provision and provision for income taxes for the three and nine months ended September 30, 2010 were computed using the discrete (or cut-off) method. The benefit provision and provision for income taxes for the three and nine months ended September 30, 2010 were principally comprised of California alternative minimum tax, other state income taxes and foreign taxes, offset by a reversal of 2009 federal alternative minimum tax previously provided for. The reversal of 2009 federal alternative minimum tax was a result of the enactment of the Worker, Homeownership and Business Assistance Act of 2009 that expanded the use of net operating losses.

The provision for income taxes for the three and nine months ended September 30, 2009 was based on the Company s estimated taxable income for that year, and was principally comprised of federal alternative minimum tax and California income tax. The change in tax computation method was made prospectively and was due to the impact of expected quarterly earnings volatility on the Company s ability to reliably forecast an effective tax rate for 2010. The difference in income tax expense between the provision at 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. For federal tax purposes, the provision was offset by the net operating loss carry-forwards that eliminate the federal regular and alternative minimum amounts.

The Company intends to continue maintaining a full valuation allowance on its deferred tax assets until sufficient evidence exists to support the reversal of all or some portion of these allowances. Should the actual timing

tax differences differ from the Company s estimates, the amount of its valuation allowance could be materially impacted.

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The Company had $685,000 of unrecognized tax benefits at both September 30, 2010 and December 31, 2009, respectively. The Company does not anticipate a material change in 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 will recognize accrued interest and penalties related to unrecognized tax benefits in income tax expense when and if incurred. As of September 30, 2010, the Company had not recognized any tax-related penalties or interest in its condensed consolidated balance sheets or statements of operations. All tax years from 2000 forward remain subject to future examination by federal, state and foreign tax authorities.

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

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. When used in this report, the words expects, anticipates, intends, estimates, plans, believes, and similar expressions are intended to identify forward-looking statements. These are statements that relate to future periods and include statements about our expectation that, for the foreseeable future, substantially all of our revenues will be derived from the Oncotype DX breast cancer test; 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 the composition of 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 successful reimbursement from third-party payors and government insurance programs for new tests or markets, including for Oncotype DX for N+ breast cancer patients, Oncotype DX for colon cancer, or for patients outside of the U.S.; 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; plans for enhancements of Oncotype DX to address different patient populations of breast cancer; plans for, and the timeframe for the development or commercial launch of, future tests addressing different patient populations or other cancers; 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; our plans with respect to potential tests for ductal carcinoma in situ, or other cancers or for patients treated with specific treatments; the occurrence, timing, outcome or success of clinical trials or studies; our intention to plan additional development or clinical studies; our expectations regarding the timing of 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 belief that multi-gene analysis provides better analytical information; our expectations regarding clinical development processes future tests may follow; our beliefs regarding the benefits of individual gene reporting; the level of investment in our sales force; our expectations regarding our general and administrative, selling and marketing and research and development expense levels and our anticipated uses of those funds; our expectations regarding capital expenditures; our ability to comply with the requirements of being a public company; our ability to attract and retain experienced personnel; the adequacy of our product liability insurance; how we intend to spend our existing cash and cash equivalents 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 plans to borrow additional amounts under existing or new financing arrangements; our belief that we are in material compliance with financial covenants; our expectations regarding repayment of debt or incurrence of additional debt; our compliance with federal, state and foreign regulatory requirements; the potential impact resulting from the regulation of Oncotype DX by the U.S. Food and Drug Administration, or FDA; our belief that Oncotype DX is 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; 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; our expectations regarding the impact of the economic environment on our liquidity and our investments; and anticipated trends and challenges in our business and the markets in which we operate.

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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; the timing of payments for our tests; the risk of unanticipated delays in research and development efforts; the risk that we may not obtain or maintain adequate reimbursement for our existing tests and any future tests we may develop; the risks and uncertainties associated with the regulation of our tests by FDA; the impact of legislation on our business; our ability to compete against third parties; our ability to obtain capital when needed; the economic environment; and our history of operating losses. These forward-looking statements speak only as of the date hereof. We expressly disclaim any obligation or undertaking to update any forward-looking statements contained herein to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based.

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

Genomic Health, the Genomic Health logo, Oncotype, Oncotype DX 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 life science company focused on the global development and commercialization of genomic-based clinical diagnostic tests for cancer that allow physicians and patients to make individualized treatment decisions. Our Onco*type* DX platform utilizes quantitative genomic analysis in standard tumor pathology specimens to provide tumor-specific information, or the oncotype of a tumor. 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. Effective June 1, 2010, the list price of our Onco*type* DX breast cancer test increased from $3,975 to $4,075. 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. The list price for our Onco*type* DX colon cancer test is $3,200. Substantially all of our historical revenues have been derived from the sale of Onco*type* DX breast cancer tests ordered by physicians in the U.S.

For the three and nine months ended September 30, 2010, more than 14,730 and 42,090 Onco*type* DX test reports were delivered for use in treatment planning, respectively, compared to more than 12,600 and 35,700 test reports delivered for the three and nine months ended September 30, 2009, 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 18,000 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.

In January 2010, we hired 8 U.S. sales representatives, increasing our domestic sales force to a total of 88 sales representatives. We have also continued to expand internationally. We plan to use essentially the same business model internationally as we use in the U.S., 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 systems or a cash-based payment system. We have sales representatives in certain countries outside the U.S. We may decide to work directly on our own in some countries while continuing to utilize distributors in other countries. Although we have continued to expand our sales, marketing and reimbursement efforts outside the U.S., we do not expect international product revenues to comprise more than 10% of our total revenues until the second half of 2011.

Oncotype 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

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unemployment levels, seasonal effects relating to physician and patient vacation schedules, our shift in commercial focus to our Onco*type* DX colon cancer test or any future products we may develop, and the number of clinical trials in process by cooperative groups or makers of other tests conducting experience studies.

Most national and regional third-party payors in the U.S., 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. In June 2009, the local carrier with jurisdiction for claims submitted by us for Medicare patients extended its coverage for our breast cancer test to include ER+ patients with node positive, or N+, disease (up to three positive lymph nodes). 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). 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 September 30, 2010, we had exclusive distribution agreements for our Onco*type* DX breast cancer test with distributors in 13 countries outside of the U.S., and have established reimbursement arrangements for this test with several public and private payors. We have completed or initiated multiple international clinical studies intended to support the adoption of our breast cancer test outside of the U.S. In October 2010, we announced positive results from our first European clinical decision impact study demonstrating that knowledge of the Onco*type* DX breast cancer Recurrence Score result changed oncologist s treatment decisions in over 30% of patients, which is consistent with U.S. decision impact studies.

Oncotype DX Colon Cancer Test

We expect to continue to focus substantial resources on obtaining adoption of and reimbursement for our Onco*type* DX colon cancer test, which we launched in January 2010. We believe the key factors that will drive adoption of this test include our 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 our ongoing commercial efforts. 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 from third-party payors for our Onco*type* DX colon cancer test. 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 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, 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.

During the second quarter of 2010, we completed sample processing for our second stage II colon cancer recurrence study and plan to report results in 2011. In June 2010, the first treatment decision impact study of our colon cancer test was initiated. We are planning additional studies to support the clinical utility and assess the treatment impact and health economic benefit of our colon cancer test.

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. In early 2010, we presented positive results from a DCIS breast cancer feasibility study demonstrating that ribonucleic acid, or RNA, extraction and reverse transcription polymerase chain reaction, or RT-PCR, technology can be successfully performed to assess gene expression profiles from fixed paraffin-embedded, or FPE, tissues. 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. We have initiated sample processing for a large DCIS clinical trial and plan to report results in the first half of 2011.

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In June 2010, we presented positive results from an evaluation of biological similarities and differences between stage II and stage III colon cancer suggesting the Onco*type* DX colon cancer Recurrence Score result may also predict recurrence risk in stage III colon cancer. We plan to continue conducting early development tests to evaluate our 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.

During the second quarter of 2010, we completed our first prostate gene identification study. We expect to report results from this study in late 2010.

In June 2010, we presented results from our first renal gene identification study 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. The study results demonstrated a strong correlation between gene expression and recurrence risk in this patient population.

Economic Environment

Continuing concerns over prolonged high unemployment levels across the U.S., the availability and cost of credit, the U.S. mortgage market, the U.S. real estate market, Federal budget proposals, inflation, deflation, taxation issues, energy costs and geopolitical issues have contributed to increased volatility and diminished expectations for the U.S. economy. These factors, combined with declines in business and consumer confidence and a volatile stock market, have precipitated an economic slowdown and expectations of slower global economic growth 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 have a negative impact on growth in tests delivered during the three and nine months ended September 30, 2010, particularly in areas of the U.S. with high unemployment levels where patients have lost healthcare coverage, delayed medical checkups or are unable to pay for our tests. 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 recently enacted Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or, collectively, the PPACA, makes changes that are expected to significantly impact the pharmaceutical and medical device industries. 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, 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, in addition to 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 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 and Significant Judgments and Estimates

This discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally

accepted in the U.S. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets and

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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 September 30, 2010, we had distributor agreements in 13 countries outside of the U.S. 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 September 30, 2010, 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 $37 million. We cannot provide any assurance as to when, if ever, and to what extent these amounts will be collected.

From time to time, we receive requests for refunds of payments, generally due to overpayments made by third-party payors. Upon becoming aware of a refund request, we establish an accrued liability for tests covered by the refund request until such time as we determine whether or not a refund is due. If we determine that a refund is due, we credit cash and reduce the accrued liability. Accrued refunds were $499,000 and $757,000 at September 30, 2010 and December 31, 2009, 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.

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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. As of September 30, 2010 and December 31, 2009, our allowance for doubtful accounts was $738,000 and $545,000, 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 early 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

Our employee stock-based compensation 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, as well as expected option forfeiture rates, 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 option forfeiture rates 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 employee stock-based awards granted in future periods may change. See Note 6, Stock-Based Compensation, in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for more information.

Results of Operations

Three and Nine Months Ended September 30, 2010 and 2009

We recorded net income of $3.7 million and $2.6 million for the three and nine months ended September 30, 2010, respectively, compared to a net loss of $502,000 and $9.1 million for the three and nine months ended September 30, 2009, respectively. On a basic per share basis, net income was $0.13 and $0.09 for the three and nine months ended September 30, 2010, respectively, compared to a net loss of $0.02 and $0.32 for the three and nine months ended September 30, 2009, respectively. On a diluted per share basis, net

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income was $0.12 and $0.09 for the three and nine months ended September 30, 2010, respectively, compared to a net loss of $0.02 and $0.32 for the three and nine months ended September 30, 2009, respectively. We may incur net losses in future periods due to future spending, and we may not achieve sustained profitability for at least the next year or more.

Revenues

Total revenues increased 17% to $46.3 million and 19% to $131.0 million for the three and nine months ended September 30, 2010, respectively, compared to $39.5 million and $110.0 million for the three and nine months ended September 30, 2009, respectively. We derive our revenues primarily from product sales and, to a lesser extent, from contract research arrangements. We operate in one industry segment. As of September 30, 2010, substantially all of our product revenues have been derived from the sale of our Onco*type* DX breast cancer test. Payors are billed upon generation and delivery of a Recurrence Score report to the physician. Product revenues are recorded on a cash basis unless a contract or arrangement 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 September 30,		For the Nine Months Ended September 30,	
	2010	2009	2010	2009
	(In thousands)			
Product revenues	$ 45,773	$ 38,910	$ 128,553	$ 107,529
Contract revenues	544	607	2,432	2,436
Total revenues	$ 46,317	$ 39,517	$ 130,985	$ 109,965
Period over period dollar increase in product revenues	$ 6,863		$ 21,024	
Period over period percentage increase in product revenues	18%		20%	

The increase in product revenues for both the three and nine month comparative periods resulted from an increase in test volume, expanded reimbursement coverage and an increase in revenues recorded on an accrual basis. Approximately 56% and 54% of product revenues for the three and nine months ended September 30, 2010, respectively, were recorded on an accrual basis and recognized at the time the test results were delivered, compared to approximately 50% of product revenues for the three and nine months ended September 30, 2009, respectively. For both periods, the balance of product revenues was recognized upon cash collection as payments were received. The timing of recognition of revenues related to third-party payments may cause fluctuations in product revenues from period to period.

Product revenues on behalf of Medicare patients were $9.4 million, or 21%, and $26.1 million, or 20%, of product revenues for the three and nine months ended September 30, 2010, respectively, compared to $7.4 million, or 19%, and $20.4 million, or 19%, of product revenues for the three and nine months ended September 30, 2009, respectively. There were no other third party payors with product revenues of 10% or more for these periods. International product revenues were $3.1 million, or 7%, and $7.2 million, or 6%, of total product revenues for the three and nine months ended September 30, 2010, respectively, compared to $1.8 million, or 5%, and $4.4 million, or 4%, of total product revenues for the three and nine months ended September 30, 2009, respectively.

Contract revenues were $544,000 and $2.4 million for the three and nine months ended September 30, 2010, respectively, compared to $607,000 and $2.4 million for the three and nine months ended September 30, 2009, respectively. Period over period variances in contract revenues are generally due to project timing for ongoing contract research and development activities. We expect that our contract revenues will continue to fluctuate based on the timing and number of studies being conducted.

Cost of Product Revenues

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2010	2009	2010	2009
	(In thousands)		(In thousands)	
Tissue sample processing costs	$ 6,120	$ 5,517	$ 18,005	$ 16,324
Stock-based compensation	86	96	275	277
Total tissue sample processing costs	6,206	5,613	18,280	16,601
License fees	2,647	2,688	7,647	7,418
Total cost of product revenues	$ 8,853	$ 8,301	$ 25,927	$ 24,019
Period over period dollar increase	$ 553		$ 1,908	
Period over period percentage increase	7%		8%	

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Cost of product revenues represents the cost of materials, direct labor, equipment and infrastructure expenses associated with processing tissue samples (including histopathology, anatomical pathology, paraffin extraction, RT-PCR, quality control analyses and shipping charges to transport tissue samples) and license fees. Infrastructure expenses include allocated facility occupancy and information technology costs. Costs associated with performing our 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 subject to 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 near future.

Tissue sample processing costs increased $603,000, or 11%, for the three months ended September 30, 2010 compared to the three months ended September 30, 2009, reflecting an 11% increase in test volume for the three month comparative periods. Tissue sample processing costs increased $1.7 million, or 10%, for the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009. This increase was driven primarily by an 18% increase in test volume for the nine month comparative periods, partially offset by cost controls and efficiency gains. License fees decreased $41,000, or 2%, for the three months ended September 30, 2010 compared to the three months ended September 30, 2009. License fees increased $229,000, or 3%, for the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009. License fees for the three and nine months ended September 30, 2010 included decreases of approximately $457,000 and $1.3 million, respectively, related to the discontinuance of certain license fees representing 1% of total product revenues, resulting from the abandonment of a patent by the licensor. These decreases were offset by increases in license fees (related to other licenses) due to increased product revenues of $366,000 and $1.2 million for the three and nine months ended September 30, 2010, respectively, and expense related to fixed annual payments to one of our collaborators triggered by the January 2010 launch of our Onco*type* DX colon cancer test of $50,000 and $300,000 for the three and nine months ended September 30, 2010, respectively. We expect the cost of product revenues to increase in future periods to the extent we process more tests.

Research and Development Expenses

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2010	2009	2010	2009
	(In thousands)			
Personnel-related expenses	$ 4,200	$ 4,723	$ 12,258	$ 13,981
Stock-based compensation	778	796	2,243	2,336
Reagents and laboratory supplies	503	925	1,323	2,201
Collaboration expenses	351	380	1,514	1,875
Infrastructure and all other costs	2,348	2,296	6,615	6,614
Total research and development expenses	$ 8,180	$ 9,120	$ 23,953	$ 27,007
Period over period dollar decrease	$ (940)		$ (3,054)	
Period over period percentage decrease	(10%)		(11%)	

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, infrastructure expenses, including allocated facility occupancy and information technology costs, contract services and other outside costs. Research and development expenses also include costs related to activities performed under contracts with biopharmaceutical and pharmaceutical companies.

The $940,000, or 10%, decrease in research and development expenses for the three months ended September 30, 2010 compared to the three months ended September 30, 2009 included a $523,000 decrease in personnel-related expenses and a $422,000 decrease in

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reagents and laboratory supplies. The $3.1 million, or 11%, decrease in research and development expenses for the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009 reflected a $1.7 million decrease in personnel-related expenses, an $878,000 decrease in reagents and laboratory supplies and a $361,000 decrease in collaboration expenses. These decreases were due primarily to cost controls, efficiency gains, project timing and reagents and supplies use for ongoing contract research and development activities, and the movement of our Onco*type* DX colon cancer test from development in the first half of 2009 to commercialization in the last half of 2009 and product launch in January 2010. 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 our product pipeline for breast, colon, renal, prostate and other cancers.

Selling and Marketing Expenses

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2010	2009	2010	2009
	(In thousands)			
Personnel-related expenses	$ 8,998	$ 7,598	$ 26,358	$ 22,286
Stock-based compensation	760	786	2,403	2,381
Promotional and marketing materials	2,736	3,204	9,792	9,153
Travel, meetings and seminars	1,998	1,559	6,110	5,544
Infrastructure and all other costs	2,844	2,166	8,205	6,355
Total selling and marketing expenses	$ 17,336	$ 15,313	$ 52,868	$ 45,719
Period over period dollar increase	$ 2,023		$ 7,149	
Period over period percentage increase	13%		16%	

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

The $2.0 million, or 13%, increase in selling and marketing expenses for the three months ended September 30, 2010 compared to the three months ended September 30, 2009 was due primarily to a $1.4 million increase in personnel-related expenses, a $678,000 increase in infrastructure and other costs, including allocations for information technology, recruiting and other expenses, and a $439,000 increase in travel, meetings and seminars expenses, partially offset by a $468,000 decrease in promotional and marketing materials. The $7.1 million, or 16%, increase in selling and marketing expenses for the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009 was due to a $4.1 million increase in personnel-related expenses, a $1.9 million increase in infrastructure and other costs, a $639,000 increase in promotional field and marketing expenses, including materials related to our colon cancer product launch and international expansion, and a $566,000 increase in travel, meetings and seminar expenses. The increase in personnel-related expenses for both the three and nine month comparative periods reflected the addition of eight domestic field sales representatives in January 2010 and higher consulting and other expenses related to our international expansion efforts. We expect selling and marketing expenses to increase in future periods due to our efforts to establish adoption of and reimbursement for our Onco*type* DX colon cancer test and the expansion of our commercial efforts in international markets.

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General and Administrative Expenses

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2010	2009	2010	2009
	(In thousands)			
Personnel-related expenses	$ 5,524	$ 4,962	$ 16,050	$ 14,590
Stock-based compensation	1,033	870	3,126	2,610
Professional fees and all other costs	2,004	1,484	6,464	5,118
Total general and administrative expenses	$ 8,561	$ 7,316	$ 25,640	$ 22,318
Period over period dollar increase	$ 1,245		$ 3,322	
Period over period percentage increase	17%		15%	

Our general and administrative expenses consist primarily of personnel-related expenses and professional fees and other costs, including intellectual property defense and prosecution costs, billing and collection costs, bad debt expense and other professional and administrative costs and related infrastructure expenses, including allocated facility occupancy and information technology costs.

The $1.2 million, or 17%, increase in general and administrative expenses for the three months ended September 30, 2010 compared to the three months ended September 30, 2009 was due primarily to a $562,000 increase in personnel-related expenses, a $291,000 increase in billing and collection fees related to increases in cash collections, a $170,000 increase in bad debt expense and a $163,000 increase in stock-based compensation expense. The $3.3 million, or 15%, increase in general and administrative expenses for the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009 was due primarily to a $1.5 million increase in personnel-related expenses, a $784,000 increase in billing and collection fees, a $741,000 increase in bad debt expense related to growth in our aged accounts receivable balance and a $516,000 increase in stock-based compensation expense. 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 fees for billing and collections.

Interest and Other Income

Interest and other income was $70,000 and $219,000 for the three and nine months ended September 30, 2010, respectively, compared to $116,000 and $591,000 for the three and nine months ended September 30, 2009, respectively. The $46,000 and $372,000 decreases for the three and nine month comparative periods were primarily due to lower market yields on our investment portfolio. We expect our interest income will remain nominal if the current low interest rate environment continues.

Interest and Other Expense

Interest and other expense was $2,000 and $31,000 for the three and nine months ended September 30, 2010, respectively, compared to $22,000 and $109,000 for the three and nine months ended September 30, 2009, respectively. The $20,000 and $78,000 decreases for the three and nine months ended comparative periods were due primarily to lower interest expense due to lower average balances on our equipment financing notes as we paid them down, partially offset by net realized foreign exchange transaction losses. We expect our interest expense to decline as we continue to make payments on the notes, which are scheduled to be paid in full by November 2010. We do not anticipate using additional equipment financing as a funding source in the next twelve months.

Income Tax Expense

For the three and nine months ended September 30, 2010, we recorded income tax benefit of $215,000 and income tax expense of $182,000, respectively, which were computed using the discrete, or cut-off , method and were principally comprised of California alternative minimum tax, other state income taxes and foreign taxes, offset by a reversal of 2009 federal alternative minimum tax previously provided for. The reversal of 2009 federal alternative

minimum income tax resulted from the enactment of the Worker, Homeownership and Business Assistance Act of 2009 that expanded the use of net operating losses. Income tax expense of $63,000 and $454,000 was recorded for the three and nine months ended September 30, 2009, respectively, which was principally comprised of California state income tax, federal alternative minimum tax and foreign taxes, and was based on our estimated taxable income for the year ended December 31, 2009. The change in tax computation method for the three and nine months ended September 30, 2010

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was made prospectively and was due to the impact of expected quarterly earnings volatility on the our ability to reliably forecast an effective tax rate for 2010.

As a result of cumulative 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. Accordingly, we continue to maintain a full valuation allowance on our net deferred tax assets until sufficient evidence exists to support the reversal of all or some portion of this allowance.

Liquidity and Capital Resources

As of September 30, 2010, we had an accumulated deficit of $175.3 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.

Sources of Liquidity

At September 30, 2010, we had cash, cash equivalents and short-term investments of $69.7 million compared to $58.9 million at September 30, 2009. The $10.8 million increase was attributable to increased cash collections from sales of our tests and payments from collaborators, which were partially offset by investments in the growth of our business, including our international expansion and activities related to our colon cancer product launch in January 2010. In accordance with our investment policy, available cash is invested in short-term, low-risk, investment-grade debt instruments. Our cash and short-term investments are held in a variety of interest-bearing instruments including money market accounts, U.S. Treasury securities, debt obligations of U.S. government-sponsored entities, high-grade corporate bonds and commercial paper. At September 30, 2010, our holdings of debt obligations of U.S. government-sponsored entities consisted entirely of debt securities issued by the Federal Home Loan Bank, the Federal National Mortgage Association and the Federal Home Loan Mortgage Corporation.

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. At September 30, 2010 and 2009, we had notes payable under these equipment financing arrangements of $43,000 and $532,000, respectively. Our existing notes payable under these arrangements are scheduled to be fully paid by November 2010.

Accounts Receivable

At September 30, 2010 and December 31, 2009, $12.3 million, or 12%, and $11.1 million, or 13%, respectively, of our total assets consisted of accounts receivable. Days sales outstanding, or DSOs, is a measure of the average number of days it takes for us to collect our accounts receivable, calculated from the date that tests are billed. At September 30, 2010 and December 31, 2009, our average DSOs were 49 days and 48 days, respectively.

The following tables summarize accounts receivable by payor mix at September 30, 2010 and December 31, 2009:

	September 30, 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	$ 9,432	72.3%	$ 4,610	$ 1,736	$ 798	$ 627	$ 563	$ 1,098
Medicare	3,617	27.7%	2,982	113	72	92	85	273
Total	$ 13,049	100.0%	$ 7,592	$ 1,849	$ 870	$ 719	$ 648	$ 1,371
Allowance for doubtful accounts	(738)							

Net accounts receivable	$ 12,311

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	December 31, 2009							
	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	$ 6,591	56.5%	$ 3,391	$ 1,164	$ 563	$ 386	$ 410	$ 677
Medicare	5,077	43.5%	1,459	2,018	885	218	193	304
Total	$ 11,668	100%	$ 4,850	$ 3,182	$ 1,448	$ 604	$ 603	$ 981
Allowance for doubtful accounts	(545)							
Net accounts receivable	$ 11,123							

The timing of our billing and cash collections causes fluctuations in our monthly DSOs and accounts receivable.

Cash Flows

	2010	2009	$ Change
		(In thousands)	
As of September 30:			
Cash, cash equivalents and short-term investments	$69,711	$ 58,902	10,809
Working capital	69,140	53,006	16,134
For the nine months ended September 30:			
Cash provided by (used in):			
Operating activities	14,134	5,202	8,932
Investing activities	(547)	713	(1,260)
Financing activities	947	(367)	1,314
Capital expenditures (included in investing activities above)	(2,809)	(2,417)	(392)

We achieved positive net cash flows for both the nine months ended September 30, 2010 and the nine months ended September 30, 2009. Net cash provided by operating activities was $14.1 million for the nine months ended September 30, 2010 compared to net cash provided by operating activities of $5.2 million for the nine months ended September 30, 2009. Net cash provided by operating activities includes net income (loss) adjusted for certain non-cash items and changes in assets and liabilities. Net cash provided by operating activities for the nine months ended September 30, 2010 reflected net income of $2.6 million, adjusted for $13.4 million of stock-based compensation and depreciation and amortization expense, and a $1.2 million increase in accounts payable, partially offset by a $1.2 million increase in accounts receivable, a $1.2 million increase in prepaid expenses and other assets, a $553,000 decrease in deferred revenues and a $132,000 decrease in accrued license fees. Net cash provided by operating activities for the nine months ended September 30, 2009 reflected a net loss of $9.1 million, adjusted for $12.5 million of stock-based compensation and depreciation expense, and a $1.4 million payment from one of our collaborators.

Net cash used in investing activities was $547,000 for the nine months ended September 30, 2010, compared to net cash provided by investing activities of $713,000 for the nine months ended September 30, 2009. Our investing activities have consisted predominately of purchases and maturities of marketable securities and capital expenditures. Net cash used in investing activities for the nine months ended September 30, 2010 included $2.8 million in capital expenditures, partially offset by $2.3 million in net maturities of marketable securities. Net cash provided by investing activities for the nine months ended September 30, 2009 included $3.1 million in net maturities of short-term investments, partially offset by $2.4 million in capital expenditures.

Net cash provided by financing activities was $947,000 for the nine months ended September 30, 2010, compared to net cash used in financing activities of $367,000 for the nine months ended September 30, 2009. Our financing activities included sales of our equity securities and payments on our capital equipment financing arrangements. Net cash provided by financing activities for the nine months ended September 30, 2010 included $1.1 million in proceeds from the issuance of our common stock upon the exercise of stock options, partially offset by $182,000 in principal payments on our debt. Net cash used in financing activities for the nine months ended September 30, 2009 included $1.5 million in principal payments on our debt, partially offset by $1.1 million in proceeds from the issuance of our common stock upon the exercise of stock options.

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Contractual Obligations

The following table summarizes our significant contractual obligations as of September 30, 2010 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	$ 7,856	$ 2,400	$ 2,174	$ 1,494	$ 1,788
Notes payable obligations	43	43			
Total	$ 7,899	$ 2,443	$ 2,174	$ 1,494	$ 1,788

Our non-cancelable operating lease obligations are for laboratory and office space. In September 2005, we entered into a non-cancelable lease for 48,000 square feet of laboratory and office space in Redwood City, California. In January 2007, we entered into a non-cancelable lease for 48,000 square feet of additional office space in a nearby location. Both leases expire in February 2012. In October 2009, we entered into a non-cancelable agreement to lease an additional 30,500 square feet of office space near our current locations, which expires in March 2018. In May 2010, our wholly-owned European subsidiary entered into a non-cancelable lease for approximately 2,500 square feet of office space in Geneva, Switzerland, which expires in June 2015.

Our notes payable obligations are for principal and interest payments on capital equipment financing. In March 2005, we entered into an arrangement to finance the acquisition of laboratory equipment, computer hardware and software, leasehold improvements and office equipment. In connection with this arrangement, we granted the lender a security interest in the assets purchased with these borrowings. We may prepay all, but not part, of the amounts owing under the arrangement so long as we also pay a 4% premium on the remaining payments. As of September 30, 2010, the outstanding notes payable balance under this arrangement totaled $43,000 at an annual interest rate of 11.30%. These notes are scheduled to be paid in full in November 2010.

We are required to make a series of annual payments under one of our collaboration agreements beginning on the date that we commercially launched our Onco*type* DX breast cancer test. At September 30, 2010, the future annual payment due under this agreement was $475,000, which is due in 2011. We were also required to make a series of fixed annual payments under a separate collaboration agreement beginning with the January 2010 launch of our Onco*type* DX colon cancer test. At September 30, 2010, future annual payments due under this agreement were $200,000 in 2011, $300,000 in 2012 and $450,000 in each of 2013, 2014 and 2015. However, because either party may terminate the agreement upon thirty 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 year ended December 31, 2009 and the nine months ended September 30, 2010. We currently anticipate that our cash, cash equivalents and short-term investments, together with collections from our Onco*type* DX breast cancer test, 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 $5.0 million over the next twelve months for planned laboratory equipment, information technology equipment, facilities expansion plans and other expenditures to support the growth of our business. We may also use cash to acquire or invest in complementary businesses, technologies, services or products. We expect that our cash, cash equivalents and short-term investments will also be used to fund working capital and for other general corporate purposes, such as licensing technology rights, partnering arrangements for our tests outside of the U.S. or establishing direct sales capabilities outside of the U.S.

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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, 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 funds to see these programs 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 early 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 are not able to generate 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. At September 30, 2010, 10,000,000 shares of our common stock were available for future issuance under a shelf registration statement. If we raise funds by issuing equity securities, dilution to stockholders may 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 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 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 may not be available on reasonable terms, if at all. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs or selling and marketing initiatives. In addition, we may have to work with a partner on one or more of our product or market development programs, which could lower the economic value of those programs to us.

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Off-Balance Sheet Arrangements

As of September 30, 2010, we had no material off-balance sheet arrangements.

Recent Accounting Pronouncements

In April 2010, the Financial Accounting Standards Board, or FASB, issued authoritative guidance for applying the milestone method of revenue recognition to research and development arrangements. Under this guidance, revenue contingent upon the achievement of a milestone in its entirety may be recognized in the period in which the milestone is achieved only if the milestone meets all the criteria within the guidance to be considered substantive. This guidance is effective on a prospective basis for research and development milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. This guidance, which we do not expect to have a material impact on our financial condition and results of operations, will become effective for us on January 1, 2011.

In October 2009, FASB issued authoritative guidance that amends existing guidance for identifying separate deliverables in a revenue-generating transaction where multiple deliverables exist, and provides guidance for allocating and recognizing revenue based on those separate deliverables. The guidance is expected to result in more multiple-deliverable arrangements being separable than under current guidance and is required to be applied prospectively to new or significantly modified revenue arrangements. This guidance, which we do not expect to have a material impact on our financial condition and results of operations, will become effective for us on January 1, 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 short-term, low-risk, investment-grade debt instruments. Our investments in marketable securities, which are comprised primarily of money market funds, obligations of U.S. Government agencies and government-sponsored entities, high-grade corporate bonds and commercial paper, are subject to default, changes in credit rating and changes in market value. Due to recent financial and economic conditions, similar investments have experienced losses in value and liquidity constraints which differ from historical patterns. These investments are also subject to interest rate risk and will decrease in value if market rate interest rates increase.

Our cash, cash equivalents and marketable securities, totaling $69.7 million at September 30, 2010, did not include any auction preferred stock, auction rate securities or mortgage-backed investments. We currently do not hedge interest rate exposure, and we do not have any foreign currency or other derivative financial instruments. The securities in our investment portfolio are classified as available for sale and are, due to their short-term nature, subject to minimal interest rate risk. To date, we have not experienced a loss of principal on any of our investments. Although we currently expect that our ability to access or liquidate these investments as needed to support our business activities will continue, we cannot ensure that this will not change. We believe that, if market interest rates were to change immediately and uniformly by 10% from levels at September 30, 2010, 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, our financial results could be affected by factors such as changes in foreign currency exchange rates or weak economic conditions in foreign markets. We recognized $15,000 in net realized foreign exchange transaction gains and $19,000 in net realized foreign exchange transaction losses for the three and nine months ended September 30, 2010, respectively. Our total payables denominated in foreign currencies as of September 30, 2010 were not material. The functional currency of our wholly-owned European subsidiary 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.

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ITEM 4. CONTROLS AND PROCEDURES.

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

We have historically incurred substantial net losses. From our inception in August 2000 through September 30, 2010, we had an accumulated deficit of $175.3 million. We expect to continue to devote substantial resources to continue to invest in our product pipeline, including our current Onco*type* DX tests and future products, and our commercial and laboratory infrastructure. We may incur additional losses in the future and we may never achieve sustained profitability.

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.

In recent years, we have incurred significant costs in connection with the development of our Onco*type* DX platform. For the nine months ended September 30, 2010 and 2009, our research and development expenses were $24.0 million and $27.0 million, respectively, and our sales and marketing expenses were $52.9 million and $45.7 million, respectively. We expect our expense levels to continue to increase for the foreseeable future as we seek to expand the clinical utility of our 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 U.S., the availability and cost of credit, the U.S. mortgage market, the U.S. real estate market, Federal budget proposals, inflation, deflation, taxation issues, energy costs and geopolitical issues have contributed to increased volatility and diminished expectations for the U.S. economy. These factors, combined with declines in business and consumer confidence and a volatile stock market, have precipitated an economic slowdown and expectations of slower economic growth going forward. The economic slowdown continued to have a negative impact on growth in tests delivered during the three and nine months ended September 30, 2010, particularly in areas of the U.S. with high unemployment

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levels where patients have lost healthcare coverage, delayed medical checkups or are unable to pay for our tests. 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.

In March 2010, President Barack Obama signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, collectively, the PPACA, which makes changes that are expected to significantly impact the pharmaceutical and medical device industries. 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. Though there are some exceptions, this tax may apply to some or all of the 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 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 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. In addition, clinical laboratory tests that are developed and validated by a laboratory for its own use are called laboratory developed tests, or LDTs. Changes in healthcare policy, such as changes in the U.S. Food and Drug Administration, or 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. For example, in 1989, the U.S. Congress passed federal self-referral prohibitions commonly known as the Stark Law, significantly restricting, regulating and changing laboratories relationships with physicians. In addition, sales of our tests outside of the U.S. 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 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,

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appropriate for the specific patient,

cost-effective,

supported by peer-reviewed publications, and

included in clinical practice guidelines.

There is uncertainty concerning third-party payor reimbursement of any test incorporating new technology, including tests developed using our Onco*type* DX platform. Several entities conduct technology assessments of new medical tests and devices and provide the results of their assessments for informational purposes to other parties. These assessments may be used by third-party payors and health care providers as grounds to deny coverage for a test or procedure. Although there are a number of favorable assessments of our Onco*type* DX breast cancer test, the test has received negative assessments in the past and our tests may receive negative assessments in the future. For example, in 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 U.S. 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 not obtained reimbursement coverage from third-party payors in the U.S. 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, or under what circumstances, 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 reimbursement from private payors and Medicare and Medicaid programs for our 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.

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 or cancel their contracts with us at any time, review and adjust the rate of reimbursement 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 for tests covered by Medicare is 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.

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If we are unable to obtain or maintain adequate reimbursement for our tests outside of the U.S., 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 U.S., 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 U.S., and our efforts may not be successful. In addition, because we rely on distributors to obtain reimbursement for our tests, to the extent we do not have direct reimbursement arrangements with payors, we may not be able to retain reimbursement coverage with a particular payor if our agreement with a distributor is terminated or expires.

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. Although we are working with Medicare and Congress, as well as with other diagnostic laboratories, to revise or reverse these billing rules, we have no assurance that Medicare will do so or that Congress will require Medicare to do so, 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 and a limited number of private payors for a significant portion of our product revenues and if these or other payors stop providing reimbursement or decrease the amount of reimbursement for our tests, our revenues could decline.

Reimbursement on behalf of patients covered by Medicare accounted for 21% and 20% of our product revenues for the three and nine months ended September 30, 2010, respectively, and 20%, 22% and 23% of our product revenues for the years ended December 31, 2009, 2008, and 2007, respectively. Reimbursement on behalf of patients covered by United HealthCare Insurance Company accounted for 8% of our product revenues for both the three and nine months ended September 30, 2010, and 9%, 9% and 13% of our product revenues for the years ended December 31, 2009, 2008 and 2007, respectively. While there were no other third-party payors with product revenues of 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 U.S. are age 65 and over, we may become more dependent on Medicare reimbursement in the future. It is possible that these or other third-party payors that provide reimbursement for our test may suspend, revoke or discontinue coverage at any time, 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. 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.

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If 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 CLIA, as administered by CMS, as well as by applicable state laws. Diagnostic kits that are sold and distributed through interstate commerce are regulated as medical devices by 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 FDA.

In January 2006, we received a letter from FDA regarding our Onco*type* DX breast cancer test inviting us to meet with FDA to discuss the nature and appropriate regulatory status of and the least burdensome ways that we may fulfill any FDA pre-market review requirements that may apply. In September 2006, FDA issued draft guidance on a new class of tests called In Vitro Diagnostic Multivariate Index Assays , or IVDMIAs. Under this draft guidance, our tests could be classified as either a Class II or a Class III medical device, which may require varying levels of FDA pre-market review depending upon intended use and on the level of control necessary to assure the safety and effectiveness of the test. In July 2007, FDA posted revised draft guidance that addressed some of the comments submitted in response to the September 2006 draft guidance. The revised draft guidance includes a transition period of FDA enforcement discretion of up to 18 months following release of final guidance for currently marketed tests if the laboratory submits a pre-market review submission within 12 months of the publication of final guidance. The comment period for this revised guidance expired in October 2007.

In May 2007, FDA issued a guidance document Class II Special Controls Guidance Document: Gene Expression Profiling Test System for Breast Cancer Prognosis. This guidance document was developed to support the classification of gene expression profiling test systems for breast cancer prognosis into Class II. In addition, in June 2007, FDA issued a guidance document Pharmacogenetic Tests and Genetic Tests for Heritable Markers which provides recommendations to sponsors and FDA reviewers in preparing and reviewing pre-market approval applications, or PMAs, and pre-market notification, or 510(k), submissions for pharmacogenetic and other human genetic tests, whether testing is for single markers or for multiple markers simultaneously (multiplex tests).

In June 2010, FDA announced a public meeting to discuss the agency s oversight of LDTs prompted by the increased complexity of LDTs and their increasingly important role in clinical decision making and disease management, particularly in the context of personalized medicine. FDA indicated that it is considering a risk-based application of oversight to LDTs and that, following public input and discussion, it may issue separate draft guidance on the regulation of LDTs which may vary from the previously issued draft guidance on the regulation of IVDMIAs. The public meeting was held in July 2010 and further public comments were submitted to FDA in September 2010.

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.

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 FDA, new enforcement policies adopted by FDA or new legislation enacted by Congress. The Kennedy-Eshoo Personalized Medicine Bill, which would create an Office of Personalized Medicine with HHS to coordinate regulatory as well as reimbursement activities related to personalized medicine technologies such as Onco*type* DX, was introduced to the House of Representatives in June 2010. In addition, the Subcommittee on Oversight and Investigations of the Congressional Energy and Commerce Committee held a hearing entitled Direct-To-Consumer Genetic Testing and the Consequences to the Public Health, in July 2010, during which, in addition to a review of certain direct-to-consumer tests, there was some commentary by FDA staff regarding the need for further regulation of LDTs generally. It is possible that legislation

will be enacted into law and may result in increased regulatory burdens for us to continue to offer our tests or to develop and introduce new tests.

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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 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 FDA, or if labeling claims 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 PMA application with FDA. If pre-market review is required by FDA, there can be no assurance that our tests will be cleared or approved on a timely basis, if at all. Ongoing compliance with FDA regulations would increase the cost of conducting our business, and subject us to inspection by and the requirements of 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.

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 harm our ability to achieve sustained profitability.

If 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. 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.

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 U.S. 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. 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.

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.

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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 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 early development studies in colon cancer for stage III patients, prostate, renal cell and lung cancers. There can be no assurance that our technologies will be capable of reliably predicting the recurrence of cancers other than breast and colon cancer with the sensitivity and specificity necessary to be clinically and commercially useful, or that our colon cancer test will result in a commercially successful product. In addition, before we can develop diagnostic tests for new cancers 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

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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.

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 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

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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.

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 FPE 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. These advances require us to continuously 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.

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 margin on our test. 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 U.S. and therefore reduce sales of our tests.

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 September 30, 2010, we had nine issued patents in the U.S. covering genes and methods that are components of the Onco*type* DX breast cancer test, five of which were issued jointly to us and our collaborators, six Australian patents, one South African patent, one Japanese patent and two European patents for methods used to determine gene expression, and a number of pending U.S. and international patent applications. 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 U.S.

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.

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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 recently reversed that decision, 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. It is unclear at this time whether the USPTO will amend its patent prosecution guidelines for determining patentability. We cannot assure you that our patent portfolio will not be negatively impacted by this decision.

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. This case is currently pending before the Federal Circuit, which has been instructed by the Supreme Court to use broader patentability principles. It is unknown how this case will be decided on appeal, 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, 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.

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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 many public and private companies that offer products or have conducted research to profile genes, gene expression or protein expression in breast or colon cancer, such as Agendia B.V., Almac Diagnostics, bioTheranostics, Celera Corporation, Clarient Incorporated, Exagen Diagnostics, Foundation Medicine Inc., GE Healthcare, a business unit of General Electric Company, Hologic, Qiagen, Response Genetics Inc. and University Genomics. We face competition from commercial laboratories with strong distribution networks for diagnostic tests, such as Genzyme Corporation, 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, as well as other companies and academic and research institutions. Our competitors may invent and commercialize technology platforms that compete with ours. In December 2005, the federal government allocated a significant amount of funding to The Cancer Genome Atlas, a project aimed at developing a comprehensive catalog of the genetic mutations and other genomic changes that occur in cancers and maintaining the information in a free public database. 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 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 U.S., 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 and clinical partners, 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

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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. 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 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.

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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.

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

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

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.

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

The marketing, sale and use of our tests could lead to the filing of product liability claims if someone were to allege that our tests failed to perform as it was designed. We may also be subject to liability for errors in the test results we provide to physicians or for a misunderstanding of, or inappropriate reliance upon, the information we provide. For example, physicians sometimes order our 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.

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

Our business strategy incorporates international expansion, including establishing and maintaining direct sales and physician outreach and education capabilities outside of the U.S. 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 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

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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 September 30, 2010, we had exclusive distribution agreements for our Onco*type* DX breast cancer test in 13 countries outside of the U.S., 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 U.S. and the reimbursement process in foreign markets may also impact our revenues from international sales or impact our ability to increase international sales in the future.

We may acquire other businesses or form joint ventures 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. 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 or joint venture.

To finance any acquisitions, we may choose to issue shares of our common stock as consideration, which would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other companies for stock. The market price of our common stock has been particularly volatile during the recent period of upheaval in the capital markets and world economy, and may continue to be volatile in the future. 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, with recent credit market conditions, similar types of investments have experienced 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:

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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;

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.

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 early 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

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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 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.

ITEM 6. EXHIBITS

Exhibit Number	Description
31.1	Rule 13a-14(a) Certification of Chief Executive Officer.
31.2	Rule 13a-14(a) Certification of Chief Financial Officer.
32.1#	Statement of Chief Executive Officer under Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. §1350).
32.2#	Statement of Chief Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. §1350).

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

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SIGNATURES

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

GENOMIC HEALTH, INC.

Date: November 9, 2010

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

Date: November 9, 2010

By: /s/ G. Bradley Cole
G. Bradley Cole
Chief Operating Officer and Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

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GENOMIC HEALTH, INC.
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