GENOMIC HEALTH INC
Form 10-Q
August 11, 2008

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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 June 30, 2008

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 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	Smaller Reporting Company o

(Do not check if smaller reporting company)

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

The number of outstanding shares of the registrant s Common Stock, $0.0001 par value, was 28,307,711 as of July 31, 2008.

GENOMIC HEALTH, INC.
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PART 1: FINANCIAL INFORMATION

Item 1. Financial Statements

GENOMIC HEALTH, INC.

Condensed Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	June 30, 2008 (Unaudited)	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 17,222	$ 39,164
Short-term investments	43,405	29,196
Accounts receivable (net of allowance for doubtful accounts; June 30, 2008 $362, December 31, 2007 $133)	7,360	5,089
Prepaid expenses and other current assets	4,649	3,105
Total current assets	72,636	76,554
Property and equipment, net	13,041	10,412
Restricted cash	500	500
Other assets	411	463
Total assets	$ 86,588	$ 87,929
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,913	$ 1,966
Accrued compensation	4,154	3,672
Accrued license fees	1,862	1,798
Accrued expenses and other current liabilities	3,595	1,948
Notes payable current portion	2,405	2,687
Deferred revenues current portion	1,682	337
Lease incentive obligations current portion	364	198
Total current liabilities	15,975	12,606
Notes payable long-term portion	940	2,039
Deferred revenues long-term portion	2,486	671
Lease incentive obligations long-term portion	971	629
Other liabilities	724	818
Stockholders equity:		
Preferred stock, $0.0001 par value per share, 5,000,000 shares authorized, none issued and outstanding at June 30, 2008 and December 31, 2007		
Common stock, $0.0001 par value per share; 100,000,000 shares authorized, 28,286,679 and 28,181,859 shares issued and outstanding at June 30, 2008 and December 31, 2007, respectively	2	2
Additional paid-in capital	228,626	223,507
Accumulated other comprehensive income (loss)	(8)	52
Accumulated deficit	(163,128)	(152,395)

Total stockholders equity	65,492	71,166
Total liabilities and stockholders equity	$ 86,588	$ 87,929

See accompanying notes.

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GENOMIC HEALTH, INC.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Revenues:				
Product revenues	$ 26,327	$ 14,555	$ 49,682	$ 27,701
Contract revenues	1,456	135	1,541	1,077
Total revenues	27,783	14,690	51,223	28,778
Operating expenses:				
Cost of product revenues	6,850	4,172	12,734	8,019
Research and development	7,322	5,224	13,728	10,394
Selling and marketing	11,827	8,740	24,194	16,893
General and administrative	6,225	4,186	12,130	8,275
Total operating expenses	32,224	22,322	62,786	43,581
Loss from operations	(4,441)	(7,632)	(11,563)	(14,803)
Interest and other income	448	612	1,069	1,128
Interest and other expense	(106)	(178)	(239)	(373)
Net loss	$ (4,099)	$ (7,198)	$ (10,733)	$ (14,048)
Basic and diluted net loss per share	$ (0.15)	$ (0.28)	$ (0.38)	$ (0.55)
Shares used in computing basic and diluted net loss per share	28,262,407	26,141,476	28,239,908	25,355,685

See accompanying notes.

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

	Six Months Ended June 30,	
	2008	**2007**
Operating activities:		
Net loss	$ (10,733)	$ (14,048)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,220	1,763
Employee stock-based compensation	4,541	2,801
Non-employee stock-based compensation	1	27
Changes in assets and liabilities:		
Accounts receivable, net	(2,271)	(1,171)
Prepaid expenses and other assets	(1,518)	(1,778)
Accounts payable	(53)	(1,231)
Accrued expenses and other liabilities	2,099	2,315
Deferred revenues	3,160	35
Lease incentive obligations	508	199
Net cash used in operating activities	(2,046)	(11,088)
Investing activities:		
Purchases of short-term investments	(73,569)	(35,847)
Maturities of short-term investments	59,299	29,048
Purchases of property and equipment	(4,823)	(2,155)
Net cash used in investing activities	(19,093)	(8,954)
Financing activities:		
Principal payments for notes payable	(1,381)	(1,239)
Proceeds from issuance of common stock	578	49,928
Net cash provided by (used in) financing activities	(803)	48,689
Net increase (decrease) in cash and cash equivalents	(21,942)	28,647
Cash and cash equivalents at the beginning of period	39,164	14,926
Cash and cash equivalents at the end of period	$ 17,222	$ 43,573
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 230	$ 373

See accompanying notes.

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GENOMIC HEALTH, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
June 30, 2008
(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 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 test, Onco*type* DX, was launched in 2004 and has been shown to predict the likelihood of breast cancer recurrence and the likelihood of chemotherapy benefit in a large portion of early-stage breast cancer patients. The Company expects to continue to incur losses for at least the next year as commercial and development efforts continue.

Principles of Consolidation

The condensed consolidated financial statements include all the accounts of the Company and its wholly-owned subsidiary. The Company has one wholly-owned subsidiary, Onco*type* Laboratories, Inc., which was established in 2003 and is inactive.

Basis of Presentation and Use of Estimates

The accompanying interim period condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). The condensed consolidated balance sheet as of June 30, 2008, condensed consolidated statements of operations for the three and six months ended June 30, 2008 and 2007 and condensed consolidated statements of cash flows for the six months ended June 30, 2008 and 2007 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, 2007 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 information included in this Quarterly Report on Form 10-Q should be read in conjunction with the consolidated financial statements and accompanying notes included in the Company s Annual Report on Form 10-K for the year ended December 31, 2007.

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.

Fair Value of Financial Instruments

The carrying amounts of certain of the Company s financial instruments, including cash and cash equivalents, trade receivables and accounts payable, approximate fair value due to their short maturities. Based on borrowing rates currently available to the Company for loans and capital lease obligations with similar terms, the carrying value of the Company s debt obligations approximates fair value.

In September 2006, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 157, *Fair Value Measurements* (SFAS 157). SFAS 157 defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. SFAS 157 applies whenever standards require (or permit) assets or liabilities to be measured at fair value, and does not expand the use of fair value in any new circumstances.

The Company adopted SFAS 157 as of January 1, 2008 for financial assets and liabilities measured at fair value. For non-financial assets and liabilities, SFAS 157 will be effective for fiscal years beginning after November 15, 2008. There was no financial statement impact as a result of adoption. See Note 7 for more information.

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In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115* (SFAS 159). SFAS 159 expands the use of fair value accounting but does not affect existing standards that require assets or liabilities to be carried at fair value. Under SFAS 159, a company may elect to use fair value to measure accounts and loans receivable, available-for-sale and held-to-maturity securities, equity method investments, accounts payable, issued debt and other financial assets and liabilities. If the use of fair value is elected, any upfront costs and fees related to the item must be recognized in earnings and cannot be deferred. The fair value election is irrevocable and generally made on an instrument-by-instrument basis, even if a company has similar instruments that it elects not to measure based on fair value. At the adoption date, unrealized gains and losses on existing items for which fair value has been elected are reported as a cumulative adjustment to beginning retained earnings. Subsequent to the adoption of SFAS 159, changes in fair value are recognized in earnings. SFAS 159 is effective for fiscal years beginning after November 15, 2007.

The Company adopted SFAS 159 effective January 1, 2008 and did not elect fair value as an alternative measurement for any financial instruments not previously carried at fair value.

Revenue Recognition

The Company derives its revenues from product sales and contract research arrangements. The Company operates in one industry segment. Product revenues are derived solely from the sale of the Onco*type* DX test for breast cancer. The Company generally bills third-party payors for Onco*type* DX 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. Onco*type* DX may not be covered under third-party reimbursement policies, or coverage may be limited to patients with specific clinical attributes. Consequently, 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 when the following revenue recognition criteria are met: (1) persuasive evidence that an arrangement exists; (2) delivery has occurred or services rendered; (3) the fee is fixed or determinable; and (4) collectibility is reasonably assured. Criterion (1) is satisfied when the Company has an agreement or contract with the payor in place, or when the payor has issued a policy addressing reimbursement for the Onco*type* DX test. Criterion (2) is satisfied when the Company performs the test and generates and delivers a Recurrence Score report to the physician. Determination of criteria (3) and (4) is based on management s judgments regarding whether the fee charged for products or services delivered is fixed or determinable, contractual agreements entered into, 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.

Prior to 2008, product revenues had largely been recognized on a cash basis because the Company had a limited number of contracts or agreements with third-party payors and limited collections experience. The Company recognizes a portion of product revenue from third-party payors, including some private payors and Medicare, on an accrual basis prospectively when the criteria described in the preceding paragraph are satisfied. For the six months ended June 30, 2008, approximately half of total product revenue recognized was recorded on an accrual basis.

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 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 from these milestones when earned, 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

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criteria, the Company typically defaults to a performance-based model, with 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 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 June 30, 2008 and December 31, 2007, the Company s allowance for doubtful accounts was $362,000 and $133,000, respectively. Write-offs for doubtful accounts of $7,000 and $138,000 were recorded against the allowance during the three and six months ended June 30, 2008, respectively. Bad debt expense was $273,000 and $357,000 for the three and six months ended June 30, 2008, respectively.

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 and other outside costs, 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.

In June 2007, FASB ratified Emerging Issues Task Force (EITF) Issue No. 07-3, *Accounting for Non-Refundable Payments for Goods or Services Received for Use in Future Research and Development Activities* (EITF 07-3). EITF 07-3 requires that non-refundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed.

The Company adopted EITF 07-03 effective January 1, 2008 for arrangements that were entered into after that date. There was no material financial statement impact as a result of adoption.

Recently Issued Accounting Pronouncements

In February 2008, FASB issued FASB Staff Position 157-2*, Effective Date of FASB Statement No. 157* (FSP 157-2). FSP 157-2 delays the effective date of SFAS 157 for all non-financial assets and non-financial liabilities, except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually), until fiscal years beginning after November 15, 2008. The Company has elected a partial deferral of SFAS 157 under the provisions of FSP 157-2. The Company is currently evaluating the impact that SFAS 157 will have on its financial condition and results of operations when the standard is applied to non-financial assets and non-financial liabilities beginning January 1, 2009.

In November 2007, FASB ratified EITF No. 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1). EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in a collaborative arrangement and third parties. EITF 07-1 is effective for fiscal years beginning after December 15, 2008, and is to be applied retrospectively to all prior periods presented for all collaborative arrangements existing as of the effective date. The Company is currently evaluating the impact that EITF 07-01 will have on its financial condition and results of operations when the standard is applied beginning January 1, 2009.

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Note 2. Net Loss Per Share and Comprehensive Loss

Net Loss Per Share

Basic net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding for the period without consideration for potential common shares. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding for the period and dilutive potential common shares for the period determined using the treasury-stock method. For purposes of this calculation, options to purchase common stock are considered to be potential common shares and are only included in the calculation of diluted loss per share when their effect is dilutive.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
	(In thousands except share and per share amounts) (Unaudited)			
Net loss	$ (4,099)	$ (7,198)	$ (10,733)	$ (14,048)
Weighted-average net common shares outstanding for basic and diluted loss per common share	28,262,407	26,141,476	28,239,908	25,355,685
Basic and diluted net loss per share	$ (0.15)	$ (0.28)	$ (0.38)	$ (0.55)
Outstanding dilutive securities not included in diluted net loss per share calculation:				
Options to purchase common stock	3,931,216	3,118,078	3,931,216	3,118,078

Comprehensive Loss

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
	(In thousands except share and per share amounts) (Unaudited)			
Net loss	$ (4,099)	$ (7,198)	$ (10,733)	$ (14,048)
Unrealized gain (loss) on available-for-sale securities	(121)	24	(60)	21
Comprehensive loss	$ (4,220)	$ (7,174)	$ 10,793	$ (14,027)

Note 3. Public Offering of Common Stock

On May 25, 2007, the Company closed an underwritten public offering of 3,450,000 shares of common stock at $15.50 per share pursuant to the Company s shelf registration statement on Form S-3. Net proceeds from the offering after deducting underwriting discounts, commissions and expenses were $49.7 million. Entities affiliated with Julian Baker, an outside director and a principal stockholder of the Company, purchased 1,000,000 shares of the Company s common stock in this offering. As of June 30, 2008, the Company had approximately $46.5 million of securities available for issuance under the shelf registration statement.

Note 4. Commercial Technology and Licensing Agreements

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 laboratory tests for Onco*type*

DX. The Company recognized costs recorded under these agreements of $1.9 million and $3.6 million for the three months and six months ended June 30, 2008, respectively, and $1.1 million and $2.2 million for the three and six months ended June 30, 2007, respectively, which were included in cost of product revenues.

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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 premium ranging from 4% to 6% on the outstanding principal balance. As of June 30, 2008, the outstanding notes payable principal balance under this arrangement was $3.3 million at annual interest rates ranging from 10.23% to 11.30%, depending on the applicable note. 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 during the six months ended June 30, 2008.

As of June 30, 2008, the Company s aggregate future commitments under its financing arrangement were as follows:

	Annual Payments (In thousands) (Unaudited)
Years Ending December 31, 2008 (remainder of the year)	$ 1,461
2009	1,934
2010	238
Total minimum payments	3,633
Less: interest portion	(288)
Present value of net minimum payments	3,345
Less: current portion of obligations	(2,405)
Long-term obligations	$ 940

Lease Obligations

In September 2005, the Company entered into a non-cancelable lease directly with the facility owner 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 and includes lease incentive obligations of $834,000 that are being amortized 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 its condensed consolidated balance sheets.

In January 2007, the Company entered into a non-cancelable lease for an additional 48,000 square feet of laboratory and office space in a nearby location. The lease expires in February 2012 and includes lease incentive obligations totaling $932,000 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 its condensed consolidated balance sheets.

Future non-cancelable commitments under these operating leases at June 30, 2008 were as follows:

	Annual Payments (In thousands)

	(Unaudited)
Years Ending December 31, 2008 (remainder of the year)	$ 690
2009	1,520
2010	1,634
2011	1,723
2012	290
Total minimum payments	$ 5,857

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Clinical Collaborator Costs

The Company has entered into a variety of collaboration and specimen transfer agreements relating to its development efforts. Certain agreements contain provisions for royalties from inventions resulting from these collaborations.

At June 30, 2008, future fixed annual payments, exclusive of royalty payments, relating to the launch and commercialization of Onco*type* DX totaled $1.4 million and were payable as follows:

	Annual Payments (In thousands) (Unaudited)
January 2009	475
January 2010	475
January 2011	475
Total	$ 1,425

These payments are recorded in cost of product revenues as license fees. Expense is recorded ratably over the year before the relevant payment is made. If at any time the Company discontinues the sale of commercial products or services resulting from the collaboration, no future annual payments will be payable and the Company will have no further obligation under the agreement. If the Company s cash balance is less than $5.0 million on the due date of any of the annual payments, the Company may be able to defer any current annual payment due for a period of up to 12 months.

In addition, the Company has secured certain options and rights relating to any joint inventions arising out of the collaborations.

Note 6. Stock-Based Compensation

The Company uses the Black-Scholes option valuation model to value stock options to employees and outside directors under Statement of Financial Accounting Standards No. 123 (Revised 2004), *Share-Based Payment* (SFAS 123R). Stock-based compensation expense was calculated based on awards ultimately expected to vest and has been reduced for estimated forfeitures. SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The following table presents the impact of the adoption of SFAS 123R on selected statements of operations line items for the three and six months ended June 30, 2008 and 2007:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
	(In thousands) (Unaudited)			
Cost of product revenues	$ 125	$ 106	$ 239	$ 184
Research and development	720	449	1,455	840
Selling and marketing	648	475	1,278	831
General and administrative	792	488	1,569	946
Total employee stock-based compensation expense	$ 2,285	$ 1,518	$ 4,541	$ 2,801

Stock-based compensation expense resulting from the adoption of SFAS 123R represents expense related to stock options granted on or after January 1, 2006, as well as stock options granted prior to, but not yet vested as of, January 1, 2006. As of June 30, 2008, total unrecognized compensation expense related to unvested stock options, net of estimated forfeitures, was $23.0 million. The Company expects to recognize this expense over a weighted-average period of 38 months.

Valuation Assumptions

Option valuation models require the input of highly subjective assumptions that can vary over time. As of January 2008, expected volatility is based on the historical volatility of the Company s common stock. Prior to January 2008, the Company s expected volatility was based primarily on comparable peer data because the Company s common stock had been publicly traded for less than two years. The expected life of options granted is estimated based on historical option exercise data and assumptions related to unsettled options.

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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 154,600 and 198,200 stock options during the three and six months ended June 30, 2008, respectively, compared to 215,125 and 374,580 stock options granted during the three and six months ended June 30, 2007, 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 June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
	(Unaudited)			
Expected volatility	60.0%	60.5%	59.9%	62.4%
Risk-free interest rate	3.22%	4.66%	3.14%	4.61%
Expected life of options in years	5.74	5.76	5.77	5.65
Weighted-average fair value	$10.95	$10.37	$11.19	$11.24

Stock Options Exercised

For the three and six months ended June 30, 2008, the Company issued 41,590 and 104,820 shares of common stock in connection with the exercise of stock options with a weighted-average exercise price of $5.12 and $5.51 per share, respectively. For the three and six months ended June 30, 2007, the Company issued 88,402 and 110,583 shares of common stock in connection with the exercise of stock options with a weighted-average exercise price of $1.66 and $2.03 per share, respectively.

Note 7. Fair Value Measurements

On January 1, 2008, the Company adopted the provisions of SFAS 157 for its financial assets and liabilities. As permitted by FSP 157-2, the Company elected to defer the adoption of SFAS 157 for all non-financial assets and non-financial liabilities, except those that are recognized or disclosed at fair value in its financial statements on a recurring basis (at least annually), until January 1, 2009. SFAS 157 provides a framework for measuring fair value under GAAP and requires expanded disclosures regarding fair value measurements. SFAS 157 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability, or an exit price, in the principal or most advantageous market for that asset or liability in an orderly transaction between market participants on the measurement date. SFAS 157 also establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

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 following table sets forth the Company s financial instruments that were measured at fair value on a recurring basis at June 30, 2008 by level within the fair value hierarchy. The Company did not have any non-financial assets or liabilities that were measured or disclosed at fair value on a recurring basis at June 30, 2008. As required by SFAS 157, 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:

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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 June 30, 2008
		(In thousands) (Unaudited)		
As of June 30, 2008:				
Assets				
Money market deposits	$ 5,826	$	$	$ 5,826
U.S. Treasury securities		1,003		1,003
Debt securities of U.S. government sponsored agencies		35,468		35,468
Commercial paper		12,459		12,459
Corporate bonds		3,805		3,805

Note 8. Income Tax

The Company has not recognized a provision for income taxes for any of the periods presented because the Company has had net operating losses since inception.

The Company adopted the provisions of Financial Accounting Standards Board Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (FIN 48) effective January 1, 2007. The Company did not recognize any adjustment to its liability for uncertain tax positions as a result of the implementation of FIN 48, and therefore did not record any cumulative adjustment to retained earnings. The Company had $413,000 of unrecognized tax benefits as of June 30, 2008. 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 June 30, 2008, the Company had not recognized any tax-related penalties or interest in its consolidated balance sheets or statements of operations. All tax years from 2001 forward remain subject to future examination by 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 Oncotype DX; the factors we believe to be driving demand for Oncotype DX and our ability to sustain such demand; our expectation that our research and development expense levels will remain high as we seek to increase the clinical utility of Oncotype DX and develop new tests; our expectation that our general and administrative and sales and marketing expenses will increase and our anticipated uses of those funds; our expectations regarding capital expenditures; the factors that may impact our financial results; the extent and duration of our net losses; our ability to comply with the requirements of being a public company; our ability to attract and retain experienced personnel; the impact changes in healthcare policy or regulation could have on our business; the adequacy of our product liability insurance; our ability to recognize revenues other than on a cash basis; the level of investment in our sales force; the capacity of our commercial laboratory to process tests and our expectations regarding future capacity; our dependence on collaborative relationships and the success of those relationships;

whether any tests will result from our collaborations; our business strategy and our ability to achieve our strategic goals; our belief that multi-gene analysis provides better analytical information than traditional methods; our belief regarding the timing of a clinical validation study and a potential test for colon cancer; our expectations regarding clinical development processes future tests may follow; the applicability of clinical results to actual outcomes; our estimates and assumptions with respect to disease incidence; the ability of our test to impact treatment decisions; our beliefs regarding the benefits of a report specific to N+ patients; our beliefs regarding the benefits of individual gene reporting and other enhancements to Oncotype DX and the timing of any such enhancements; our plans with respect to potential tests for ductal carcinoma in situ, or other cancers or for patients treated with aromatase inhibitors or

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other treatments; the economic benefits of our test to the healthcare system; our compliance with federal, state and foreign regulatory requirements; our expectations regarding levels of product and contract revenues; how we intend to spend our existing cash and cash equivalents and how long we expect our existing cash to last; our expected future sources of cash; our plans to borrow additional amounts under existing or new financing arrangements; the potential impact resulting from the regulation of Oncotype DX by the U.S. Food and Drug Administration, or FDA, and our belief that Oncotype DX is properly regulated under the Clinical Laboratory Improvement Amendments of 1988, or CLIA; the impact of new or changing regulation or legislation on our business; 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; our beliefs regarding Palmetto s coverage of our test; our intent to expand our investment in foreign markets, including both direct investment and additional foreign distribution arrangements; the benefits of our technology platform; our beliefs regarding our competitive benefits; the factors that we believe will drive the establishment of coverage policies; the impact of changing interest rates; the amount of future revenues that we may derive from Medicare patients or categories of patients; 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 or to report single gene results; plans for, and the timeframe for the development or commercial launch of, future tests addressing different patient populations or other cancers; the occurrence, timing, outcome or success of clinical trials or studies; our intellectual property and our strategies regarding filing additional patent applications to strengthen our intellectual property rights; our belief that we are in material compliance with our financial covenants; our beliefs regarding our unrecognized tax benefits; the impact of accounting pronouncements and our critical accounting policies, estimates, models and assumptions on our financial results; our anticipated cash needs and our estimates regarding our capital requirements and our needs for additional financing; and anticipated trends and challenges in our business and the markets in which we operate.

Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those expected. These risks and uncertainties include, but are not limited to, those risks discussed in Item 1A of this report, as well as our ability to develop and commercialize new products; the risk of unanticipated delays in research and development efforts; the risk that we may not obtain reimbursement for our existing test and any future tests we may develop; the risks and uncertainties associated with the regulation of our test by FDA; our ability to compete against third parties; our ability to successfully respond to rapid growth; our ability to obtain capital when needed; 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 development and commercialization of genomic-based clinical diagnostic tests for cancer that allow physicians and patients to make individualized treatment decisions. Our first test, Onco*type* DX, was launched in 2004 and has been shown to predict the likelihood of breast cancer recurrence and the likelihood of chemotherapy benefit in a large portion of early-stage breast cancer patients. All tumor samples are sent to our laboratory in Redwood City, California for analysis. Upon generation and delivery of a Recurrence Score report to the physician, we generally bill third-party payors for Onco*type* DX. Effective July 1, 2008, we increased the list price of our test from $3,650 to $3,820.

Adoption and Reimbursement

For the three and six months ended June 30, 2008, more than 9,690 and 18,850 test reports were delivered for use in treatment planning, respectively, compared to more than 5,750 and 11,200 test reports for the three and six months ended June 30, 2007, respectively. As of June 30, 2008, more than 65,000 test reports had been delivered for use in

treatment planning. We believe increased demand resulted from the inclusion of Onco*type* DX in the clinical practice guidelines of the American Society of Clinical Oncologists, or ASCO, and the National Comprehensive Cancer Network, or NCCN, continued publication of peer-reviewed articles on studies we sponsored, conducted or collaborated on that support the use and reimbursement of Onco*type* DX, clinical presentations at major

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symposia, and our ongoing commercial efforts. However, this increased demand is not necessarily indicative of future demand, 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 Onco*type* DX. We believe that each year we may experience slower demand for our test in the second and third calendar quarter, which may be attributed to physicians, surgeons and patients scheduling vacations during this time. As of June 30, 2008, our laboratory had the capacity to process up to 13,000 tests per quarter.

We have recently expanded the clinical utility of Onco*type* DX. In February 2008, we introduced quantitative gene expression reporting for estrogen receptor, or ER, and progesterone receptor, or PR, genes with the Onco*type* DX Recurrence Score report to provide additional information for clinical decision making. We believe that reporting individual gene scores in addition to the Recurrence Score result may have utility in predicting outcomes for specific therapies or disease subtypes. In June 2008, the Journal of Clinical Oncology published results of a study demonstrating the utility of Onco*type* DX in measuring gene expression for ER and PR status, indicating that quantitative reverse transcription polymerase chain reaction, or RT-PCR, is a reliable method for determining hormone receptor status in breast cancer. At the December 2007 San Antonio Breast Cancer Symposium, we presented results from a study suggesting that Onco*type* DX may be useful in predicting survival without disease recurrence and the benefit of chemotherapy for node positive, or N+, patients, in addition to patients with node negative, or N-, estrogen receptor positive, or ER+, breast cancer. As a result, we have experienced an increase in usage of Onco*type* DX for N+ patients. However, most of our existing reimbursement coverage is limited to women with early-stage N-, ER+ breast cancer. We may not be able to obtain reimbursement coverage for Onco*type* DX for breast cancer patients with N+, ER+ disease.

As of July 2008, Cigna HealthCare, Humana, Inc., Health Net, Inc., United HealthCare Insurance Company, Aetna, Inc., Kaiser Foundation Health Plan, Inc., Wellpoint, Inc. and National Heritage Insurance Company, or NHIC, the local Medicare carrier for California with jurisdiction for claims submitted by us for Medicare patients, have issued positive coverage determinations for Onco*type* DX for patients with N-, ER+ disease. In January 2008, Medi-Cal became the first Medicaid agency to establish a policy covering our test. In addition, a number of regional payors, including many regional Blue Cross and Blue Shield plans, have issued policies authorizing coverage for Onco*type* DX. As of July 2008, more than 80% of all U.S. insured lives were covered by health plans that provide reimbursement for Onco*type* DX through contracts, agreements or policy decisions.

In late 2007, the Centers for Medicare and Medicaid Services, or CMS, announced that Palmetto Government Benefits Administrators, or Palmetto, will be replacing NHIC as the California Medicare administrative contractor with jurisdiction for all claims submitted in California to Medicare. Medicare claims processing responsibility will transition from NHIC to Palmetto over the next several months with Palmetto expected to assume full responsibility for claims submitted by us in September 2008. In June 2008, Palmetto posted a local coverage determination for California that includes Onco*type* DX. This coverage decision follows identical criteria as those previously set forth by NHIC. In the future, it is possible that Palmetto or other third-party payors could adopt different coverage or payment policies which may not include reimbursement for Onco*type* DX or may provide for reimbursement on different terms than are presently in effect.

During the three months ended June 30, 2008, we continued to expand our commercial efforts outside of the United States. We have established exclusive distribution networks for Onco*type* DX in Israel, Japan, the United Kingdom, Greece and Turkey. Additionally, we initiated a study supporting Japanese investigators as they gain clinical experience with Onco*type* DX for early-stage breast cancer patients.

Product Pipeline

We are conducting studies with the goal of continuing to expand the clinical utility of Onco*type* DX in breast cancer. We are targeting the introduction of single gene reporting for the human epidermal growth factor receptor 2, or HER2, gene with the Onco*type* DX Recurrence Score report by the end of 2008, which we believe may provide additional information for enhanced treatment decision-making. We are investigating the utility of Onco*type* DX in patients with ductal carcinoma in situ, or DCIS, which generally refers to a pre-invasive tumor with reduced risk of recurrence. We plan to evaluate the use of the Onco*type* DX gene panel and also seek to identify other genes that may be used for treatment planning in DCIS. We are also conducting studies of Onco*type* DX with clinical samples from

breast cancer patients who were treated with aromatase inhibitors and expect to report results from these studies in late 2008.

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We continue to conduct research and development studies in a variety of cancers other than breast cancer. For example, we selected a final set of genes that have been observed to be statistically significantly correlated to clinical outcome in colon cancer, which is now undergoing analytical validation. We received the first trial specimens for our clinical validation study for colon cancer, which we expect to begin in late 2008; data from the study is expected to be available in 2009. In addition, we began gene identification work under our collaboration with Pfizer 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, which is the most common type of kidney cancer in adults. We also recently established collaborators and identified sources of clinical samples in connection with our prostate and lung cancer programs.

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

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

Revenue Recognition

We exercise judgment in determining 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 product revenues for tests performed are recognized when the following criteria are met: (1) persuasive evidence that an arrangement exists; (2) delivery has occurred or services rendered; (3) the fee is fixed or determinable; and (4) collectibility is reasonably assured. We assess whether the product or service fee is fixed and 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 when test results are delivered, product revenues are recognized on a cash basis when cash is received from the payor.

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 expected revenue method of revenue recognition, which requires that we estimate the total amount of costs to be expended for a project then 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.

Allowance for Doubtful Accounts

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 June 30, 2008 and December 31, 2007, our allowance for doubtful accounts was $362,000 and $133,000, respectively. Changes in our allowance for doubtful accounts resulted in a $187,000 reduction of bad debt expense for the six months ended June 30, 2007.

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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 and other outside costs, 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. Non-refundable 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 in accordance with Emerging Issues Task Force Issue No. 07-3, *Accounting for Non-Refundable Payments for Goods or Services Received for Use in Future Research and Development Activities*

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.

All potential future product programs outside of breast and colon cancer are in the research or early development phase. The expected time frame in which a test for one of these other cancers can be brought to market is uncertain given the technical challenges and clinical variables that exist between different types of cancers. In 2008, we began maintaining 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

Under the provisions of Statement of Financial Accounting Standards No. 123 (Revised 2004), *Share-Based Payment*, or SFAS 123R, 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-pricing model and is recognized as expense ratably over the requisite service period. The application of SFAS 123R requires significant judgment and the use of estimates, particularly surrounding assumptions used in determining fair value. The Black-Scholes valuation method 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. As of January 2008, expected volatility was based on the historical volatility of our common stock. Prior to January 2008, expected volatility was based primarily on comparable peer data because our common stock had been publicly traded for less than two years. 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.

As required under SFAS 123R, we review our valuation assumptions on an ongoing basis, and, as a result, our valuation 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 Months Ended June 30, 2008 and 2007

We recorded a net loss of $4.1 million for the three months ended June 30, 2008 compared to a net loss of $7.2 million for the three months ended June 30, 2007. On a basic and diluted per share basis, net loss was $0.15 for the three months ended June 30, 2008 compared to $0.28 for the three months ended June 30, 2007.

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Revenues

We derive our revenues from product sales and contract research arrangements. We operate in one industry segment. Our product revenues are derived solely from the sale of our Onco*type* DX 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 policy 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.

	Three Months Ended June 30,	
	2008	2007
	(In thousands)	
Product revenues	$ 26,327	$ 14,555
Contract revenues	1,456	135
Total revenues	$ 27,783	$ 14,690

Total revenues increased to $27.8 million for the three months ended June 30, 2008 from $14.7 million for the three months ended June 30, 2007. Product revenues from Onco*type* DX increased to $26.3 million for the three months ended June 30, 2008 from $14.6 million for the three months ended June 30, 2007. This increase was due primarily to increased adoption of our test, reflected by a 69% increase in test volume period over period, and expanded reimbursement coverage, resulting in an increase in the amount recognized per test. Approximately $13.4 million, or 51%, of product revenue for the three months ended June 30, 2008 was recorded on an accrual basis and recognized at the time the test results were delivered, compared to $4.9 million, or 34%, of product revenues for the three months ended June 30, 2007. For both periods, the balance of product revenue was recognized upon cash collection as payments were received.

Product revenue from Medicare, which was recorded on an accrual basis, was $5.7 million, or 22% of product revenue, for the three months ended June 30, 2008, compared to $3.3 million, or 23% of product revenue, for the three months ended June 30, 2007.

Contract revenues were $1.5 million for the three months ended June 30, 2008 compared to $135,000 for the three months ended June 30, 2007. Contract revenues for the three months ended June 30, 2008 reflected our continued collaboration with pharmaceutical partners to explore the development of tests for predicting benefit from certain targeted therapies and included $1.4 million related to completion of a contract.

We expect that our product revenues will increase for at least the next two quarters as we process more tests due to increased adoption of and reimbursement for Onco*type* DX related to the inclusion of Onco*type* DX in ASCO and NCCN clinical guidelines and the results of recent N+ clinical studies. We expect that our contract revenues will continue to fluctuate based on the number and timing of studies being conducted.

Cost of Product Revenues

	Three Months Ended June 30,	
	2008	2007
	(In thousands)	
Tissue sample processing costs	$ 4,837	$ 2,917
Stock-based compensation	125	106
Total tissue sample processing costs	4,962	3,023
License fees	1,888	1,149

Total cost of product revenues	$ 6,850	$ 4,172

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

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sample processing represent the cost of all the tests processed during the period regardless of whether revenue was recognized with respect to that test. License fees for royalties due on product revenues and contractual obligations are recorded in cost of product revenues at the time product revenues are recognized or in accordance with other contractual obligations. License fees represent a significant component of our cost of product revenues and are expected to remain so for the foreseeable future.

Cost of product revenues increased to $6.9 million for the three months ended June 30, 2008 from $4.2 million for the three months ended June 30, 2007. Test volume increased 69% period over period, driving the $1.9 million, or 66%, increase in tissue sample processing costs. The $739,000, or 64%, increase in license fees included higher royalties due to an increase of $11.8 million, or 81%, in product revenues recognized. We expect the cost of product revenues to increase as we process more tests.

Research and Development Expenses

	Three Months Ended June 30,	
	2008	2007
	(In thousands)	
Personnel-related expenses	$ 4,037	$ 2,716
Stock-based compensation	720	449
Collaboration expenses	416	406
Infrastructure and all other costs	2,149	1,653
Total research and development expenses	$ 7,322	$ 5,224

Research and development expenses increased to $7.3 million for the three months ended June 30, 2008 from $5.2 million for the three months ended June 30, 2007. The $2.1 million increase in research and development expenses was primarily due to a $1.3 million increase in personnel-related expenses, a $496,000 increase in infrastructure and other expenses and a $271,000 increase in stock-based compensation. We expect that our research and development expenses will continue to increase as we increase investment in our product pipeline for a variety of cancers, including cancers other than breast and colon.

Selling and Marketing Expenses

	Three Months Ended June 30,	
	2008	2007
	(In thousands)	
Personnel-related expenses	$ 5,334	$ 3,997
Stock-based compensation	648	475
Promotional and marketing materials	2,960	2,277
Travel, meetings and seminars	1,621	1,249
Infrastructure and all other costs	1,264	742
Total sales and marketing expenses	$ 11,827	$ 8,740

Our selling and marketing expenses consist primarily of personnel-related expenses, education and promotional expenses associated with Onco*type* DX 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 test was developed and validated and the value of the quantitative information that Onco*type* DX provides. Selling and marketing expenses also include the costs of sponsoring continuing medical education, medical meeting participation and dissemination of

our scientific and economic publications related to Onco*type* DX.

Selling and marketing expenses increased to $11.8 million for the three months ended June 30, 2008 from $8.7 million for the three months ended June 30, 2007. The $3.1 million increase in selling and marketing expenses was due to a $1.3 million increase in personnel-related expenses, reflecting our continued investment in our field sales and support organization, a $683,000 increase in promotional field and marketing materials, a $522,000 increase in infrastructure and other costs, including allocated facilities and information technology expenses, $372,000 in higher travel-related expenses primarily associated with field personnel and a $173,000 increase in stock-based compensation expense. Of the $1.3 million increase in personnel-related expenses, $1.0 million was due to higher salaries and other expenses related to an increase in the number of selling and marketing personnel, and $301,000 was due to

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higher commissions and bonus payments related to increased personnel and increased product revenues. We expect that selling and marketing expenses will continue to increase in future periods as we expand our marketing and sales programs, including ongoing physician and patient education programs.

General and Administrative Expenses

	Three Months Ended June 30,	
	2008	2007
	(In thousands)	
Personnel-related expenses	$ 3,736	$ 2,185
Stock-based compensation	792	488
Professional fees and all other costs	1,697	1,513
Total general and administrative expenses	$ 6,225	$ 4,186

Our general and administrative expenses consist primarily of personnel-related expenses and professional fees and other costs, including intellectual property defense and prosecution costs, advisory and auditing expenses, 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.

General and administrative expenses increased to $6.2 million for the three months ended June 30, 2008 from $4.2 million for the three months ended June 30, 2007. The $2.0 million increase in general and administrative expenses included a $1.6 million increase in personnel-related expenses due primarily to additional staff needed to support the growth of our business, a $304,000 increase in stock-based compensation expense and $229,000 in higher billing and collection fees paid to third-party billing and collection vendors, which are primarily based on payments we receive for our test. We expect general and administrative expenses to increase we as incur expenses associated with the growth of our business and to the extent we spend more on fees for billing and collections as a result of increased adoption of and reimbursement for our test.

Interest and Other Income

Interest and other income was $448,000 for the three months ended June 30, 2008 compared to $612,000 for the year ended June 30, 2007. The $164,000 decrease was due primarily to lower interest income due to lower market yields on our short term investments.

Interest and Other Expense

Interest and other expense was $106,000 for the three months ended June 30, 2008 compared to $178,000 for the three months ended June 30, 2007. The $72,000 decrease was due primarily to lower interest expense as we continued to pay down our capital equipment financing arrangements.

Six Months Ended June 30, 2008 and 2007

We recorded a net loss of $10.7 million for the six months ended June 30, 2008 compared to a net loss of $14.0 million for the six months ended June 30, 2007. On a basic and diluted per share basis, net loss was $0.38 for the six months ended June 30, 2008 compared to $0.55 for the six months ended June 30, 2007.

Revenues

	Six Months Ended June 30,	
	2008	2007
	(In thousands)	
Product revenues	$ 49,682	$ 27,701
Contract revenues	1,541	1,077
Total revenues	$ 51,223	$ 28,778

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Total revenues increased to $51.2 million for the six months ended June 30, 2008 from $28.8 million for the six months ended June 30, 2007. Product revenues from Onco*type* DX increased to $49.7 million for the six months ended June 30, 2008 from $27.7 million for the six months ended June 30, 2007. This increase was due primarily to increased adoption and expanded reimbursement coverage. Approximately $25.0 million, or 50%, of product revenues for the six months ended June 30, 2008 was recorded on an accrual basis and recognized at the time the test results were delivered, compared to $9.5 million, or 34%, of product revenues for the six months ended June 30, 2007. For both periods, the balance of product revenue was recognized upon cash collection as payments were received.

Product revenues from Medicare, which was recorded on an accrual basis, was $11.4 million, or 23%, of product revenues for the six months ended June 30, 2008, compared to $6.6 million, or 24%, of product revenues for the six months ended June 30, 2007.

Contract revenues were $1.5 million for the six months ended June 30, 2008 compared to $1.1 million for the six months ended June 30, 2007. Contract revenues for the six months ended June 30, 2008 included $1.4 million related to completion of a contract.

Cost of Product Revenues

	Six Months Ended June 30,	
	2008	**2007**
	(In thousands)	
Tissue sample processing costs	$ 8,897	$ 5,628
Stock-based compensation	240	184
Total tissue sample processing costs	$ 9,137	$ 5,812
License fees	3,597	2,207
Total cost of product revenues	$ 12,734	$ 8,019

Cost of product revenues increased to $12.7 million for the six months ended June 30, 2008 from $8.0 million for the six months ended June 30, 2007. Test volume increased 68% period over period, driving the $3.3 million, or 58%, increase in tissue sample processing costs. The $1.4 million, or 63%, increase in license fees included higher royalties due to an increase of $22.0 million, or 79%, in product revenues recognized.

Research and Development Expenses

	Six Months Ended June 30,	
	2008	**2007**
	(In thousands)	
Personnel-related expenses	$ 7,788	$ 5,257
Stock-based compensation	1,455	840
Collaboration expenses	493	1,089
Infrastructure and all other costs	3,992	3,208
Total research and development expenses	$ 13,728	$ 10,394

Research and development expenses increased to $13.7 million for the six months ended June 30, 2008 from $10.4 million for the six months ended June 30, 2007. The $3.3 million increase in research and development expenses was primarily due to a $2.5 million increase in personnel-related expenses, a $781,000 increase in infrastructure and other expenses and a $615,000 increase in stock-based compensation, partially offset by a $596,000 decrease in collaboration expenses related to the timing of our clinical research projects.

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Selling and Marketing Expenses

	Six Months Ended June 30,	
	2008	2007
	(In thousands)	
Personnel-related expenses	$ 11,192	$ 7,791
Stock-based compensation	1,278	831
Promotional and marketing materials	5,841	4,264
Travel, meetings and seminars	3,297	2,526
Infrastructure and all other costs	2,586	1,481
Total sales and marketing expenses	$ 24,194	$ 16,893

Selling and marketing expenses increased to $24.2 million for the six months ended June 30, 2008 from $16.9 million for the six months ended June 30, 2007. The $7.3 million increase in selling and marketing expenses was due to a $3.4 million increase in personnel-related expenses, reflecting our continued investment in our field sales and support organization, a $1.6 million increase in promotional field and marketing materials, a $1.1 million increase in infrastructure and other costs, including allocated facilities and information technology expenses, $771,000 in higher travel-related expenses primarily associated with field personnel and a $447,000 increase in stock-based compensation. Of the $3.4 million increase in personnel-related expenses, $2.5 million was due to higher salaries and other expenses related to an increase in the number of selling and marketing personnel and $903,000 was due to higher commissions and bonus payments related to increased personnel and increased product revenues.

General and Administrative Expenses

	Six Months Ended June 30,	
	2008	2007
	(In thousands)	
Personnel-related expenses	$ 7,126	$ 4,405
Stock-based compensation	1,569	946
Professional fees and all other costs	3,435	2,924
Total general and administrative expenses	$ 12,130	$ 8,275

General and administrative expenses increased to $12.1 million for the six months ended June 30, 2008 from $8.3 million for the six months ended June 30, 2007. The $3.8 million increase in general and administrative expenses included a $2.7 million increase in personnel-related expenses due primarily to additional staff needed to support the growth of our business, a $623,000 increase in stock-based compensation and $565,000 in higher billing and collection fees paid to third-party billing and collection vendors.

Interest and Other Income

Interest and other income was $1.1 million for the both the six months ended June 30, 2008 and the six months ended June 30, 2007. For the first six months of 2008, the impact of higher average short-term investment balances resulting from our investment of a portion of the cash proceeds from our May 2007 public offering was offset by lower market yields during the period.

Interest and Other Expense

Interest and other expense was $239,000 for the six months ended June 30, 2008 compared to $373,000 for the six months ended June 30, 2007. The $134,000 decrease was due primarily to lower interest expense as we continued to pay down our capital equipment financing arrangements.

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Liquidity and Capital Resources

As of June 30, 2008, we had an accumulated deficit of $163.1 million. We have not yet achieved profitability and anticipate that we will continue to incur net losses for at least the next year. We expect that our research and development, selling and marketing and general and administrative expenses will continue to increase and, as a result, we will need to generate significant product revenue to achieve profitability.

	June 30, 2008	December 31, 2007
	(In thousands)	
Cash, cash equivalents and short-term investments	$60,627	$ 68,360
Working capital	56,661	63,948

	Six Months Ended June 30,	
	2008	2007
	(In thousands)	
Cash provided by (used in):		
Operating activities	$ (2,046)	$(11,088)
Investing activities	(19,093)	(8,954)
Financing activities	(803)	48,689
Capital expenditures (included in investing activities above)	(4,823)	(2,155)

Sources of Liquidity

At June 30, 2008, we had cash, cash equivalents and short-term investments of $60.6 million compared to $68.4 million at December 31, 2007. Our cash and short-term investments are held in a variety of interest-bearing instruments including money market accounts, obligations of U.S. Government agencies and government-sponsored entities, high-grade corporate bonds and commercial paper. In accordance with our investment policy, available cash is invested in short-term, low-risk, investment-grade debt instruments.

Historically we have financed our operations primarily through sales of our equity securities and cash received from customers. In May 2007, we completed a public offering of our common stock, resulting in net proceeds of $49.7 million. At June 30, 2008, we had approximately $46.5 million of securities available for issuance under our shelf registration statement. Purchases of equipment and leasehold improvements have been partially financed through capital equipment financing arrangements. At June 30, 2008 and 2007, we had notes payable under these equipment financing arrangements of $3.3 million and $6.0 million, respectively.

Cash Flows

Net cash used in operating activities was $2.0 million for the six months ended June 30, 2008 compared to $11.1 million for the six months ended June 30, 2007. Net cash used in operating activities includes net loss adjusted for certain non-cash items and changes in assets and liabilities. The $9.1 million decrease in net cash used in operating activities was primarily due to the receipt of $3.7 million in advance payments under a collaboration arrangement with Pfizer and a $5.5 million decrease in net loss excluding depreciation and stock-based compensation.

Net cash used in investing activities was $19.1 million for the six months ended June 30, 2008, compared to $9.0 million for the six months ended June 30, 2007. Our investing activities have consisted predominately of purchases and maturities of marketable securities and capital expenditures. The $10.1 million increase in net cash used in investing activities was due to a $7.5 million increase in net purchases of short-term investments and a $2.7 million increase in capital expenditures for facility expansion and improvements.

Net cash used in financing activities was $803,000 for the six months ended June 30, 2008, compared to net cash provided by financing activities of $48.7 million for the six months ended June 30, 2007. Our financing activities include sales of our equity securities and payments on our capital equipment financing arrangements. The $49.5 million decrease in net cash provided by financing

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activities reflects the May 2007 receipt of net proceeds from a public offering of our common stock. No similar financing occurred during the six months ended June 30, 2008.

Contractual Obligations

The following summarizes our significant contractual obligations as of June 30, 2008 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)		
Notes payable obligations	$ 3,633	$ 2,646	$ 987	$	$
Non-cancelable operating lease obligations	5,857	1,436	3,262	1,159	
Total	$ 9,490	$ 4,082	$ 4,249	$ 1,159	$

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 can prepay all, but not part, of the amounts owing under the arrangement so long as we also pay premium ranging from 4% to 6% on the remaining payments. As of June 30, 2008, notes payable under this arrangement totaled $3.3 million at annual interest rates ranging from 10.23% to 11.30%, depending upon the applicable note.

Our non-cancelable operating lease obligations are for laboratory and office space. In January 2007, we executed an agreement to lease an additional 48,000 square feet of office space. This space is located near 48,000 square feet of laboratory and office space we occupy under a lease we entered into in September 2005. Both leases expire in February 2012.

In addition, we are required to make a series of annual payments under one of our collaboration agreements beginning on the date that we commercially launched Onco*type* DX. We are required to make payments of $475,000 in each of the years 2009 through 2011. 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.

Off-Balance Sheet Arrangements

As of June 30, 2008, we had no material off-balance sheet arrangements other than the lease obligations and collaboration payments discussed above.

Operating Capital and Capital Expenditure Requirements

We expect to continue to incur substantial operating losses in the future and to make capital expenditures to keep pace with the expansion of our research and development programs and to scale our commercial operations. It may take years to move any one of a number of product candidates in research through development and validation to commercialization. We expect that our cash and cash equivalents will be used to fund working capital and for capital expenditures and other general corporate purposes, such as licensing technology rights, partnering arrangements for our tests outside the United States or reduction of debt obligations. We may also use cash to acquire or invest in complementary businesses, technologies, services or products. We have no current plans, agreements or commitments

with respect to any such acquisition or investment, and we are not currently engaged in any negotiations with respect to any such transaction.

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The amount and timing of actual expenditures may vary significantly depending upon a number of factors, such as the progress of our product development, regulatory requirements, commercialization efforts, the amount of cash used by operations and progress in reimbursement. As reimbursement contracts with third-party payors continue to be put into place, we expect an increase in the number and level of payments received for Onco*type* DX billings.

We currently anticipate that our cash, cash equivalents and short-term investments, together with collections from Onco*type* DX and amounts available under our equipment credit facility, will be sufficient to fund our operations and facilities expansion plans for at least the next 12 months. We cannot be certain that any of our reimbursement contract programs or 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.

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

the rate of progress in establishing reimbursement arrangements with 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 Onco*type* DX for breast cancer;

the rate of progress and cost of research and development activities associated with products in the early development and development phase focused on cancers other than breast 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; and

the economic and other terms and timing of any collaborations, licensing or other arrangements into which we may enter.

Until we can generate a sufficient amount of product revenues to finance our cash requirements, which we may never do, we expect to finance future cash needs primarily through public or private equity offerings, debt financings, borrowings or strategic collaborations. The issuance of equity securities may result in dilution to stockholders, or may provide for rights, preferences or privileges senior to those of our holders of 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. We do not know whether additional funding will be available on acceptable 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 would lower the economic value of those programs to our company.

Recent Accounting Pronouncements

In February 2008, the Financial Accounting Standards Board, or FASB, issued FASB Staff Position 157-2*, Effective Date of FASB Statement No. 157,* or FSP 157-2. FSP 157-2 delays the effective date of SFAS 157 for all non-financial assets and non-financial liabilities, except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually), until fiscal years beginning after November 15, 2008. We

have elected a partial deferral of SFAS 157 under the provisions of FSP 157-2. We are currently evaluating the impact that SFAS 157 will have on our financial condition and results of operations when the standard is applied to non-financial assets and non-financial liabilities beginning January 1, 2009.

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In November 2007, FASB ratified Emerging Issues Task Force Issue No. 07-1, *Accounting for Collaborative Arrangements,* or EITF 07-1. EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in a collaborative arrangement and third parties. EITF 07-1 is effective for fiscal years beginning after December 15, 2008, and is to be applied retrospectively to all prior periods presented for all collaborative arrangements existing as of the effective date. We are currently evaluating the impact that EITF 07-01 will have on our financial condition and results of operations when the standard is applied beginning January 1, 2009.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is confined to our cash, 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. 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 $60.6 million at June 30, 2008 did not include any auction preferred stock, auction rate securities or mortgage-backed investments. The securities in our investment portfolio are classified as available for sale and are, due to their very short-term nature, subject to minimal interest rate risk. We believe that, if market interest rates were to change immediately and uniformly by 10% from levels at June 30, 2008, the impact on the fair value of these securities or our cash flows or income would not be material. We currently do not hedge interest rate exposure.

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.

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PART II. OTHER INFORMATION

ITEM 1A. RISK FACTORS.

We are an early stage company with a history of net losses, and we expect to incur net losses for the foreseeable future.

We have incurred substantial net losses since our inception. For the six months ended June 30, 2008 and 2007, we incurred net losses of $10.7 million and $14.0 million, respectively. From our inception in August 2000 through June 30, 2008, we had an accumulated deficit of $163.1 million. To date, we have not, and we may never, achieve revenues sufficient to offset expenses. We expect to devote substantially all of our resources to continue to invest in our product pipeline, including Onco*type* DX and future products, and our commercial and clinical laboratory infrastructure.

We expect to incur additional losses in the future and we may never achieve profitability. We do not expect our losses to be mitigated by revenues from Onco*type* DX or future products, if any, for at least the next year.

We expect to continue to incur significant research and development expenses, which may make it difficult for us to achieve profitability.

In recent years, we have incurred significant costs in connection with the development of Onco*type* DX. Our research and development expenses were $13.7 million for the six months ended June 30, 2008 and $22.1 million for the year ended December 31, 2007. We expect our research and development expense levels to remain high and to continue to increase for the foreseeable future as we seek to expand the clinical utility of our existing test and develop new tests. As a result, we will need to generate significant revenues in order to achieve profitability. Our failure to achieve profitability in the future could cause the market price of our common stock to decline.

If third-party payors, including managed care organizations and Medicare, do not provide reimbursement or rescind their reimbursement policies for Oncotype DX, its commercial success could be compromised.

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

not experimental or investigational,

medically necessary,

appropriate for the specific patient,

cost-effective,

supported by peer-reviewed publications, and

included in clinical practice guidelines.

There is uncertainty concerning third-party payor reimbursement of any test incorporating new technology, including Onco*type* DX. 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. Onco*type* DX has in the past received negative assessments and may receive additional negative assessments in the future.

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 secured policy-level reimbursement approval from a number of third-party payors.

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We cannot be certain that coverage for Onco*type* DX will be provided in the future by additional third-party payors or that existing reimbursement policies will remain in place.

Under current Medicare billing rules, claims for Onco*type* DX tests performed on Medicare beneficiaries who were hospital inpatients at the time the tumor tissue samples were obtained or when the test is ordered less than 14 days from discharge must be incorporated in the payment that the hospital receives for the inpatient services provided related to the patient s breast cancer. Medicare billing rules also require hospitals to bill for the test when performed or ordered for hospital outpatients less than 14 days following the date of the hospital outpatient procedure where the tumor tissue samples were obtained. Accordingly, we are required to bill individual hospitals for tests performed during these time frames. Because we generally do not have a written agreement in place with these hospitals, we may not be paid for the cost of 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 3% of our total testing population. We believe these billing rules may lead to confusion regarding whether Medicare provides adequate reimbursement for our test, and could discourage Medicare patients from using our test. Although we are working with Medicare and other diagnostic laboratories to revise or reverse these billing rules, we have no assurance that Medicare will do so, and we also cannot ensure that hospitals will agree to arrangements to pay us for tests performed on patients falling under these rules.

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 health care services. From time to time, Congress has considered and implemented changes in the Medicare fee schedules in conjunction with budgetary legislation. Further reductions of reimbursement for Medicare services may be implemented from time to time. Reductions in the reimbursement rates of other third-party payors have occurred and may occur in the future. These measures have resulted in reduced prices and decreased test utilization for the clinical laboratory industry.

We have conducted clinical studies to support the use of Onco*type* DX in patients with N+, ER+ breast cancer and have experienced an increase in usage for N+ patients. Most of our existing reimbursement coverage is limited to women with early-stage N-, ER+ breast cancer. We may not be able to obtain reimbursement coverage for Onco*type* DX for breast cancer patients who are N+, ER+ patients that is similar to the coverage we have obtained for early-stage N-, ER+ patients. In addition, we may not be able to obtain reimbursement coverage for any other new test or product enhancement we may develop in the future.

If we are unable to obtain reimbursement approval from private payors and Medicare and Medicaid programs for Onco*type* DX, or if the amount reimbursed is inadequate, our ability to generate revenues from Onco*type* DX could be limited. Even if we are being reimbursed, insurers may withdraw their coverage policies or cancel their contracts with us at any time or stop paying for our test, which would reduce our revenue.

We depend on a limited number of 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 test, our revenues could decline.

For the six months ended June 30, 2008 and 2007, one payor, Medicare, as administered by NHIC, accounted for 23% and 24% of our product revenues, respectively. Another payor, United HealthCare Insurance Company, accounted for 10% and 19% of our product revenues for the six months ended June 30, 2008 and 2007, respectively. NHIC is the local Medicare carrier for California with jurisdiction for claims submitted by us for Medicare patients in the United States. The responsibility for processing Medicare claims submitted by us is being transitioned from NHIC to another entity, Palmetto, which is expected to take over full responsibility for processing such claims by September 2008. In June 2008, Palmetto adopted a local coverage determination for California that includes Onco*type* DX. This coverage decision follows identical criteria as those previously set forth by NHIC. In the future, it is possible that Palmetto 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 actions could have a negative impact on our revenues.

If FDA were to begin regulating our test, we could be forced to stop sales of Oncotype DX, we could experience significant delays in commercializing any future products, 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 test.

Clinical laboratory tests like Onco*type* DX are regulated under CLIA, as administered through 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. Clinical laboratory tests that are developed and validated by a laboratory for its own use are called laboratory developed tests, or LDTs. Most

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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 Onco*type* DX is not a diagnostic kit and also believe that it is an LDT. As a result, we believe Onco*type* DX 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 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 Onco*type* DX 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, Onco*type* DX 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 an 18 month transition period of FDA enforcement discretion following release of final guidance for currently available 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 PMA, 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 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. Draft recommendations were published in November 2007 and were open for public comment through late December 2007, and 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 are continuing our ongoing dialogue with FDA and HHS regarding the Onco*type* DX breast cancer assay. We cannot provide any assurance that FDA regulation, including pre-market review, will not be required in the future for Onco*type* DX, either through new enforcement policies adopted by FDA or new legislation enacted by Congress. It is possible that legislation will be enacted into law and may result in increased regulatory burdens for us to continue to offer the Onco*type* DX assay.

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 test pending pre-market clearance or approval. If our test is allowed to remain on the market but there is uncertainty about our test, if it is 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 test 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 FDA and to 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 Onco*type* DX if we determine that doing so would be appropriate.

Should any of the reagents obtained by us from vendors and used in conducting our test 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 Oncotype DX or marketing any new test, those trials could lead to delays or failure to obtain necessary regulatory approvals and harm our ability to become profitable.

If FDA decides to regulate our tests, it may require extensive pre-market clinical testing prior to submitting a regulatory application for commercial sales. If we are required to conduct pre-market clinical trials, whether using prospectively acquired samples or archival

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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 test. 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 test, or to become profitable.

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

We are subject to CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. We have a current certificate of accreditation under CLIA to perform testing. To renew this certificate, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of our 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 laboratory, including the training and skills required of personnel and quality control. Moreover, several states require that we hold licenses to test specimens from patients residing 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 test.

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 Onco*type* DX, which would limit our revenues and harm our business. If we were to lose our license 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 Medicare and Medicaid 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 civil and criminal False Claims Act 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

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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.

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

For the foreseeable future, we expect to derive substantially all of our revenues from sales of one test, Onco*type* DX. We have been selling this test since January 2004. We are in various stages of research and development for other tests that we may offer as well as for enhancements to our existing test. We do not currently expect to commercialize tests for colon cancer until at least 2009, and we are not currently able to estimate when we may be able to commercialize tests for other cancers or whether we will be successful in doing so. If we are unable to increase sales of Onco*type* DX or to successfully develop and commercialize other tests or enhancements, our revenues and our ability to achieve profitability would be impaired, and the market price of our common stock could decline.

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 various stages of development and devote considerable resources to research and development. For example, we are currently in the development stage of the application of our technology to predict recurrence and the therapeutic benefit of chemotherapy in colon cancer, and we are conducting early development studies in prostate, renal cell and lung cancers and melanoma. There can be no assurance that our technologies will be capable of reliably predicting the recurrence of other types of cancer or other cancers, such as colon, with the sensitivity and specificity necessary to be clinically and commercially useful for the treatment of other cancers, or that we can develop those technologies at all. 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 process involves a high degree of risk and takes several years. Our product development efforts may fail for many reasons, including:

failure of the product at the research or development stage;

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

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

Few research and development projects result in commercial products, and success in early clinical trials often is not replicated in later studies. At any point, we may abandon development of a product candidate or we may be required to expend considerable resources repeating clinical trials, which would adversely impact the timing for generating potential revenues from those product candidates. In addition, as we develop products, we will have to make significant investments in product development, marketing and selling resources. If a clinical validation study fails to demonstrate the prospectively defined endpoints of the study, we would likely abandon the development of the product or product feature that was the subject of the clinical trial, which could harm our business.

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If we are unable to support demand for our tests, our business may suffer.

We have added a second shift at our clinical laboratory facility and will need to ramp up our testing capacity as our test volume grows. We will need to continue to implement increases in scale and related processing, customer service, billing and systems process improvements, and to expand our internal quality assurance program 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, 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 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 Onco*type* DX or future products, 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 test.

If medical practitioners do not order Onco*type* DX 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 become profitable. To generate demand, we will need to continue to make oncologists, surgeons and pathologists aware of the benefits of Onco*type* DX and any products we may develop in the future 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 adequate reimbursement coverage from third-party payors.

Prior to the inclusion of Onco*type* DX in clinical guidelines, guidelines and practices regarding the treatment of breast cancer often 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 Onco*type* DX for their patients, which could limit our ability to generate revenues and our ability to achieve profitability.

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

Some patients may decide not to use our test due to its price, part or all 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 test, patients may still decide not to use Onco*type* DX, 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. If only a small portion of the patient population decides to use our test, we will experience limits on our revenues and our ability to achieve profitability.

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

In recent years, there have been numerous advances in technologies relating to the diagnosis and treatment of cancer. For example, technologies in addition to ours now reportedly permit measurement of gene expression in fixed paraffin embedded, or FPE, tissue specimens. Also, new hormonal therapies such as aromatase inhibitors are viewed by physicians as promising therapies for breast cancer with more tolerable side effects than those associated with tamoxifen, the hormonal therapy commonly used today in treatment. For advanced cancer, new chemotherapeutic strategies are being developed that may increase survival time and reduce toxic side effects. These advances require us to continuously develop new products and enhance existing products to keep pace with evolving standards of care. Our test could become obsolete unless we continually innovate and expand our product 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 test to new treatments, then sales of our test could decline, which would harm our revenues.

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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 laboratory to conduct our test. 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 technology 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.

Our competitive position depends on maintaining intellectual property protection.

Our ability to compete and to achieve and maintain profitability depends on our ability to protect our proprietary discoveries and technologies. We currently rely on a combination of patent applications, copyrights, trademarks, trade secret laws and confidentiality agreements, material data transfer agreements, license agreements and invention assignment agreements to protect our intellectual property rights. We also rely upon unpatented know-how and continuing technological innovation 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 cannot guarantee that a joint owner will cooperate with us in the enforcement of patent rights.

As of June 30, 2008, we had two issued patents covering genes that are components of the Onco*type* DX assay, one of which was issued jointly to us and to the National Surgical Adjuvant Breast and Bowel Project, or NSABP. Our pending patent applications may not result in issued patents, and we cannot assure you that our issued patent or any patents that might ultimately be issued by the U.S. Patent and Trademark Office will protect our technology. Any patents that may be issued to us might be challenged by third parties as being invalid or unenforceable, or third parties may independently develop similar or competing technology that avoids our patents. We cannot be certain that the steps we have taken will prevent the misappropriation and use of our intellectual property, particularly in foreign countries where the laws may not protect our proprietary rights as fully as in the United States.

From time to time, the United States Supreme Court, other federal courts, the U.S. Congress or the U.S. Patent and Trademark Office 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.

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 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. 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 test 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 test to include the non-infringing technologies would require us to re-validate our test, which would be costly and time-consuming. Also, we may be unaware of pending patent applications that relate to our test. Parties making infringement claims on future issued patents may be able to obtain an injunction that

would prevent us from selling our test or using technology that contains the allegedly infringing intellectual property, which could harm our business.

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There are a number of patents and patent applications that may constitute prior art in the field of genomic-based diagnostics. We may be required to pay royalties, damages and costs to firms who own the rights to these patents, or we might be restricted from using any of the inventions claimed in those patents.

If we are unable to compete successfully, we may be unable to increase or sustain our revenues or achieve 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 Onco*type* DX that are performed outside the pathology laboratory. In addition, few diagnostic methods are as expensive as Onco*type* DX.

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 cancer, such as Celera Corporation, Clarient Diagnostic Services, Agendia B.V., Applied Genomics, AviaraDX, Exagen and University Genomics. Commercial laboratories with strong distribution networks for diagnostic tests, such as Genzyme Corporation, Laboratory Corporation of America Holdings and Quest Diagnostics Incorporated, may become competitors. Other potential competitors include companies that develop diagnostic tests such as Bayer Diagnostics, a division of Siemens AG, Roche Diagnostics, a division of F. Hoffmann-La Roche Ltd, 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 addition, 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 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.

Our test is considered relatively expensive for a diagnostic test. We increased the list price of our test from $3,650 to $3,820 effective July 1, 2008, and we may raise prices in the future. This could impact reimbursement of and demand for Onco*type* DX. 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 test, which could force us to lower the list price of our test and impact our operating margins and our ability to achieve 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, and that may discourage adoption and reimbursement of our test. 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 test, which could prevent us from increasing or sustaining our revenues or achieving or sustaining profitability and could cause the market price of our common stock to decline.

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

Under standard clinical practice in the United States, tumor biopsies removed from patients are chemically preserved and embedded in paraffin wax and stored. Our clinical development relies on our ability to secure access to these archived tumor biopsy samples, as well as information pertaining to their associated clinical outcomes. Others have demonstrated their ability to study archival samples and often compete with us for access. Additionally, the process of negotiating access to archived samples is lengthy since it typically involves numerous parties and approval levels to resolve complex issues such as usage rights, institutional review board approval, privacy rights, publication rights, intellectual property ownership and research parameters. If we are not able to negotiate access to archival tumor tissue samples with hospitals and collaborators, or if other laboratories or our competitors secure access to these

samples before us, our ability to research, develop and commercialize future products will be limited or delayed.

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

We rely on and expect to continue to rely on clinical collaborators to perform a substantial portion of our clinical trial functions. If any of our collaborators were to breach or terminate its agreement with us or otherwise fail to conduct its collaborative activities successfully and in a timely manner, the research, development or commercialization of the products contemplated by the collaboration could be delayed or terminated. If any of our collaboration agreements are terminated, or if we are unable to renew those collaborations on acceptable terms, we would be required to seek alternative collaborations. 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, 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 collaborative agreement or the entity s announcement of a collaboration with an entity other than us may 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 attempt to transition to a company with more than one commercialized product. 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 intense 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 will adversely affect our ability to support our discovery, 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 test and our business will be harmed.

We do not have redundant laboratory facilities. We perform all of our diagnostic testing in our laboratory located in Redwood City, California. Redwood City is situated on or 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

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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, or at all.

In order to rely on a third party to perform our tests, we could only use another facility with established state licensure and CLIA accreditation under the scope of which Onco*type* DX 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 adopt Onco*type* DX and 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 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 time, to replicate our testing processes or results in a new facility. Additionally, any new clinical laboratory facility opened by us would be subject to certification under CLIA and licensed by several states, including California and New York, which can take a significant amount of time and result in delays in our ability to begin operations.

Changes in healthcare policy could subject us to additional regulatory requirements that may interrupt sales of Oncotype DX and increase our costs.

Healthcare policy has been a subject of extensive discussion in the executive and legislative branches of the federal and many state governments. We developed our commercialization strategy for Onco*type* DX based on existing healthcare policies. Changes in healthcare policy, such as changes in the FDA regulatory policy for LDTs, the creation of broad limits for diagnostic products in general or requirements that Medicare patients pay for portions of clinical laboratory tests or services received, could substantially interrupt the sales of Onco*type* DX, increase costs and divert management s attention. 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, selling our tests outside of the United States makes us subject to applicable foreign regulatory requirements, which may also change over time. We cannot predict what changes, if any, will be proposed or adopted or the effect that such proposals or adoption may have on our business, financial condition and results of operations.

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.

We rely solely on Applied Biosystems Inc. 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 Onco*type* DX. 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 Onco*type* DX, we may need to reconfigure our test process, 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, delays in commercialization or an interruption in sales could occur.

We may be unable to manage our future growth effectively, which would 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 will place strain on our administrative and operational infrastructure, including customer service and our clinical laboratory. Our ability to manage our operations and growth will require us to

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continue to improve our operational, financial and management controls, reporting systems and procedures. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy.

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

The marketing, sale and use of our test could lead to the filing of product liability claims if someone were to allege that our test 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 Onco*type* DX for patients who do not have the same specific clinical attributes indicated on the Onco*type* DX 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 Onco*type* DX for such patients, including N+ patients, ER- patients, or male breast cancer patients. 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 collaborators to terminate existing agreements and potential collaborators 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 be significant and could negatively affect our operating results.

Our dependence on distributors for foreign sales of Oncotype DX could limit or prevent us from selling our test in foreign markets and from realizing long-term international revenue growth.

We have established exclusive distribution networks for Onco*type* DX in Israel, Japan, the United Kingdom, Greece and Turkey and may enter into other similar arrangements in other countries in the future. Over the long term, we intend to grow our business internationally, and to do so we will need to attract additional distributors to expand the territories in which we sell Onco*type* DX. Distributors may not commit the necessary resources to market and sell Onco*type* DX to the level of our expectations. If current or future distributors do not perform adequately, or we are unable to locate distributors in particular geographic areas, we may not realize long-term international revenue growth. Regulatory requirements, costs of doing business outside of the United States and the 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 collaborations, 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.

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

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

sustain commercialization of our initial test or enhancements to that test;

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;

fund our clinical validation study activities;

expand our research and development activities;

acquire or license technologies; and

finance capital expenditures and our general and administrative expenses.

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

the level of research and development investment required to maintain and improve our technology position;

costs of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;

our need or decision to acquire or license complementary technologies or acquire complementary businesses;

changes in product development plans needed to address any difficulties in commercialization;

changes in the regulatory environment, including any decision by FDA to regulate our activities;

competing technological and market developments;

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

changes in regulatory policies or laws that affect our operations.

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, and the terms of the debt securities issued 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. If adequate funds are not available, we may have to scale back our operations or limit our research and development activities.

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We must implement additional 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.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

On May 21, 2008 we held our Annual Meeting of Stockholders. The following actions were taken at the annual meeting:

1. The following directors were elected:

	For	Withheld
Randal W. Scott, Ph.D.	26,286,207	79,928
Kimberly J. Popovits	26,322,279	43,856
Julian C. Baker	26,309,722	56,413
Brook H. Byers	26,190,159	175,976
Fred E. Cohen, M.D., Ph.D.	25,933,648	432,487
Samuel D. Colella	26,190,099	176,036
Randall S. Livingston	26,320,608	45,527
Woodrow A. Myers, Jr., M.D.	26,188,368	177,767

2. The appointment of Ernst & Young LLP as our independent registered public accounting firm was ratified.

For	Against	Abstain
26,323,339	17,521	25,275

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 Nos. 33-8238 and 34-47986, Final Rule: Management s Reports on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, 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. Such certifications will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act.

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SIGNATURES

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

GENOMIC HEALTH, INC.

Date: August 11, 2008

By: /s/ Randal W. Scott

Randal W. Scott, Ph.D.
Chief Executive Officer and Chairman of the Board of Directors
(Principal Executive Officer)

Date: August 11, 2008

By: /s/ G. Bradley Cole

G. Bradley Cole
Executive Vice President, Operations and Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

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GENOMIC HEALTH, INC.
EXHIBIT INDEX

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