GENOMIC HEALTH INC
Form 10-Q
May 10, 2007

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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 March 31, 2007

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 or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large Accelerated Filer o Accelerated Filer þ Non-Accelerated Filer o

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

The number of outstanding shares of the registrant s Common Stock, $0.0001 par value, was 24,634,186 as of April 30, 2007.

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PART 1: FINANCIAL INFORMATION

Item 1. Financial Statements

GENOMIC HEALTH, INC.
Condensed Consolidated Balance Sheets
(In thousands, except share amounts)

	March 31, 2007 (Unaudited)	December 31, 2006
ASSETS		
Current assets:		
Cash and cash equivalents	$ 10,548	$ 14,926
Short-term investments	24,547	29,289
Accounts receivable (net of allowance for doubtful accounts; 2007-$245, 2006-$510)	2,479	1,862
Collaboration revenue receivable	712	
Prepaid expenses and other current assets	2,987	1,609
Total current assets	41,273	47,686
Property and equipment, net	10,284	9,421
Restricted cash	500	500
Other assets	542	417
Total assets	$ 52,599	$ 58,024
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,087	$ 2,523
Accrued compensation	2,144	1,868
Accrued expenses and other current liabilities	2,727	1,474
Accrued license fees	1,041	907
Notes payable current portion	2,617	2,547
Deferred revenues current portion	495	710
Lease incentive obligations current portion	199	141
Total current liabilities	10,310	10,170
Notes payable long-term portion	4,045	4,726
Deferred revenues long-term portion	521	137
Lease incentive obligations long-term portion	778	587
Other liabilities	605	575
Total liabilities	16,259	16,195
Stockholders equity:		
Preferred stock, $0.0001 par value, 5,000,000 shares authorized, no shares issued and outstanding at March 31, 2007 and December 31, 2006, respectively	2	2

Common stock, $0.0001 par value; 100,000,000 shares authorized, 24,570,241 and 24,548,060 shares issued and outstanding at March 31, 2007 and December 31, 2006, respectively		
Additional paid-in capital	168,287	166,922
Accumulated other comprehensive income	4	8
Accumulated deficit	(131,953)	(125,103)
Total stockholders equity	36,340	41,829
Total liabilities and stockholders equity	$ 52,599	$ 58,024

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 March 31,	
	2007	**2006**
Revenues:		
Product revenues	$ 13,146	$ 4,189
Contract revenues	942	871
Total revenues	14,088	5,060
Operating expenses:		
Cost of product revenues	3,847	2,059
Research and development	5,170	2,711
Selling and marketing	8,153	5,095
General and administrative	4,089	2,622
Total operating expenses	21,259	12,487
Loss from operations	(7,171)	(7,427)
Interest income	516	692
Interest expense	(195)	(95)
Net loss	$ (6,850)	$ (6,830)
Basic and diluted net loss per share	$ (0.28)	$ (0.28)
Shares used in computing basic and diluted net loss per share	24,561,164	24,480,267

See accompanying notes.

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

	Three Months Ended March 31,	
	2007	**2006**
Operating activities		
Net loss	$ (6,850)	$ (6,830)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	918	469
Employee stock-based compensation	1,283	569
Non-employee stock-based compensation	1	36
Changes in assets and liabilities:		
Accounts receivable, net	(617)	(591)
Collaboration revenue receivable	(712)	
Employee note receivable		18
Prepaid expenses and other current assets	(1,378)	(312)
Other assets	(151)	(834)
Accounts payable	(1,435)	(420)
Accrued expenses and other liabilities	1,417	332
Accrued compensation	276	405
Deferred revenues	169	(21)
Lease incentive obligations	249	834
Net cash used in operating activities	(6,830)	(6,345)
Investing activities		
Purchase of short-term investments	(8,726)	(2,771)
Maturities of short-term investments	13,464	9,975
Purchase of property and equipment	(1,755)	(2,471)
Net cash provided by investing activities	2,983	4,733
Financing activities		
Proceeds from notes payable		1,075
Principal payments for notes payable	(611)	(417)
Proceeds from issuance of common stock	80	30
Net cash provided by (used in) financing activities	(531)	688
Net decrease in cash and cash equivalents	(4,378)	(924)
Cash and cash equivalents at the beginning of period	14,926	18,839
Cash and cash equivalents at the end of period	$ 10,548	$ 17,915
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 195	$ 95

See accompanying notes.

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GENOMIC HEALTH, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2007
(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 is used for early stage breast cancer patients to predict the likelihood of cancer recurrence, the likelihood of patient survival within ten years of diagnosis and the likelihood of chemotherapy benefit. The Company has incurred significant losses and expects to incur additional losses for at least the next two years as commercial and development efforts continue.

Basis of Presentation

The accompanying interim period condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). The condensed consolidated balance sheet as of March 31, 2007, condensed consolidated statements of operations for the three months ended March 31, 2007 and 2006, and condensed consolidated statements of cash flows for the three months ended March 31, 2007 and 2006 are unaudited, but include all adjustments, consisting only of normal recurring adjustments, which the Company considers necessary for a fair presentation of the financial position, operating results and cash flows for the periods presented. The condensed consolidated balance sheet at December 31, 2006 has been derived from audited financial statements. However, it does not include certain information and notes required by GAAP for complete consolidated financial statements.

Results for any interim period are not necessarily indicative of results for any future interim period or for the entire year. The accompanying financial statements should be read in conjunction with the financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2006, as subsequently amended.

Income Taxes

In July 2006, the Financial Accounting Standards Board (FASB) issued Interpretation 48, *Accounting for Uncertainty in Income Taxes* (FIN 48), which became effective for the Company beginning January 1, 2007. FIN 48 addresses how tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under FIN 48, the tax benefit from an uncertain tax position can be recognized only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than fifty percent likelihood of being realized upon ultimate resolution. The adoption of FIN 48 had no impact on the Company s financial condition, results of operations or cash flows.

At December 31, 2006, the Company had federal and state tax net operating loss (NOL) carryforwards of approximately $114.2 million and $111.1 million, respectively, and federal and state research and development (R&D) tax credit carryforwards of approximately $1.6 million and $1.6 million, respectively. The NOL and R&D tax credit carryforwards will expire at various dates beginning in 2013 if not utilized. Because realization of such tax benefits is uncertain, the Company has provided a 100% valuation allowance as of December 31, 2006 and March 31, 2007. Utilization of the NOL and R&D tax credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred previously or that could occur in the future as provided in Section 382 of the Internal Revenue Code of 1986, as well as similar state and foreign provisions. These ownership changes may limit the amount of NOL and R&D tax credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than fifty percentage points over a three-year period. Since its formation, the Company has raised capital through the issuance of capital stock which, combined with the purchasing shareholders subsequent disposition of those shares,

may have resulted in a change of control, as defined by Section 382, or could result in a change of control in the future upon subsequent disposition.

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The Company has initiated a study to assess whether a change in control has occurred or whether there have been multiple changes of control since the Company s formation. If the Company has experienced a change of control at any time since its formation, utilization of NOL or R&D tax credit carryforwards would be subject to an annual limitation under Section 382. This annual limitation is determined by first multiplying the value of the Company s stock at the time of the ownership change by the applicable long-term tax-exempt rate, and could then be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the NOL or R&D tax credit carryforwards before utilization. Until the study is completed and any limitation known, no amounts are being presented as an uncertain tax position. Interest and penalties related to uncertain tax positions will be reflected in income tax expense. As of March 31, 2007, the Company had not recognized any tax penalties or interest in its balance sheets or statements of operations. All tax years since the Company s inception remain subject to future examination by the major tax jurisdictions in which it is subject to tax.

Recent Accounting Pronouncements

In February 2007, FASB issued Statement of Financial Accounting Standards No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS 159). SFAS 159, which includes an amendment to Statement of Financial Accounting Standards No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, permits entities the option to measure many financial instruments and certain other items at fair value. SFAS 159 is effective for fiscal years beginning after November 15, 2007. The Company is in the process of determining the impact that SFAS 159 will have on its financial condition, results of operations and cash flows.

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 less the weighted-average unvested common shares subject to repurchase 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 March 31,	
	2007	2006
	(In thousands except share and per share amounts) (Unaudited)	
Net loss	$ (6,850)	$ (6,830)
Weighted-average net common shares outstanding for basic and diluted loss per common share	24,561,164	24,480,267
Basic and diluted net loss per share	$ (0.28)	$ (0.28)
Outstanding dilutive securities not included in diluted net loss per share calculation:		
Options to purchase common stock	3,016,944	2,041,907

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Comprehensive Loss

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

	Three Months Ended March 31,	
	2007	2006
	(In thousands) (Unaudited)	
Net loss	$ (6,850)	$ (6,830)
Unrealized loss on available-for-sale securities	(4)	(18)
Comprehensive loss	$ (6,854)	$ (6,848)

Note 3. 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. Costs recorded under these agreements for the three months ended March 31, 2007 and 2006 were $1.1 million and $350,000, respectively, and were included in cost of product revenues.

Note 4. Notes Payable

In March 2005, the Company 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, the Company granted the lender a security interest in the assets purchased with the borrowed amounts. The Company could not prepay any amounts owing under this arrangement until April 2006, at which point it could prepay all, but not part, of the amounts outstanding under the arrangement so long as the Company also pays a 6% premium on the outstanding principal balance. This premium is reduced to 5% of the outstanding principal balance in April 2007 and 4% of the outstanding principal balance in April 2008.

As of March 31, 2007, the Company s aggregate commitments under its financing arrangement were as follows:

	Annual Payment Amounts (In thousands) (Unaudited)
Years Ending December 31, 2007 (remainder of the year)	$ 2,417
2008	3,073
2009	1,934
2010	238
Total minimum payments	7,662
Less: interest portion	(1,000)
Present value of net minimum payments	6,662
Less: current portion of obligations	(2,617)
Long-term obligations	$ 4,045

Note 5. Commitments

Lease Obligations

In September 2005, the Company entered into a non-cancelable lease for 48,000 square feet of laboratory and office space, which the Company occupied as of March 31, 2007. The lease has a term of six years and includes lease incentive obligations totaling $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 sheet.

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In January 2007, the Company entered into a non-cancelable lease for an additional 48,000 square feet of laboratory and office space in a nearby location, which the Company occupied as of March 31, 2007. The lease has a term of five years and includes lease incentive obligations totaling $283,000 that are being amortized on a straight-line basis over the life of the lease. In connection with this lease, the Company paid a $151,000 cash security deposit, which is included in other assets on its condensed consolidated balance sheet.

Future non-cancelable commitments at March 31, 2007 under these leases, which are considered operating leases, were as follows:

	Annual Payment Amounts (In thousands) (Unaudited)
Years Ending December 31, 2007 (remainder of the year)	$ 888
2008	1,348
2009	1,520
2010	1,634
2011	1,723
Thereafter	290
Total minimum payments	$ 7,403

Note. 6 Stock-Based Compensation

Employee Stock-Based Compensation Expense

The Company uses the Black-Scholes option valuation model to value stock options under Statement of Financial Accounting Standards No. 123 (Revised 2004), *Share-Based Payment* (SFAS 123R). The Company recorded stock-based compensation expense of $1.3 million and $569,000 for the three months ended March 31, 2007 and 2006, respectively. Employee 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 FAS 123R on selected statements of operations line items for the three months ended March 31, 2007 and 2006:

	Three Months Ended March 31,	
	2007	2006
	(In thousands) (Unaudited)	
Cost of product revenues	$ 78	$ 32
Research and development	393	175
Selling and marketing	356	156
General and administrative	456	206
Total employee stock-based compensation expense	$ 1,283	$ 569

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 March 31, 2007, total compensation expense related to non-vested stock options not yet

recognized was $14.3 million, which is expected to be allocated to expenses over a remaining vesting period of forty-four months.

Valuation Assumptions

Option valuation models require the input of highly subjective assumptions that can vary over time. Expected volatility is based on comparable peer data as well as the historical volatility of the Company s stock. The expected life of options granted is estimated based on comparable peer data and historical option exercise and employee termination data. The risk-free interest rate is estimated using rates available on U.S. Treasury securities with a remaining term approximating the expected life of the

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options. 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 159,455 and 73,150 employee stock options for the three months ended March 31, 2007 and 2006, 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 March 31,	
	2007	2006
	(Unaudited)	
Volatility factor	65%	75%
Risk-free interest rate	4.54%	4.60%
Dividend yield	0%	0%
Expected life of options in years	5.5	5.0
Weighted-average fair value	$ 12.39	$ 7.49

Stock Options Exercised

For the three months ended March 31, 2007, the Company issued 22,181 shares of common stock in connection with the exercise of stock options by employees and consultants with a weighted-average exercise price of $3.52 per share and total intrinsic value of $78,175. For the three months ended March 31, 2006, the Company issued 15,866 shares of common stock in connection with the exercise of stock options by employees and consultants with a weighted-average exercise price of $1.91 per share and total intrinsic value of $30,265.

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

The following discussion of our financial condition and results of operations should be read in conjunction with the financial statements and notes to those statements included elsewhere in this Quarterly Report on Form 10-Q for the three months ended March 31, 2007 and our audited financial statements for the year ended December 31, 2006 included in our Annual Report on Form 10-K, as subsequently amended. 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 and when we expect we will recognize a majority of revenues upon providing tests; the level of investment in our sales force; the capacity of our commercial laboratory to process tests and our expected expanded capacity; our dependence on collaborative relationships and the success of those relationships; whether any tests will result from our collaborations; our belief that clinical results support our development of a 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; the economic benefits of our test to the healthcare system; our compliance with federal, state and foreign regulatory requirements; our expectation that product revenues will increase; 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; our statement that we may submit comments on FDA s guidance document; our beliefs regarding reimbursement for Medicare inpatients; 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 intent to enter into additional foreign distribution arrangements; the factors that we believe will drive the establishment of coverage policies; the

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impact of changing interest rates; the amount of future revenues that we may derive from Medicare patients or categories of patients; increases in patient and physician demand resulting from 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 and commercial launch of, future tests addressing different patient populations or other cancers; our expectation regarding when we may move another potential test into development; the timing, outcome or success of clinical trials; our intellectual property and our strategies regarding filing additional patent applications to strengthen our intellectual property rights; 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; the ability to compete against third parties; 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 the section of this report entitled Management s Discussion and Analysis of Financial Condition and Results of Operations, 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 diagnostic test, Onco*type* DX™, is used for early stage breast cancer patients to predict the likelihood of cancer recurrence, the likelihood of patient survival within ten years of diagnosis and the likelihood of chemotherapy benefit. 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. The current list price of our test is $3,460.

We have experienced a significant increase in demand for Onco*type* DX since the test was launched in January 2004. For the three months ended March 31, 2007, more than 5,450 tests were delivered for use in treatment planning, compared to more than 2,900 for the three months ended March 31, 2006. As of March 31, 2007, more than 27,000 tests had been delivered for use in treatment planning by more than 5,500 physicians. We believe this increased demand resulted from the publication of our validation study in 2004 and peer-reviewed articles in 2006 on other large studies we conducted or collaborated on supporting the use and reimbursement of Onco*type* DX, clinical presentations at major symposia, and the continued expansion of our domestic field sales organization. However, this increased demand is not necessarily indicative of future growth rates, and we cannot assure you that this level of increased demand can be sustained or that future appearances or presentations at medical conferences, publication of articles or increases in sales personnel will have a similar impact on demand for Onco*type* DX. Moreover, we believe that each year we may experience decreased demand for our test in the months of April, July and August, which may be attributed to physicians and patients scheduling vacations during this time. As of March 31, 2007, our laboratory had the capacity to process up to 8,000 tests per quarter.

We believe the key factors that will drive broader adoption of Onco*type* DX will be acceptance by healthcare providers of its clinical benefits, demonstration of the cost-effectiveness of using our test, expanded reimbursement by third-party payors, expansion of our sales force, increased marketing efforts and the establishment of industry guidelines for use of Onco*type* DX. Reimbursement of Onco*type* DX by third-party payors is essential to our

commercial success. As a relatively new test, Onco*type* DX may be considered investigational by payors and not covered under their reimbursement policies. Consequently, we have pursued case-by-case reimbursement and expect the test will continue to be reviewed on this basis until policy decisions have been made by individual

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payors. We are also working with public and private payors and health plans to secure coverage for Onco*type* DX based upon clinical evidence showing the utility of the test. As of April 2007, health plans covering approximately 125 million lives have approved our test for coverage through either a reimbursement contract or policy.

As of March 31, 2007, United HealthCare Insurance Company, Aetna, Inc., Kaiser Foundation Health Plan, Inc. and National Heritage Insurance Company, or NHIC, the local Medicare carrier for California with jurisdiction for claims submitted by us for Medicare patients, had issued positive coverage determinations for Onco*type* DX. We believe that as much as 20% of our future test volume may be derived from Medicare patients. In April 2007, CIGNA HealthCare entered into a national laboratory services agreement supporting reimbursement for our test and Humana, Inc. executed a payor contract covering subscribers in multiple states in the Midwest and Southeast. In addition, a number of regional payors had issued policies supporting reimbursement for our test. New regional payors supporting reimbursement in 2007 include Blue Shield of California and Horizon Blue Cross Blue Shield of New Jersey. Until we reach agreement with a payor on contract terms or a payor establishes a policy for payment of Onco*type* DX, we recognize revenue on a cash basis. Where contracts or policies are not in place, we pursue case-by-case reimbursement. We are working with many payors to establish policy-level reimbursement which, if in place, should allow us to recognize revenues upon completing our test, generating and delivering a Recurrance Score report to the physician and submitting an invoice to the payor. We do not expect to recognize the majority of revenues in this manner until the end of 2007 or later.

We are conducting clinical studies with the goal of expanding the clinical utility of Onco*type* DX in breast cancer. Our test is currently used for breast cancer patients with tumors that are node negative, or N , and estrogen receptor positive, or ER+. During 2007, we may introduce single gene reporting for ER and progesterone receptor, or PR, genes into the Onco*type* DX patient report to provide better information for improved treatment decision-making. We also plan to conduct studies using Onco*type* DX in N , ER+ patients who were treated with an aromatase inhibitor. We are continuing to work on extending Onco*type* DX for breast cancer into node positive, or N+, and estrogen receptor negative, or ER , populations. We plan to complete two further studies in 2007 using Onco*type* DX in N+ patients which, if successful, could result in a product offering in 2008.

We continue to conduct research and early development studies in a variety of cancers other than breast cancer. In January 2007 we announced that we had moved our program for early stage colon cancer patients into full-scale development. We expect our colon program will follow a clinical development process similar to that of our Onco*type* DX breast cancer test. We have established a collaborative agreement with the National Surgical Adjuvant Breast and Bowel Project, or NSABP, as well as other academic groups to access colon tissue samples that have associated clinical outcome data. We developed an investigational gene panel for colon cancer and have recently completed two studies to refine the gene set. Two additional studies to identify the final gene set are in progress which, if successful, may lead to a validation study in 2008, and could result in a commercial product launch in 2009.

Since our inception, we have generated significant net losses. We incurred a net loss of $6.9 million for the three months ended March 31, 2007. As of March 31, 2007, our accumulated deficit was $132.0 million. We expect our net losses to continue for at least the next two years. We anticipate that a substantial portion of our capital resources and efforts over the next several years will be focused on research and development, both to develop additional tests for breast cancer and to develop tests for colon and other cancers, to scale up our commercial organization, and for other general corporate purposes. Our financial results will be limited by a number of factors, including establishment of coverage policies by third-party insurers and government payors, our ability in the short term to collect from payors often requiring a case-by-case manual appeals process, and our ability to recognize revenues other than from cash collections on tests billed until such time as reimbursement agreements or contracts are in effect. Until we receive routine reimbursement and are able to record revenues as tests are performed and reports delivered, we are likely to continue reporting net losses.

Financial Operations Overview

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 agreement 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 recognized as costs are incurred, assays are processed or milestones are completed.

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Cost of Product Revenues

Cost of product revenues represents the direct material costs, direct labor costs, equipment costs and other infrastructure costs associated with processing tissue samples including histopathology, anatomical pathology, paraffin extraction, reverse transcription polymerase chain reaction, or RT-PCR, and quality control analyses, license fees and shipping charges necessary to render an individualized test result. Costs associated with performing our test are recorded as tests are processed. License fees are recorded 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.

Research and Development Expenses

Research and development expenses represent costs incurred to develop our technology and carry out our clinical studies to validate our multi-gene tests and include 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.

We charge all research and development expenses to operations as they are incurred. All potential future product programs outside of breast and colon cancer are in the 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.

We do not record or maintain information regarding costs incurred in research and development on a product-program specific basis. Our research and development staff and associated infrastructure resources are deployed across several product programs. Many of our costs are therefore not attributable to individual product programs. We believe that allocating costs on the basis of time incurred by our employees does not accurately reflect the actual costs of individual product programs.

As a result of the uncertainties discussed above, 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.

Selling and Marketing Expenses

Our selling and marketing expenses consist primarily of personnel costs and education and promotional expenses associated with Onco*type* DX. 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.

General and Administrative Expenses

Our general and administrative expenses consist primarily of personnel related costs, legal costs, including intellectual property, accounting costs, billing and collections costs, bad debt expense and other professional and administrative costs.

Critical Accounting Policies and Significant Judgments and Estimates

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

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

Revenue Recognition

Product revenues for our first product, Onco*type* DX, from its commercial launch in January 2004 through March 31, 2007, have largely been recognized on a cash basis because we have limited collection experience and a limited number of contracts. We recognize a portion of product revenue from third-party payors, including some private payors and Medicare, on an accrual basis.

Our 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 (2) is satisfied when we perform the test and generate and deliver a report to the physician. Determination of criteria (3) and (4) is based on management s judgments regarding the nature of the fee charged for products or services delivered and the collectibility of those fees. Product revenues where all the criteria set forth above are not met are recognized when cash is received.

We generally bill third-party payors for Onco*type* DX upon generation and delivery of a Recurrence Score report to the physician. As such, we take assignment of benefits and the risk of collection with the third-party payor. We usually bill the patient directly for amounts owed after multiple requests for payment have been denied or only partially paid by the insurance carrier. As a relatively new test, Onco*type* DX may be considered investigational by payors and not covered under their reimbursement policies. Consequently, we pursue case-by-case reimbursement where policies are not in place or payment history has not been established.

In late 2006 we began accruing an allowance for doubtful accounts against our accounts receivable consistent with historical payment experience. Bad debt expense is included in general and administrative expense on our condensed consolidated statements of operations. Accounts receivable over ninety days 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 March 31, 2007, our allowance for doubtful accounts was $245,000 compared to $510,000 at December 31, 2006. Write-offs for doubtful accounts of $254,000 were recorded against the allowance during the three months ended March 31, 2007; no write-offs were recorded during the year ended December 31, 2006.

Contract revenues are derived from studies conducted with biopharmaceutical and pharmaceutical companies and are recognized on a contract specific basis. Under certain contracts, our input, measured in terms of full-time equivalent level of effort or running a set of assays through our laboratory under a contractual protocol, triggers payment obligations and revenues are recognized as costs are incurred or assays are processed. Certain contracts have payment obligations that are triggered as milestones are completed, such as completion of a successful set of experiments. In these cases, revenues are recognized when the milestones are achieved.

Stock-based Compensation Expense

On January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (Revised 2004), *Share-Based Payment*, or SFAS 123R. SFAS 123R addresses the accounting for stock-based payment transactions whereby an entity receives employee services in exchange for equity instruments, including stock options. SFAS 123R requires that such transactions be accounted for using a fair-value based method. The application of SFAS 123R requires significant judgment and the use of estimates, particularly surrounding assumptions used in determining fair value. We use the Black-Scholes valuation method, which requires the use of estimates such as stock price volatility and expected option lives, as well as expected option forfeiture rates, to value equity-based compensation. We have limited historical evidence with respect to developing these assumptions. Expected volatility is based on comparable peer data as well as the historical volatility of our stock. The expected life of options granted is estimated based on peer group data and historical option exercise and employee termination experience.

We elected the modified prospective transition method, which requires that stock-based compensation expense be recorded for all new and unvested stock options that are ultimately expected to vest as the requisite service is rendered beginning on January 1, 2006. Stock-based compensation expense resulting from the adoption of SFAS 123R represents expense related to stock options granted since January 1, 2006, as well as stock options granted prior to, but not yet vested as of, January 1, 2006. As of March 31, 2007, total

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compensation expense related to non-vested stock options not yet recognized was $14.3 million, which is expected to be recognized over a period of forty-four months.

Equity instruments granted to non-employees are valued using the Black-Scholes method and accounted for as prescribed by SFAS 123R and Emerging Issues Task Force, or EITF, Consensus No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, and will be subject to periodic revaluation over their vesting terms.

Clinical Collaborator Costs

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 upon completion of work performed by our collaborators under contract terms.

In addition to costs for research and development, we make annual payments resulting from the commercial launch of Onco*type* DX under one of our collaboration agreements. These payments are recorded in cost of product revenues as a license payment. Expense is recorded ratably over the year before the relevant payment is made. However, either party may terminate the agreement upon thirty days prior written notice.

Results of Operations

Three Months Ended March 31, 2007 and 2006

Revenues. Total revenues were $14.1 million for the three months ended March 31, 2007 compared to $5.1 million for the comparable period in 2006. Product revenues from Onco*type* DX were $13.1 million for the three months ended March 31, 2007 compared to $4.2 million for the comparable period in 2006. This increase resulted from increased adoption and expanded reimbursement coverage for our test. Approximately 35% of product revenue for the three months ended March 31, 2007 was recorded on an accrual basis, reflecting established payment patterns from payors with coverage policies in place, compared to 23% for the three months ended March 31, 2006. The balance of product revenue was recognized upon cash collection. Product revenue from Medicare was $3.2 million, representing 25% of total product revenue for the three months ended March 31, 2007, compared to $2.0 million or 49% of total product revenue for the three months ended March 31, 2006. Medicare revenue for the three months ended March 31, 2006 included the receipt of payments in the period for services provided to Medicare patients prior to Medicare s February 27, 2006 effective coverage date for Onco*type* DX.

Contract revenues were $942,000 for the three months ended March 31, 2007, compared to $871,000 for the comparable period in 2006. Contract revenues are from studies assessing our gene expression technology or collaborative work in gene selection and protocol design with our pharmaceutical partners. Contract revenues for the three months ended March 31, 2007 and 2006 reflected ongoing collaboration work with Bristol-Meyers Squibb and Imclone Systems as well as Aventis, Inc. and the Eastern Cooperative Oncology Group.

Cost of Product Revenues. For the three months ended March 31, 2007, cost of product revenues was $3.8 million for Onco*type* DX, consisting of tissue sample processing costs of $2.7 million and license fees of $1.1 million. For the three months ended March 31, 2006, cost of product revenues was $2.1 million, consisting of tissue sample processing costs of $1.7 million and license fees of $350,000. Test volume for the three months ended March 31, 2007 increased 88% from the comparable period in 2006, resulting in a decrease in the cost per test delivered. During the three months ended March 31, 2007 and 2006, we recorded tissue sample processing costs for Onco*type* DX that included direct material costs, direct labor costs, equipment costs, shipping costs and other infrastructure costs. All costs recorded for tissue sample processing in those periods represent the cost of all the tests processed regardless of whether revenue was recognized with respect to that test. License fees were recorded in cost of product revenues for contractual obligations and royalties due on product revenues.

Research and Development Expenses. Research and development expenses increased to $5.2 million for the three months ended March 31, 2007, from $2.7 million for the comparable period in 2006. The increase in research and development expenses was primarily due to a $1.2 million increase in personnel-related costs, a $554,000 increase in clinical collaboration expenses, a $478,000 increase in infrastructure-related expenses and a $138,000 increase in reagents and lab supplies. We expect that our research and

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development expenses will 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. Selling and marketing expenses increased to $8.1 million for the three months ended March 31, 2007 from $5.1 million for the comparable period in 2006. The $3.0 million increase in selling and marketing expenses was primarily due to a $1.3 million increase in personnel-related costs, mostly to expand our domestic field sales organization, $802,000 in higher promotional field and marketing expense, $612,000 in higher travel-related expenses associated with field sales personnel and $327,000 in higher infrastructure-related expense. We expect that selling and marketing expenses will continue to increase in future periods as we continue to expand our sales force and conduct ongoing physician and patient education programs.

General and Administrative Expenses. General and administrative expenses increased to $4.1 million for the three months ended March 31, 2007 from $2.6 million for the comparable period in 2006. The $1.5 million increase in general and administrative expenses was primarily due to a $1.1 million increase in personnel-related costs, $246,000 in higher legal and accounting fees, and $157,000 in higher billing and collection fees paid to third-party billing and collection vendors. We expect general and administrative expenses to continue to increase as we spend more on fees for billing and collections due to revenue growth and continue to incur costs associated with regulatory matters and other expenses related to the growth of our business.

Interest Income. Interest income was $516,000 for the three months ended March 31, 2007 compared to $692,000 for the comparable period in 2006. The decrease in interest income was due to lower average cash balances partially offset by higher market yields.

Interest Expense. Interest expense was $195,000 for the three months ended March 31, 2007 compared to $95,000 for the comparable period in 2006. This increase was related to higher borrowings on our equipment financing line under which draws have been made and interest expense has been incurred.

Liquidity and Capital Resources

Since our inception in August 2000, we have incurred significant losses and, as of March 31, 2007, we had an accumulated deficit of approximately $132.0 million. We have not yet achieved profitability and anticipate that we will continue to incur net losses for at least the next two years. We expect that our research and development, selling and marketing and general and administrative expenses will continue to grow and, as a result, we will need to generate significant product revenue to achieve profitability. We may never achieve profitability.

Sources of Liquidity

At March 31, 2007, we had cash, cash equivalents and short-term investments of $35.1 million and working capital of $31.0 million, compared with cash, cash equivalents and short-term investments of $44.2 million and working capital of $37.5 million at December 31, 2006. Historically we have financed our operations primarily through sales of our equity securities. Since our inception in August 2000 through March 31, 2007, we have received net proceeds of $161.7 million from the sale of preferred and common stock and $655,000 from the issuance of common stock in connection with the exercise of stock options. Purchases of equipment and leasehold improvements have been partially financed through loans. Notes payable under our equipment loan were $6.7 million and $7.3 million at March 31, 2007 and 2006, respectively.

Cash Flows

For the three months ended March 31, 2007, we used $6.8 million of net cash for operating activities principally as the result of our net loss of $6.9 million and a net change in operating assets and liabilities of $2.2 million, partially offset by non-cash charges for stock-based compensation of $1.3 million and depreciation and amortization of $918,000. For the three months ended March 31, 2006, we used $6.3 million of cash for operating activities due primarily to our net loss for the period of $6.8 million and a net change in operating assets and liabilities of $589,000, partially offset by non-cash charges for stock-based compensation of $605,000 and depreciation and amortization of $469,000.

For the three months ended March 31, 2007, we received net cash from investing activities of $3.0 million compared to $4.7 million for the three months ended March 31, 2006. This decrease of $1.7 million in cash provided was due to a decrease of $2.5 million

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in net proceeds from short-term investments offset by a decrease in cash used of $716,000 million for the acquisition of property and equipment and for leasehold improvements.

For the three months ended March 31, 2007, we used net cash of $531,000 for financing activities, primarily for payments on our equipment financing loans. For the three months ended March 31, 2006, we received net cash of $688,000 from financing activities due to draws on our capital equipment financing loan, partially offset by loan payments.

Contractual Obligations

The following summarizes our significant contractual obligations as of March 31, 2007 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	$ 7,662	$ 3,223	$ 4,266	$ 173	$
Non-cancelable operating lease obligations	7,403	1,200	2,951	3,252	
Total	$ 15,065	$ 4,423	$ 7,217	$ 3,425	$

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 a 5% premium on the remaining payments. This premium is reduced to 4% in 2008. As of March 31, 2007, notes payable under this arrangement totaled $6.7 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, which we occupied in March 2007. The lease has a term of five years. 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 which has a term of six years.

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. For a period of seven years on each anniversary of this first payment, we are required to make additional payments in increasing amounts. The initial payment of $150,000 was made in January 2004. Subsequent payments of $150,000, $300,000 and $300,000 were made in January 2005, 2006 and 2007, respectively. We are required to make additional payments of $475,000 in each of the years 2008 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.

Off-Balance Sheet Arrangements

As of March 31, 2007, we have 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 several 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 for Onco*type* DX and amounts available under our equipment financing facility, will be sufficient to fund our operations and expansion plans for at least the next twelve 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 product 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;

the cost and delays in product development as a result of any changes in regulatory oversight applicable to our products; 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. We do not know whether additional funding will be available on acceptable terms, or 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 development programs or market development programs, which would lower the economic value of those programs to our company.

Recent Accounting Pronouncements

In February 2007, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, or SFAS 159. SFAS 159, which includes an amendment to Statement of Financial Accounting Standards No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, permits entities the option to measure many financial instruments and certain other items at fair value. SFAS 159 is effective for fiscal years beginning after November 15, 2007. We are in the process of determining the impact that SFAS 159 will have on our financial condition, results of operations and cash flows.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to interest rate risk primarily through our investment portfolio. Our marketable securities consist of high-quality debt securities with maturities beyond ninety days at the date of acquisition, which mature within one

year or less. As of March 31,

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2007, we had cash, cash equivalents and short-term investments totaling $35.1 million. Our investment policy calls for investments in short-term, low risk, investment-grade instruments. Based on our portfolio content and our ability to hold investments to maturity, we believe that, if market interest rates were to increase immediately and uniformly by 10% from levels at March 31, 2007, the decline in fair value would not be material.

ITEM 4. CONTROLS AND PROCEDURES.

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

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

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

PART II. OTHER INFORMATION

ITEM 1A. RISK FACTORS.

RISKS RELATED TO OUR COMPANY

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

We have incurred substantial net losses since our inception. For the three months ended March 31, 2007 and the year ended December 31, 2006, we incurred net losses of $6.9 million and $28.9 million, respectively. From our inception in August 2000 through March 31, 2007, we had an accumulated deficit of approximately $132.0 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 commercializing and enhancing our existing test, Onco*type* DX, and to develop future tests.

We expect to incur additional losses in the future and we may never achieve profitability. We do not expect our losses to be substantially mitigated by revenues from Onco*type* DX or future products, if any, for a number of years.

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 $5.2 million for the three months ended March 31, 2007 and $12.8 million for the year ended December 31, 2006. We expect our research and development expense levels to remain high 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.

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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.

Oncotype DX has a current list price of $3,460. 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 s price. There is significant uncertainty concerning third-party reimbursement of any test incorporating new technology, including Onco*type* DX. 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, and

supported by peer-reviewed publications.

Since each payor makes its own decision as to whether to establish a policy to reimburse, seeking these approvals is a time-consuming and costly process. To date, we have secured policy-level reimbursement approval from a limited number of third-party payors and have a limited number of approvals for state Medicaid programs. We cannot be certain that coverage for Onco*type* DX will be provided in the future by any third-party payors.

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 such as Blue Cross and Blue Shield plans, which collectively provide healthcare coverage for nearly one-third of all Americans, as grounds to deny coverage for a test or procedure. Onco*type* DX has received negative assessments and may receive additional negative assessments in the future. For example, in early 2005, the Medical Advisory Panel of the Blue Cross and Blue Shield Association s Technology Evaluation Center, a technology assessment group, concluded that the existing clinical data in support of Onco*type* DX did not meet the panel s technology criteria for clinical effectiveness and appropriateness.

In January 2006, NHIC, the California Medicare contractor with responsibility for processing and paying claims submitted by us, released a local coverage determination providing coverage for Onco*type* DX when used in accordance with the terms of the determination. The local coverage determination is effective for Onco*type* DX tests provided on or after February 27, 2006. Until recently, there had been some question as to whether claims for Onco*type* DX tests performed on Medicare beneficiaries who were hospital inpatients at the time the tumor tissue samples were obtained may be billed by us to NHIC or must be incorporated in the payment that the hospital receives for their services related to the patient s breast cancer. As of March 31, 2007, the volume of patients who fell into this category represented approximately 2% of our total testing population.

Based on a final rule effective January 1, 2007, we are permitted to submit claims to NHIC for the Onco*type* DX tests performed on Medicare beneficiaries who were hospital inpatients or outpatients at the time the tumor tissue samples were obtained, but only if the test was ordered at least 14 days following the date of the patient s discharge from the hospital and where other specified conditions are met. We are in the process of making arrangements with hospitals for payment of the test when performed for the small portion of Medicare beneficiaries, representing approximately 3% of our total testing population, who are hospital inpatients or outpatients at the time specimens are collected and who do not meet criteria under the final rule for billing by us. Finally, we have been engaged in discussions with the Centers for Medicare/Medicaid Services, or CMS, about the application of the final rule to hospital outpatients, including the effective date and any transition policy for compliance with the final rule. We believe the final rule should not apply to the Onco*type* DX tests performed on tumor tissue samples obtained while the patient is a hospital outpatient, and that tests performed on tissue samples taken from hospital outpatients should be billable by us under the Medicare program, regardless of when the testing of such tissue samples takes place. While we are continuing to pursue this matter, at this point, CMS intends for the final rule to apply to outpatients as well as

inpatients, and we are notifying hospitals accordingly.

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Insurers, including managed care organizations as well as government payors such as Medicare, 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, added costs and decreased test utilization for the clinical laboratory industry.

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.

If the U.S. Food and Drug Administration, or 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 approval or we could experience decreased demand for or reimbursement of our test.

Clinical laboratory tests like Onco*type* DX are regulated under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, as administered through the 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 development tests, or LDTs. Most LDTs currently are not 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 is 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. This draft guidance represents the first public discussion surrounding FDA s position regarding the regulation of certain laboratory-developed tests. 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. The draft guidance was open for public comment until March 5, 2007, during which time we and others submitted comments on the draft guidance. In addition, FDA held a public meeting on February 8, 2007 at which several interested parties commented on the draft guidance.

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. On March 1, 2007, Senator Edward Kennedy introduced the Laboratory Test Improvement Act which, if enacted as introduced, would deem laboratory-developed tests to be medical devices subject to labeling and registration requirements for laboratory-developed tests as set forth in the bill. On March 23, 2007, Senator Barack Obama introduced the Genomics and Personalized Medicine Act of 2007 which, if enacted as introduced, would call for an Institute of Medicine study to make recommendations to improve federal oversight and regulation of genetic tests and would also require the Secretary of the U.S. Department of Health and Human Services to implement a decision matrix, taking into consideration the recommendations of the Institute of Medicine report, to improve the oversight and regulation of genetic tests. In addition, on May 9, 2007, the Senate passed the Food and Drug Administration Revitalization Act, which included an amendment, introduced by Senator Obama, calling for the Institute of Medicine to conduct a study to assess the overall safety and quality of genetic tests and prepare a report that includes recommendations to improve federal oversight and regulation of genetic tests. The House of Representatives has not considered comparable legislation at this point. It is unclear whether any of these proposals will be passed by Congress. If one of these proposals does pass, it is unclear what the final legislative language would be. It is possible that one of these proposals will be enacted into law and may result in increased regulatory burdens

for us to continue to offer the Onco*type* DX assay.

On March 26, 2007, the Secretary s Advisory Committee on Genetics, Health and Society discussed a charge the Committee was given by the Secretary of the Department of Health and Human Services to make recommendations about the oversight of genetic testing. Draft recommendations are expected to be submitted to the Secretary in the summer of 2007.

On May 9, 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. We do not believe the release of this guidance document directly or immediately impacts the status of FDA s draft guidance on In Vitro Diagnostic Multivariate Index Assays. We are studying this guidance document and may submit comments on the guidance to FDA in the future.

If pre-market review is required, our business could be negatively impacted until such review is completed and approval or clearance to market is obtained, and FDA could require that we stop selling our test pending pre-market approval. If our test is allowed to remain on the market but there is uncertainty about our test or if it is labeled investigational by FDA, orders or reimbursement may decline. The regulatory approval process may involve, among other things, successfully completing additional clinical trials and submitting a pre-market clearance notice or filing a pre-market approval application with 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. Notwithstanding the above, we may 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 LDT be affected by future regulatory actions, our business could be adversely affected by those actions, including increasing the cost of testing or delaying, limiting or prohibiting the purchase of reagents necessary to perform testing.

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If we were required to conduct additional clinical trials prior to marketing our 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 test, 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 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 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 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 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.

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The risk of our being found in violation of these laws and regulations is 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 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.

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.

Existing guidelines and practices regarding the treatment of breast cancer recommend that chemotherapy be considered in most cases, including many cases in which our test may indicate that, based on our clinical trial results, chemotherapy is of little or no benefit. Accordingly, physicians may be reluctant to order a test that may suggest recommending against chemotherapy in treating breast cancer where current guidelines recommend consideration of such treatment. 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 order or 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 order 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 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

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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.

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

We license from third parties technology necessary to develop our products. For example, we license technology from Roche Molecular Systems, Inc. that we use to analyze genes 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 March 31, 2007, we had two issued patents, one of which was issued jointly to us and to 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.

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, misappropriation or misuse of other parties proprietary rights and may from time to time receive additional notices. Some of these claims may lead to litigation. We cannot assure you that we will prevail in such actions, or that other actions alleging misappropriation or misuse by us of third-party trade secrets, infringement by us of third-party patents and trademarks or the validity of our patents, will not be asserted or prosecuted against us. We may also initiate claims to defend our intellectual property. 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 companies that offer products or have conducted research to profile genes, gene expression or protein expression in breast cancer, including Agendia B.V., Applied Genomics, Inc., AviaraDX, Celera Genomics, a business segment of Applera Corporation, and Exagen Diagnostics, Inc. 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 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.

Our test is considered relatively expensive for a diagnostic test, and we expect to 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.

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

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collaboration could be delayed or terminated. If any of our collaboration agreements is 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 NSABP and Northern California Kaiser Permanente. 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.

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. We plan to complete two studies in N+ breast cancer with Onco*type* DX in 2007. 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

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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.

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 may result in the loss of customers or harm our reputation, and we may be unable to regain those customers in the future. Although we possess insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, 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, or that this laboratory would be willing to perform the tests for us on commercially reasonable terms. 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. 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 commercialization 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 the creation of broad limits for diagnostic products in general or requirements that Medicare patients pay for portions of 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,

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significantly restricting, regulating and changing laboratories relationships with physicians. 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 supplier no longer supplies that equipment.

We rely solely on Applied Biosystems, a division of Applera Corporation, to supply some of the laboratory equipment on which we perform our tests. We periodically forecast our needs for laboratory equipment and enter into standard purchase orders with Applied Biosystems based on these forecasts. We believe that there are relatively few equipment manufacturers other than Applied Biosystems that are currently capable of supplying the equipment necessary for 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.

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

We recently completed the expansion of our clinical laboratory facilities and have ramped up our testing capacity. We have begun 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 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. 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. If we encounter difficulty meeting market demand for Onco*type* DX, our reputation could be harmed and our future prospects and our business could suffer.

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 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, 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 information we provide to customers or for a misunderstanding of, or inappropriate reliance upon, the information we provide. A product liability claim could result in substantial damages and be costly and time consuming for us to defend. Although we believe that our existing product liability insurance is adequate, we cannot assure you that our insurance would fully protect us from the financial impact of defending against product liability claims. Any product 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

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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 might 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.

International sales as a percentage of net revenues are expected to remain minimal in the near term as we focus our efforts on the sale of Onco*type* DX in the United States. We have established an exclusive distribution network to sell Onco*type* DX in Israel 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.

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.

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;

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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.

We must implement additional and expensive finance and accounting systems, procedures and controls as we grow our business and organization and to satisfy new 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, including expanded disclosures and accelerated reporting requirements and more complex accounting rules. Compliance with Section 404 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.

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ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

On September 28, 2005, a Registration Statement on Form S-1 (File No. 333-126626) relating to our initial public offering was declared effective by the Securities and Exchange Commission. The closing was October 4, 2005 and the net offering proceeds to us were approximately $53.5 million, all of which had been used as of March 31, 2007. We used $31.4 million of the net proceeds to build our commercial capabilities in selling and marketing related to Onco*type* DX, $15.3 million to fund research and development programs for Onco*type* DX and for other cancers, and $6.8 million to expand facilities and laboratory operations capacity and for information systems infrastructure.

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ITEM 6. EXHIBITS

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

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: May 10, 2007

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

Date: May 10, 2007

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

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GENOMIC HEALTH, INC.
EXHIBIT INDEX

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