GENOMIC HEALTH INC
Form 10-Q
May 15, 2006

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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, 2006

or

o **TRANSITION REPORTS 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 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 o Non-Accelerated Filer þ

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 24,486,847 as of April 30, 2006.

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PART 1: FINANCIAL INFORMATION

Item 1. Financial Statements

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

	March 31, 2006 (Unaudited)	December 31, 2005
Assets		
Current assets:		
Cash and cash equivalents	$ 17,915	$ 18,839
Short-term investments	43,466	50,688
Accounts receivable	905	314
Other receivable	834	
Prepaid expenses and other current assets	1,896	1,584
Employee note receivable current portion	19	37
Total current assets	65,035	71,462
Property and equipment, net	5,599	3,597
Restricted cash	500	500
Other assets	240	240
Total assets	$ 71,374	$ 75,799
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 973	$ 1,393
Accrued compensation	1,360	955
Accrued expenses and other current liabilities	1,806	1,438
Accrued license fees	549	585
Lease incentive obligations	834	
Notes payable current portion	1,313	1,052
Deferred revenues	217	238
Total current liabilities	7,052	5,661
Notes payable long-term portion	3,018	2,621
Stockholders equity		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized; no shares issued and outstanding at March 31, 2006 and December 31, 2005;		
Common stock, $0.0001 par value; 100,000,000 shares authorized, 24,486,847 and 24,470,981 shares issued and outstanding at March 31, 2006 and December 31, 2005;	2	2
Additional paid-in capital	164,391	167,053
Deferred stock-based compensation		(3,297)
Accumulated other comprehensive income (loss)	(76)	(58)
Accumulated deficit	(103,013)	(96,183)

Total stockholders equity		61,304		67,517
Total liabilities and stockholders equity	$	71,374	$	75,799

See accompanying notes.

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

	Three Months Ended March 31,	
	2006	**2005**
Revenues:		
Product revenues	$ 4,189	$ 442
Contract revenues	871	
Total revenues	5,060	442
Operating expenses:		
Cost of product revenues	2,059	1,286
Research and development	2,711	2,205
Selling and marketing	5,095	3,382
General and administrative	2,622	1,352
Total operating expenses	12,487	8,225
Loss from operations	(7,427)	(7,783)
Interest income	692	197
Interest expense	(95)	
Net loss	$ (6,830)	$ (7,586)
Basic and diluted net loss per share	$ (0.28)	$ (3.85)
Shares used in computing basic and diluted net loss per share	24,480,267	1,970,202

See accompanying notes.

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

	Three Months Ended March 31,	
	2006	**2005**
Operating activities		
Net loss	$ (6,830)	$ (7,586)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	469	291
Employee stock-based compensation	569	232
Non-employee stock-based compensation expense	36	21
Changes in assets and liabilities:		
Accounts receivable	(591)	
Other receivable	(834)	
Employee note receivable	18	19
Prepaid expenses and other current assets	(312)	(712)
Other assets		(18)
Accounts payable	(420)	120
Lease incentive obligations	834	
Accrued expenses and other liabilities	368	(123)
Accrued compensation	405	143
Accrued license fees	(36)	(68)
Deferred revenues	(21)	
Net cash used in operating activities	(6,345)	(7,681)
Investing activities		
Purchase of property and equipment	(2,471)	(207)
Purchase of short-term investments	(2,771)	
Maturities of short-term investments	9,975	
Restricted cash		
Net cash provided (used) in investing activities	4,733	(207)
Financing activities		
Proceeds from notes payable	1,075	2,115
Principal payments of notes payable	(417)	
Net proceeds from issuance of common stock	30	29
Net cash provided by financing activities	688	2,144
Net decrease in cash and cash equivalents	(924)	(5,744)
Cash and cash equivalents at the beginning of period	18,839	38,275
Cash and cash equivalents at the end of period	$ 17,915	$ 32,531

Supplemental disclosure of cash flow information		
Cash paid for interest	$ 95	$

See accompanying notes.

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GENOMIC HEALTH, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2006
(Unaudited)

Note 1. Organization and Summary of Significant Accounting Policies

Genomic Health, Inc. (the Company) was incorporated in Delaware in August 2000. The Company was organized to deliver individualized genomic information to patients and their physicians to improve the quality of treatment decisions for patients with cancer.

Since the Company s inception in 2000, the focus of its operations has consisted principally of the development of initial products, raising capital, establishing facilities and recruiting personnel. In January 2004, the Company commercialized its first product, Onco*type* DX, a genomic service used to quantify the likelihood of recurrence in early stage breast cancer. The Company has incurred significant losses and expects to incur additional losses in the foreseeable future as commercial and development efforts continue.

Initial Public Offering

On October 4, 2005, the Company closed an initial public offering of 5,016,722 shares of its common stock at $12.00 per share. Net proceeds from the offering after deducting underwriting discounts, commissions and expenses were $53.5 million. On the closing of the Company s initial public offering, all of the convertible preferred stock outstanding automatically converted into 16,160,273 shares of common stock and a dividend of 654,046 common shares was distributed to stockholders.

An additional $5.0 million was raised on October 4, 2005, through the private sale of 416,666 shares of common stock to Incyte Corporation, a related party.

Reverse Stock Split

On September 23, 2005, the Company effected a 1-for-3 reverse split of its common stock. All common share and per share amounts have been retroactively restated in the accompanying consolidated financial statements and notes for all periods presented.

Dividend

On September 8, 2005, the Board of Directors of the Company declared a conditional dividend of 791,210 shares of common stock, which was allocated upon the closing of the Company s initial public offering on a pro rata basis to all of the Company s stockholders and option holders of record as of September 28, 2005. The Company issued 740,030 shares to its stockholders pursuant to this dividend at the closing of the initial public offering on October 4, 2005, less an aggregate of 86 shares for which cash was paid in lieu of fractional interests, and the number of shares underlying outstanding stock options were increased by approximately 51,080 shares, less any fractional shares resulting from such adjustment. The dividend has been given retroactive effect in the accompanying consolidated financial statements.

Basis of Presentation

The accompanying unaudited consolidated financial statements as of March 31, 2006 and for the three months ended March 31, 2006 have been prepared on the same basis as the annual financial statements. The unaudited consolidated balance sheet as of March 31, 2006 and consolidated statements of operations for the three months ended March 31, 2006 and 2005 and the consolidated statements of cash flows for the three months ended March 31, 2006 and 2005 are unaudited, but include all adjustments, consisting only of normal recurring adjustments, which we consider necessary for a fair presentation of the financial position, operating results and cash flows for the periods presented. The results for the three months ended March 31, 2006 are not necessarily indicative of results to be expected for the year ended December 31, 2006 or for any future interim period. The consolidated balance sheet at December 31, 2005 has been derived from audited statements. However, it does not include all of the information and notes required by accounting principles generally accepted in the United States for complete consolidated financial statements. The accompanying consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in the Company s Annual Report on Form 10-K for the year ended December 31, 2005.

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Stock-based Compensation

On January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment (or FAS 123R), which addresses the accounting for stock-based payment transactions whereby an entity receives employee services in exchange for equity instruments, including stock options. FAS 123R eliminates the ability to account for stock-based compensation transactions using the intrinsic value method under Accounting Principles Board Opinion (APB) No. 25, and instead generally requires that such transactions be accounted for using a fair-value based method. The Company has elected to use the modified prospective transition method as permitted under FAS 123R and, accordingly, prior periods have not been restated to reflect the impact of FAS 123R. The modified prospective transition method 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.

Equity instruments granted to nonemployees are valued using the Black-Scholes method and accounted for as prescribed by SFAS 123 and Emerging Issues Task Force (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.

Net Loss Per Share

Basic net loss per share is calculated by dividing the 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 the 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, preferred stock and options to purchase 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,	
	2006	**2005**
	(In thousands, except share and per share data) (Unaudited)	
Numerator:		
Net loss	$ (6,830)	$ (7,586)
Denominator:		
Weighted-average net common shares outstanding for basic and diluted loss per common share	24,480,267	1,970,202
Basic and diluted net loss per share	$ (0.28)	$ (3.85)
Historical outstanding dilutive securities not included in diluted net loss per share calculation		
Preferred stock		16,160,273
Options to purchase common stock	2,041,907	1,418,035
	2,041,907	18,232,353

Comprehensive Loss

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

	Three Months Ended March 31,	
	2006	2005
	(Unaudited)	
Net loss	$ (6,830)	$ (7,586)
Unrealized (loss) on available for sale securities	(76)	
Comprehensive loss	$ (6,906)	$ (7,586)

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Note 2. 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 services for Onco*type* DX. Cost recorded under these agreements for the three months ended March 31, 2005 and 2006 were $120,000 and $350,000, respectively, and were included in cost of product revenues.

Note 3. Commitments

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 the arrangement until April 2006, at which point it could prepay all, but not part, of the amounts outstanding under the arrangement so long as it 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. In March 2006, the Company increased the amount borrowed under this financing arrangement by $910,000.

As of March 31, 2006, the Company s aggregate commitments under its financing arrangement were as follows (in thousands):

	Annual Payment Amounts (Unaudited)
Years Ending December 31, 2006 (remainder of the year)	$ 1,285
2007	1,713
2008	1,563
2009	528
Total minimum payments	5,089
Less: interest portion	(758)
Present value of net minimum payments	4,331
Less: current portion of obligations	(1,313)
Long-term obligations	$ 3,018

Note. 4 Stock-Based Compensation

2005 Stock Incentive Plan

On September 8, 2005, the Board of Directors approved the 2005 Stock Incentive Plan (the 2005 Plan) that was later approved by the Company s stockholders. The Company has reserved 5,000,000 shares of the Company s common stock for issuance under the 2005 Plan. The 2005 Plan became effective upon the closing of the Company s initial public offering on October 4, 2005. Pursuant to the 2005 Plan, stock options, restricted shares, stock units, and stock appreciation rights may be granted to employees, consultants, and outside directors of the Company. Options granted may be either incentive stock options or nonstatutory stock options.

Stock options are governed by stock option agreements between the Company and recipients of stock options. Incentive stock options may be granted under the 2005 Plan at an exercise price of not less than 100% of the fair market value of the common stock on the date of grant, determined by the Compensation Committee of the Board of Directors. Nonstatutory stock options may be granted under the 2005 Plan at an exercise price of not less than 80% of the fair market value of the common stock on the date of grant, determined by the Compensation Committee of the Board of Directors. Options become exercisable and expire as determined by the Compensation Committee, provided

that the term of incentive stock options may not exceed 10 years from the date of grant. Stock option agreements may provide for accelerated exercisability in the event of an optionee s death, disability, or retirement or other events.

Under the 2005 Plan, each outside director who joins the board after the effective date of the 2005 Plan will receive an automatic nonstatutory stock option grant that vests at a rate of 25% at the end of the first year, with the remaining balance vesting monthly over

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the next three years. On the first business day following the annual meeting of the Company s stockholders, each outside director who is continuing board service and who was not initially elected to the board at the annual meeting will receive an additional nonstatutory stock option grant, which will vest in full immediately prior to the next annual meeting of the Company s stockholders. Nonstatutory stock options granted to outside directors must have an exercise price equal to 100% of the fair market value of the common stock on the date of grant. Nonstatutory stock options terminate on the earlier of the day before the tenth anniversary of the date of grant or the date twelve months after termination of the outside director s service as a member of the board of directors.

Restricted shares, stock appreciation rights, and stock units granted under the 2005 Plan are governed by restricted stock agreements, SAR agreements, and stock unit agreements between the Company and recipients of the awards. Terms of the agreements are determined by the Compensation Committee.

2001 Stock Incentive Plan

The Company s 2001 Stock Incentive Plan (the 2001 Plan) was terminated upon completion of the Company s initial public offering in October 2005. No shares of common stock are available under the 2001 Plan other than to satisfy exercises of stock options granted under the 2001 Plan prior to its termination. Under the 2001 Plan, incentive stock options and nonstatutory stock options were granted to employees, officers, and directors of, or consultants to, the Company and its affiliates. Options granted under the 2001 Plan expire no later than 10 years from the date of grant.

Adoption of FAS 123R

Employee stock-based compensation expense recognized in the first quarter of 2006 was calculated based on awards ultimately expected to vest and has been reduced for estimated forfeitures. FAS 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 Company recorded employee stock-based compensation expense of $569,000 for the three months ended March 31, 2006 as a result of the adoption of FAS 123R. 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, 2006:

(in thousands)	**For the Three Months Ended March 31, 2006 (Unaudited)**
Share-based compensation expense for stock options recorded in accordance with SFAS 123R for loss from operations:	
Cost of product revenues	$ 32
Research and development	175
Selling and marketing	156
General and administrative	206
Total	$ 569

The following table presents the impact of stock-based compensation due to the adoption of FAS 123R for the three months ended March 31, 2006:

	For the Three Months Ended March 31, 2006 (Unaudited)		
(in thousands)	**As Reported Under FAS 123R**	**Under APB 25**	**Difference**
Net loss	$ (6,830)	$ (6,545)	$ (285)

Net loss per share:			
Basic and diluted	$ (0.28)	$ (0.27)	$ (0.01)

Stock-based compensation expense resulting from the adoption of FAS 123R represents expense related to stock options granted during the first quarter of 2006, as well as stock options granted prior to, but not yet vested as of, January 1, 2006. As of March 31, 2006, total compensation cost related to non-vested stock options not yet recognized was $7.2 million, which is expected to be allocated to expenses over a remaining vesting periods, of 39 months.

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Pro Forma Information for Period Prior to Adoption of FAS 123R

The following pro forma net loss and loss per share were determined as if the Company had accounted for employee stock-based compensation for its employee stock option plans under the fair value method prescribed by FAS 123:

(in thousands)	Three Months Ended March 31, 2005 (Unaudited)
Net loss as reported	$ (7,586)
Add: Total stock-based employee compensation expense included in net loss	232
Deduct: Total stock-based employee compensation expense determined under the fair-value based method for all awards	(299)
Net loss	$ (7,653)
Net loss per share:	
Basic and diluted, as reported	$ (3.85)
Basic and diluted , pro forma	$ (3.88)

Valuation Assumptions

The employee stock-based compensation expense recognized under FAS 123R and presented in the pro forma disclosure required under FAS 123 was determined using the Black-Scholes option valuation model. Option valuation models require the input of highly subjective assumptions and these assumptions can vary over time. Expected volatility is based on comparable peer data as well as historical volatility of the Company s stock. The expected life of options granted is estimated based on historical option exercise and employee termination data. The weighted average fair values and the assumptions used in calculating such values during each fiscal period are as follows:

	Three Months Ended March 31,	
	2006	2005
	(Unaudited)	
Volatility factor	75%	80%
Risk-free interest rate	4.60%	4.00%
Dividend yield	0%	0%
Expected life of options	5 years	4 years
Weighted-average fair value	$7.49	$7.29

Stock Option Activity

The following is a summary of option activity for the first quarter of 2006:

	Shares Available for Grant	Shares Outstanding	Weighted Average Exercise Price
Balance at December 31, 2005	4,290,631	2,021,276	$ 4.75
Options granted	(73,150)	73,150	$ 11.69
Options exercised		(15,866)	$ 1.91
2001 Plan shares expired	(20,973)		

Options cancelled	36,653	(36,653)	$ 5.19
Balance at March 31, 2006	4,233,161	2,041,907	$ 5.04

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The following table summarizes information concerning outstanding and exercisable options under the 2001 and 2005 Plans as of March 31, 2006:

	Options Outstanding			Options Exercisable	
Exercise Price Range	Shares Outstanding	Weighted Average Years Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$0.58 $1.33	206,323	7.38	$ 1.10	168,084	$ 0.96
$1.33 $2.88	962,888	8.51	$ 2.20	292,140	$ 2.07
$3.17 $3.17	69,348	3.67	$ 3.17	21,671	$ 3.17
$9.39 $9.39	628,089	9.67	$ 9.39	0	$ 0.00
$9.55 $16.70	175,259	8.27	$ 10.93	2,449	$ 10.73
	2,041,907			484,344	

Deferred Stock-based Compensation

Prior to the adoption of FAS 123R, the Company presented deferred stock-based compensation as a separate component of stockholders equity. In accordance with the provisions of FAS 123R, on January 1, 2006 the Company reversed the balance in deferred compensation to additional paid-in capital on its balance sheet.

Stock Options Granted to Nonemployees

The Company grants options to consultants from time to time in exchange for services performed for the Company. During the three months ended March 31, 2006 and 2005, the Company granted options to purchase 2,350 and 0 shares, respectively, of common stock to consultants. The fair value of these option grants was determined using the Black-Scholes option pricing model using the following assumptions:

	Three Months Ended March 31,	
	2006	2005
	(Unaudited)	
Volatility factor	75%	80%
Average risk-free interest rate	4.60%	4.00%
Dividend yield	0%	0%
Expected life of options	10 years	10 years

In general, the options vest over the contractual period of the consulting arrangement and, therefore, the Company will revalue the options periodically and record additional compensation expense related to these options over the remaining vesting period. During the three months ended March 31, 2006 and 2005, compensation expense related to these options was $36,000 and $29,000, respectively.

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

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 quarter ended March 31, 2006 and our audited financial statements for the year ended December 31, 2005 included in our Annual Report on Form 10-K. 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; our expectation that our research and development expense levels will remain high as we seek to enhance Oncotype DX and develop new services; the level of investment in our sales force; our intention to expand capacity in our commercial laboratory; our dependence on collaborative relationships; our compliance with federal, state and foreign regulatory requirements; our expectation that product revenues will grow; how we intend to spend our existing cash and cash equivalents; our plans to borrow additional amounts under existing or new financing arrangements; the regulation of Oncotype DX by the U.S. Food and Drug Administration; 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; the factors that will drive broad market acceptance of our services and the establishment of coverage policies; the impact of changing interest rates; the amount of future revenues that we may derive from Medicare; 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; plans for, and the timeframe for the development of, future services addressing multiple cancers; the outcome or success of clinical trials; the ability of genomics to change the diagnosis and treatment of diseases and provide significant economic benefits to the healthcare system; the capacity of our laboratory to process services; the ability of our technology to screen increasing numbers of genes in tissue samples; our intellectual property and our strategies regarding filing additional patent applications to strengthen our intellectual property rights; our expected stock-based compensation expense in future periods; 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 projected. 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 products we may develop; the risks and uncertainties associated with the regulation of our products by the U.S. Food and Drug Administration; 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. The Company expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in the Company s 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.

The Genomic Health logo, Oncotype, Oncotype DX and Recurrence Score are trademarks or registered trademarks of Genomic Health, Inc. We also refer to trademarks of other corporations and organizations in this Report.

Business Overview

We are a life science company focused on the development and commercialization of genomic-based clinical diagnostic tests for cancer that allow physicians and patients to make individualized treatment decisions. Our first service, Onco*type* DX, is used for early stage breast cancer patients to predict the likelihood of cancer recurrence, the

likelihood of patient survival within 10 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. As of March 31, 2006, Onco*type* DX has been ordered by over 3,000 physicians throughout the United States. The list price of our service is $3,460.

We launched Onco*type* DX in January 2004 and initially made sales to a select number of physicians in a few markets in the United States through a small direct sales force. Late in 2004 and continuing into 2006, we have experienced a significant increase in demand for Onco*type* DX. In the year ended December 31, 2005, and the three months ended March 31, 2006, more than 7,000 and more than 2,900 services, respectively, were ordered by treating physicians. Since the commercial launch of Onco*type* DX more than

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10,000 test services have been delivered for use in treatment planning. We believe increased demand in 2005 resulted from the publication of our validation study in *The New England Journal of Medicine* and the presentation of our chemotherapy benefit study at the San Antonio Breast Cancer Symposium, both of which occurred in December 2004. We also experienced increased demand in the first quarter of 2006 following clinical presentations at the San Antonio Breast Cancer Symposium in December 2005 and the Miami Breast Cancer Symposium in February 2006. However, this increased demand for our product is not necessarily indicative of future growth rates, and we cannot assure you that this level of increased demand can be sustained or that appearances or presentations at medical conferences will have similar impact on demand for Onco*type* DX. Moreover, we believe that each year we may experience decreased demand for our service in the summer months of July and August, which may be attributed to physicians, surgeons and patients scheduling vacations during this time. As of March 31, 2006, our laboratory had the capacity to process up to 4,500 services per quarter, and our current expansion plan contemplates that we will have capacity to process up to 6,000 services per quarter by the end of 2006.

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 service, expanded reimbursement by third-party payors, expansion of our sales force and increased marketing efforts. Reimbursement of Onco*type* DX by third-party payors is essential to our commercial success. In general, clinical laboratory services, when covered, are paid under various methodologies, including prospective payment systems and fee schedules. Reimbursement from payors depends upon whether a service is covered under the patient s policy and if payment practices for the service have been established. As a relatively new service, Onco*type* DX may be considered investigational by payors and not covered under current reimbursement policies. Until we reach agreement with an insurer on contract terms or establish a policy for payment of Onco*type* DX, we expect to recognize revenue on a cash basis.

Upon commercialization of Onco*type* DX, we began working with third-party payors to establish reimbursement coverage policies. As of March 31, 2006, National Heritage Insurance Company (NHIC), the local Medicare carrier for California, with jurisdiction for claims submitted by the Company for Medicare patients issued a positive coverage determination, and several regional payors, including Harvard Pilgrim Health Care, Inc., Highmark Blue Cross and Premera Blue Cross had also issued policies supporting reimbursement for our service. In addition, Kaiser Foundation Health Plan, Inc. has entered into a national clinical laboratory services agreement to reimburse us for Onco*type* DX performed for their patients. Where policies are not in place, we pursue case-by-case reimbursement. We believe that as much as 20% of our future revenues may be derived from services billed to Medicare. We are working with many payors to establish policy-level reimbursement which, if in place, will allow us to recognize revenues upon completing our service and submitting an invoice. We do not expect to recognize the majority of revenues in this manner until 2007, at the earliest.

In July 2005 we signed a collaborative agreement with Bristol-Myers Squibb Company and ImClone Systems Incorporated to develop a genomic test to predict the likelihood of response to Erbitux in colorectal carcinoma. Erbitux is a targeted therapy currently approved for the treatment of metastatic colorectal carcinoma. The agreement provides for research funding support and milestone payments and gives us commercial rights to diagnostic tests that may result from the collaboration.

In July 2005 we signed a collaborative agreement with National Surgical Adjuvant Breast and Bowel Project (NSABP) to begin work in colon cancer using our clinical development platform. This is the same group with which we conducted our successful clinical validation studies in breast cancer which led to our Onco*type* DX. The agreement requires certain payments to be made by us during the research and development period. If the collaboration results in a commercial product, additional payments will be due upon first commercial sale and during commercialization of the product.

We entered into collaborative agreements with Aventis, Inc., a member of the sanofi-aventis group, and the Eastern Cooperative Oncology Group to investigate the ability of gene expression in fixed-paraffin-embedded tissues to predict the likelihood of response to adjuvant chemotherapy, including Taxotere, in patients with early breast cancer and zero to three involved lymph nodes. The agreements provide Genomic Health with commercial rights to diagnostic tests that may result from the collaboration and were effective as of December 1, 2005. Collaborative work

began between all three parties and revenue began to be recognized under these agreements in the first quarter of 2006.

Since our inception, we have generated significant net losses. As of March 31, 2006, we had an accumulated deficit of $103.0 million. We incurred a net loss of $6.8 million in the three months ended March 31, 2006. We expect our net losses to continue for at least the next several years. We anticipate that a substantial portion of our capital resources and efforts will be focused on research and development, both to develop additional tests for breast cancer and to develop products for other cancers, scale up our commercial organization, and 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

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services billed until such time as reimbursement policies or contracts are in effect. Until we receive routine reimbursement and are able to record revenues as services are preformed 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 and operate in one industry segment. Our product revenues are derived solely from the sale of Onco*type* DX. Payors are billed upon generation and delivery of a Recurrence Score report to the physician. Product revenues are recorded on a cash basis unless a contract or policy is in place with the payor at the time of billing and collectibility is reasonably assured. Contract revenues are derived from studies conducted with biopharmaceutical and pharmaceutical companies and are recorded on an accrual basis as contractual obligations are completed.

Cost of Product Revenues

Cost of product revenues represents the cost of materials, direct labor, 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 delivery 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 to 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 cancer are in the clinical research phase, and the earliest we expect another cancer program to reach the clinical development stage is later in 2006. However, the expected time frame that a product related to 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 program or project specific basis. Our research and development staff and associated infrastructure resources are deployed across several programs. Many of our costs are thus not attributable to individual programs. We believe that allocating costs on the basis of time incurred by our employees does not accurately reflect the actual costs of a project.

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 service 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 and other professional and administrative costs.

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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 U.S. generally accepted accounting principles. 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.

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 the commercial launch in January 2004 through March 31, 2006, have largely been recognized on a cash basis. We have historically recognized the majority of our product revenues on a cash basis because we have limited collection experience and a limited number of contracts. During the fourth quarter of 2005, the Company began to recognize some product revenue from private payors on an accrual basis. In the first quarter of 2006, a portion of Medicare-related product revenue was recognized on a accrual basis. In accordance with our policy, revenues for services performed will be recognized on an accrual basis when the related costs are incurred, provided there is a contract or coverage policy in place and the following criteria are met:

persuasive evidence that an arrangement exists;

delivery has occurred or services rendered;

the fee is fixed and determinable; and

collectibility is reasonably assured.

Determination of the last two criteria will be based on management s judgments regarding the nature of the fee charged for products or services delivered and the collectibility of those fees.

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 service, 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.

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 complete, 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, the Company adopted Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment (or FAS 123R). FAS 123R, which addresses the accounting for stock-based payment transactions whereby an entity receives employee services in exchange for equity instruments, including stock options. FAS 123R eliminates the ability to account for stock-based compensation transactions using the intrinsic value method under Accounting Principles Board Opinion (APB) No. 25, and instead generally requires that such transactions be accounted for using a fair-value based method. SFAS 123R is a new and very complex accounting standard, the application of which requires significant judgment and the use of estimates, particularly surrounding

assumptions used in determining fair value using the Black-Scholes valuation method, such as stock price volatility and expected options lives, as well as expected option forfeiture rates, to value equity-based compensation. There is little historical evidence or guidance available with respect to developing these assumptions and models. Expected volatility for the Company is based on comparable peer data as well as historical volatility of our stock. The expected life of options granted is estimated based on historical option exercise and employee termination data. There is also uncertainty as to how the

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standard will be interpreted and applied as more companies adopt the standard and companies and their advisors gain experience with the standard.

The Company has elected the modified prospective transition method as permitted under FAS 123R and, accordingly, prior periods have not been restated to reflect the impact of FAS 123R. The modified prospective transition method 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 FAS 123R represents expense related to stock options granted during the first quarter of 2006, as well as stock options granted prior to, but not yet vested as of, January 1, 2006. As of March 31, 2006, total compensation cost related to non-vested stock options not yet recognized was $7.2 million, which is expected to be recognized over a period of 39 months. Refer to Note 4 of notes to our consolidated financial statements included elsewhere in this report for further information.

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 comprised of work performed by our collaborators under contract terms. All clinical collaborators enter into agreements with us which specify work content and payment terms.

In addition to costs for research and development, under one of our collaboration agreements, we make annual payments resulting from the commercial launch of Onco*type* DX. These payments are recorded in cost of product revenues as a license payment. Expense is recorded ratably over the year in which the relevant payment is made. However, either party may terminate the agreement upon 30 days prior written notice. If this collaborative arrangement were not cancelable, a liability for the entire stream of remaining payments of $2.2 million would be recorded, payments would be made annually and expense would be recognized ratably through 2011.

Results of Operations

Three Months Ended March 31, 2006 and 2005

Revenues. Total revenues were $5.1 million for the three months ended March 31, 2006, as compared to $442,000 for the comparable period in 2005. Product revenues from Onco*type* DX were $4.2 million in the first quarter of 2006 compared to $442,000 for the comparable period in 2005. This increase resulted from increased demand and progress made in reimbursement for our service. Product revenues were primarily recognized upon cash receipt. Approximately 23 percent of product revenue in the first quarter of 2006 was recorded on an accrual basis as compared to none during the first quarter of 2005. Product revenue from Medicare represented 49 percent of total product revenue in the first quarter of 2006 as compared to none in the first quarter of 2005. This is a result of the February 27, 2006 effective coverage date for Medicare patients, as determined by Medicare s California contractor, and the receipt of payments in the quarter for services provided to Medicare patients prior to the effective coverage date. The majority of Medicare revenue in the quarter reflects Medicare payments for services performed prior to the effective date of the coverage decision. Prior to the effective date, approximately 1,300 Medicare services were performed and continued to be recognized on a cash basis. We have received retroactive payment for approximately one-third of these services as of March 31, 2006. We anticipate that additional retrospective payments from Medicare will be received in future quarters, some of which may be the result of test services for Medicare patients prior December 31, 2005; however, once these retroactive payments are received we do not expect Medicare-related payments to comprise as large a percentage of product revenues in future quarters. Revenue from services for Medicare patients after February 27, 2006 are recognized at the time the service is performed.

Contract revenues were $871,000 for the three months ended March 31, 2006, compared with none in the comparable period in 2005. Increased contract revenue reflects the initiation of the collaboration with sanofi-aventis and the Eastern Cooperative Oncology Group as well as ongoing work with Bristol-Myers Squibb and ImClone Systems. Contract revenues represent studies assessing our gene expression technology or collaborative work in gene selection and protocol design with our pharmaceutical partners

Cost of Product Revenues. For the three months ended March 31, 2006, cost of product revenues was $2.1 million for Onco*type* DX, consisting of tissue sample processing costs of $1.7 million and license fees of $350,000. For the three months ended March 31, 2005, cost of product revenues was $1.3 million, consisting of tissue sample processing

costs of $1.2 million and license fees of $120,000. During the three months ended March 31, 2006 and 2005, we recorded cost for Onco*type* DX that included direct material costs, direct labor costs, equipment 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.

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Research and Development Expenses. Research and development expenses increased to $2.7 million for the three months ended March 31, 2006, from $2.2 million for the comparable period in 2005. The increase in research and development expenses is primarily due to a $575,000 increase personnel and related costs and a $146,000 increase in collaboration expense partially offset by a $239,000 decrease in license payments. We expect that our research and development expenses will increase as investment in cancers other than breast cancer continue.

Selling and Marketing Expenses. Selling and marketing expenses increased to $5.1 million for the three months ended March 31, 2006, from $3.4 million for the comparable period in 2005. The increase is primarily due to a $1.3 million increase in personnel related costs, mostly to expand our domestic field sales organization, and $306,000 in higher travel expenses associated with field sales personnel. We expect that selling and marketing expenses will continue to increase in future periods. We plans to expand our field sales organization over the next couple of quarters which is an acceleration over our previous planned expansion timeline.

General and Administrative Expenses. General and administrative expenses increased to $2.6 million for the three months ended March 31, 2006 from $1.4 million for the comparable period 2005. The increase in general and administrative expenses is due to a $391,000 increase in personnel costs, an increase of $323,000 in billing and collection fees paid to third-party billing and collection vendors, an increase of $268,000 in legal and accounting fees, an increase of $116,000 in insurance related costs and an increase of $95,000 related to infrastructure costs. We expect general and administrative expenses to continue to grow due to increasing costs of billing and collections, complying with regulatory matters and other costs associated with the growth of our business.

Interest Income. Interest income was $691,000 for the three months ended March 31, 2006, compared with $196,000 in the comparable period in 2005. This increase of $495,000 was due to higher average cash balances from our initial public offering which closed in October 2005 and higher interests rates.

Interest Expense. Interest expense was $95,000 for the three months ended March 31, 2006, compared with zero in the comparable period in 2005. This increase resulted from the initiation of an equipment financing line established at the end of March 2005 under which draws have been made and interest expense has been incurred. No such arrangement existed in the comparable period in the prior year. We expect interest expense to increase as we make interest payments on borrowings under our equipment loan.

Liquidity and Capital Resources

Since our inception in August 2000, we have incurred significant losses and, as of March 31, 2006, we had an accumulated deficit of approximately $103.0 million. We have not yet achieved profitability and anticipate that we will continue to incur net losses for the foreseeable future. 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 revenues to achieve profitability. We may never achieve profitability.

Sources of Liquidity

Since our inception through March 31, 2006, we have received net proceeds of $103.2 million from the sale of preferred stock and $282,000 from the issuance of common stock to employees, consultants and directors in connection with the exercise of stock options. In October 2005, we completed our initial public offering and a concurrent private placement of our common stock, resulting in net proceeds of $58.5 million. Purchases of equipment and leasehold improvements have been partially financed through loans. At March 31, 2006 and December 31, 2005, cash, cash equivalents and short-term investments were $61.4 million and $69.5 million, respectively, and debt under our equipment loan was $4.3 million and $4.3 million, respectively.

Cash Flows

As of March 31, 2006, cash, cash equivalents and short-term investments were $61.4 million, compared to $32.5 million at March 31, 2005. This increase of $28.9 million was primarily due to net proceeds from our initial public offering of $53.5 million, proceeds from a sale of common stock of $5.0 million and proceeds from our equipment loans of $2.9 million, partially offset by cash used in operating activities of $26.3 million and purchases of property, equipment and leasehold improvements of $5.2 million.

Net cash used in operating activities was $6.3 million for the three months ended March 31, 2006, compared to $7.7 million for the three months ended March 31, 2005. The decrease in cash used in operating activities of $1.4 million was primarily due to a decrease

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in net loss of $756,000 and an increase in accrued other liabilities of $491,000, partially. The decrease in net loss resulted from an increase in cash collected for Onco*type* DX and from pharmaceutical collaborators of $4.6 million and an increase in net interest income of $400,000, partially offset by an increase in operating expenses of $4.2 million.

Net cash provided by investing activities was $4.7 million for the three months ended March 31, 2006, compared to $207,000 cash used in investing activities for the three months ended March 31, 2005. This increase of $4.9 million in cash provided was due to an increase of $7.2 million in short-term investments offset by an increase in cash used of $2.3 million for the acquisition of property and equipment and for leasehold improvements.

Net cash provided by financing activities during the three months ended March 31, 2006 was $688,000, compared to $2.1 million for the three months ended March 31, 2005. Substantially all amounts represented net proceeds from our equipment loan of $658,000 and $2.1 million for the three months ended March 31, 2006 and 2005, respectively.

Contractual Obligations

As of March 31, 2006, we had the following contractual commitments:

		Payments Due by Period			
Contractual Obligations	**Total**	**Less than 1 Year**	**1-3 Years**	**3-5 Years**	**More than 5 Years**
		(In thousands)			
Notes payable obligations	$ 5,089	$ 1,285	$ 3,276	$ 528	$
Operating lease obligations	4,579	728	1,500	1,589	762
Total	**$ 9,668**	**$ 2,013**	**$ 4,776**	**$ 2,117**	**$ 762**

In addition to the above, 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. The initial payment of $150,000 was made in January 2004. For a period of seven years on each anniversary of this first payment, we are required to make additional payments in increasing amounts. A payment of $150,000 was made in January 2005 and $300,000 was made in January 2006. We are required to make additional payments of $300,000 in 2007, and $475,000 in each of 2008 through 2011. However, either party may terminate the agreement upon 30 days prior written notice.

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 the borrowed amounts. We could not prepay any amounts owed until April 2006, at which point we could prepay all, but not part, of the amounts owing under the arrangement so long as we also pay a 6% premium on the remaining payments. This premium is reduced to 5% in 2007 and 4% in 2008. As of March 31, 2006, borrowings under this arrangement were $5.0 million at an annual interest rate of 10.23%, 10.30%, 10.49%, 10.56%, 10.65%, 11.01% or 11.18%, depending on the applicable note. As of March 31, 2006, we are required to make payments under this arrangement of $1.3 million in 2006, $1.7 million in 2007, $1.6 million in 2008 and $528,000 in 2009, all of which are included in the table above.

As March 31, 2006, we subleased approximately 25,000 square feet of laboratory and office space under a sublease that expired in February 2006. In September 2005, we entered into a new lease directly with the facility owner that has a term of six years. At the expiration of our sublease in February 2006, the new lease was for the existing 25,000 square feet of laboratory and office space we currently occupy. In March 2006, under the new lease, we lease approximately 23,000 square feet of additional space. Under the two lease agreements we are required to make aggregate rent payments of $728,000 in 2006, $730,000 in 2007, $753,000 in 2008, $779,000 in 2009 and $1.8 million in 2010 and thereafter, all of which are included in the table 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 up our commercial operations. It may take several years to move any one of a number of product candidates in clinical research through the development phase and validation phase 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 services outside the United States or reduction of debt obligations. We expect to spend approximately $4.0 million in 2006 for planned facility expansion and are

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considering an additional approximate $3.0 million in further facility expansion. 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.

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. We expect that we will receive limited payments for Onco*type* DX billings in the foreseeable future. As reimbursement contracts with third-party payors are 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 credit facility, will be sufficient to fund our operations and facility expansion plans for at least the next 12 months. We cannot be certain that any of our reimbursement contract programs or development of future products will be successful or that we will be able to raise sufficient additional funds to see these programs through to a successful result.

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

- the rate of progress in establishing reimbursement arrangements with third-party payors;
- the cost of expanding our commercial and laboratory operations, including our selling and marketing efforts;
- the rate of progress and cost of research and development activities associated with expansion of Oncotype DX for breast cancer;
- the rate of progress and cost of research and development activities associated with products in the research phase focused on cancers, other than breast cancer;
- the cost of acquiring or achieving access to tissue samples and technologies;
- the costs 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.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE 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 90 days at the date of acquisition, which mature within one year or less. As of March 31, 2006, we had cash, cash equivalents and short-term investments totaling $61.4 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, 2006, 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 (the Exchange Act), that are designed to ensure that information

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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 controls***. There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) identified in connection with the evaluation described in Item 4(a) above that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1A. RISK FACTORS.

We 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 year ended December 31, 2005 and the three months ended March 31, 2006, we had a net loss of $31.4 million and $6.8 million, respectively. From our inception in August 2000 through March 31, 2006, we had an accumulated deficit of approximately $103.0 million. To date, we have generated only minimal revenues, and we may never achieve revenues sufficient to offset expenses. We expect to devote substantially all of our resources to continue commercializing our existing product, Onco*type* DX, and to develop future products.

We expect to incur additional losses this year and in future years, and we may never achieve profitability. In addition, we have only recently begun to commercialize Onco*type* DX and 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 $9.5 million for the year ended December 31, 2005 and $2.7 million for the three months ended March 31, 2006. We expect our research and development expense levels to remain high for the foreseeable future as we seek to enhance our existing product and develop new products. As a result, we will need to generate significant revenues in order to achieve profitability. Our failure to achieve profitability in the future could cause the market price of our common stock to decline.

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

Oncotype DX has a 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,

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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 only 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 services 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, which provide healthcare coverage for nearly one-third of all Americans, as grounds to deny coverage for a service 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, 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 services provided on or after February 27, 2006.

The local coverage determination explains that most or all coverage decisions for Medicare beneficiaries related to the Onco*type* DX tests are made by the California Medicare contractor. However, there has been some question as to whether claims for Onco*type* DX tests performed on Medicare beneficiaries who were hospital patients at the time the tumor tissue sample was obtained may be billed by us to the California Medicare contractor or must be billed by the hospital to the Medicare contractor that processes the hospital s claims. In February 2005, CMS issued a notice that would affect how the date of service for a laboratory service is determined, which could also affect how payment is determined for various services. In December 2005, CMS issued an instruction to Medicare contractors to implement the February 2005 notice with an effective date of April 3, 2006. On February 23, 2006 the California Medicare contractor published an article clarifying that when Onco*type* DX is performed on a specimen collected during an inpatient admission and stored for less than 30 days prior to testing the Company should bill the hospital for the service rather than the Medicare contractor. As a result, for these services, we would be required to bill and be paid by the hospital, and the hospital s payment for the test would be included in the prospective payment for the inpatient admission. We have been working with Medicare program officials to address the hospital billing requirements, but we cannot be certain that CMS will make a favorable determination and allow us to bill for those cases. If we are not permitted to bill the California Medicare contractor for those cases, we would need to seek payment from the hospitals and the hospitals would be reimbursed for the test by Medicare. This could result in lower reimbursement rates for those cases.

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, most recently in November 2005. 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 cancel their contracts with us at any time or stop paying for our test which would reduce our revenue.

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If the U.S. Food and Drug Administration, or FDA, were to begin regulating our products, 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 premarket approval or we could experience decreased demand for or reimbursement of our test.

Clinical laboratory services like Onco*type* DX are regulated under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, as administered through the Center for Medicare/Medicaid Services, as well as by applicable state laws. Diagnostic kits that are sold and distributed as products 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 home brew tests. Most home brew tests currently are not subject to FDA regulation, although reagents or software provided by third parties and used to perform home brew tests may be subject to regulation. We believe that Onco*type* DX is not a diagnostic kit and also believe that it is a home brew test. As a result, we believe Onco*type* DX is not subject to regulation under current 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 premarket 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 the Company may fulfill any FDA premarket review requirements that may apply. The Company continues its ongoing dialogue with FDA with respect to the regulatory status of the Onco*type* DX breast cancer service. We have presented information regarding Onco*type* DX to FDA and believe that our services are appropriately regulated under CLIA. We cannot provide any assurance that FDA regulation, including premarket review, will not be required in the future for Onco*type* DX. If premarket 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 premarket approval. If our test is allowed to remain on the market but there is uncertainty about our test, orders or reimbursement may decline. The regulatory approval process may involve, among other things, successfully completing additional clinical trials and submitting a premarket clearance notice or filing a premarket approval application with FDA. If premarket 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, subject us to inspection by FDA and to the requirements of FDA and penalties for failure to comply with these requirements. Should any of the reagents obtained by us from vendors and used in conducting our home brew test be affected by future regulatory actions, our business could be adversely affected by those actions, including increasing cost of testing or delaying, limiting or prohibiting the purchase of reagents necessary to perform testing.

If we were required to conduct additional clinical trials prior to marketing our products, those trials could lead to delays or failure to obtain necessary regulatory approvals and harm our ability to become profitable.

If FDA decides to regulate our tests, it may require extensive premarket clinical testing prior to submitting a regulatory application for commercial sales. If we are required to conduct premarket clinical trials, whether using prospectively acquired samples or archival samples, delays in the commencement or completion of clinical testing could significantly increase our product development costs and delay product 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 products. 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 product, 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

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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.

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, 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 product, Oncotype DX, and we will need to generate sufficient revenues from this and other products to run our business.

For the foreseeable future, we expect to derive substantially all of our revenues from sales of one product, Onco*type* DX. We have only been selling this test since January 2004. We are in the early stages of research and development for other products that we may offer as well as for enhancements to our existing product. We are not currently able to estimate when we may be able to commercialize products 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 products or product 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 only a small number of physicians decide to adopt 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.

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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, based on our clinical trial results, that 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 only a small number of patients decide to use our test.

Some patients may decide not to order our test due to its list price of $3,460, 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 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, 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 continuously to develop new products and enhance existing products to keep pace with evolving standards of care. Our test could become obsolete unless we continually innovate and expand our product to demonstrate recurrence and treatment benefit in patients treated with new therapies. New treatment therapies typically have only a few years of clinical data associated with them, which limits our ability to perform clinical studies and correlate sets of genes to a new treatment s effectiveness. If we are unable to demonstrate the applicability of our tests to new treatments, then sales of our tests 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 tests. In return for the use of a third party s technology, we may agree to pay the licensor royalties based on sales of our products. Royalties are a component of cost of product revenues and impact the margin on our tests. 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.

We do not have any issued patents. Our pending patent applications may not result in issued patents, and we cannot assure you that 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.

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From time to time, the United States Supreme Court, other federal courts or the U.S. Patent and Trademark Office may change the standards of patentability. For example, at issue in a case pending before the United States Supreme Court, LabCorp v. Metabolite, is the question of whether the correlation between molecular markers, such as genes, and disease is patentable. There could be a negative impact on our business should these types of correlations not be patentable.

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.

From time to time, we may receive notices of claims of infringement, misappropriation or misuse of other parties proprietary rights. Some of these claims may lead to litigation. We cannot assure you that we will prevail in these 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 or using technology that contains the allegedly infringing intellectual property, which could harm our business.

One of the genes in the Onco*type* DX 21-gene panel may be the subject of a patent, the rights of which are exclusively licensed by a subsidiary of Pfizer Inc. We have initiated discussions with Pfizer and a licensor regarding a license of the patent but have not reached an agreement. If we are not able to negotiate a license on acceptable terms, and if our test is determined to infringe this patent, then we may be forced to develop an alternate method for performing our test. Revising our test may take more than a year and may require that we spend considerable amounts of money to develop a non-infringing gene panel and to validate our findings through a clinical study or studies. We may be forced to pay Pfizer royalties, damages and costs, or we may be prevented from selling our test altogether, which would greatly damage our business and operating results. Also, we are aware of other patents owned by Pfizer that relate to another gene in the Onco*type* DX 21-gene panel and are currently investigating whether any of the claims warrant a license. In addition, 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 companies, such as Agendia B.V., that offer products or have conducted research to profile gene expression in breast cancer using fresh or frozen tissue. 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 Healthcare LLC, Celera Genomics, a business segment of Applera Corporation, Roche

Diagnostics, a division of F. Hoffmann-La Roche Ltd, and Veridex LLC, a Johnson & Johnson company, other small 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.

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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. 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 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 the National Surgical Adjuvant Breast and Bowel Project, or 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. For example we have held discussions with the National Cancer Institute regarding conducting a large clinical study utilizing Onco*type* DX. 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 product development involves a lengthy and complex process, and we may be unable to commercialize any of the products we are currently developing.

We have multiple products under development and devote considerable resources to research and development. For example, we are currently conducting research on the application of our technology to predict recurrence and the therapeutic benefit of chemotherapy in colon, prostate, renal cell and lung cancers and melanoma. There can be no assurance that our technologies will be

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capable of reliably predicting the recurrence of cancers, beyond breast cancer, 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-up our laboratory processes.

This process involves a high degree of risk and takes several years. Our product development efforts may fail for many reasons, including:

failure of the product at the research or development stage;

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

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

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

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. The efforts of each of these persons 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 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. We maintain key-person life insurance only on Randal Scott, our Chief Executive Officer, Joffre Baker, our Chief Scientific Officer, and Steven Shak, our Chief Medical Officer. We may discontinue this insurance in the future, it may not continue to be available on commercially reasonable terms or, if continued, it may prove inadequate to compensate us for the loss of these individuals services.

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If our sole laboratory facility becomes inoperable, we will be unable to perform our tests and our business will be harmed.

We do not have redundant laboratory facilities. We perform all of our diagnostic services 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, 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 sole supplier for some of our laboratory instruments and may not be able to find replacements in the event our sole 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.

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

Since we only began the commercialization of Onco*type* DX in January 2004, we have limited experience in processing our test and even more limited experience in processing large volumes of tests. If demand for Onco*type* DX increases, we will be required 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

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procedures or to hire the necessary personnel could result in higher cost of processing or an inability to meet market demand. Since we have limited experience handling large volumes of Onco*type* DX tests, 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 product 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 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 products 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 currently depend on one third-party distributor to sell Onco*type* DX in Israel. 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 your ownership of us, 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,

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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 your interest in us. 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 products 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 product or enhancements to that product;

increasing our selling and marketing efforts to drive market adoption and address competitive developments;

expand our clinical laboratory operations;

expand our technologies into other areas of cancer;

fund our clinical validation study activities;

expand our research and development activities;

acquire or license technologies; and

finance capital expenditures and our general and administrative expenses.

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

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

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

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

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

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.

Our operating results may fluctuate, which could cause our stock price to decrease.

Fluctuations in our operating results may lead to fluctuations, including declines, in our share price. Our operating results and our share price may fluctuate from period to period due to a variety of factors, including:

demand by physicians and patients for Onco*type* DX;

reimbursement decisions by third-party payors and announcements of those decisions;

clinical trial results and publication of results in peer-reviewed journals or the presentation at medical conferences;

the inclusion or exclusion of our services in large clinical trials conducted by others;

new or less expensive services or new technology introduced or offered by our competitors or us;

the level of our development activity conducted for new services, and our success in commercializing these developments;

the level of our spending on Onco*type* DX commercialization efforts, licensing and acquisition initiatives, clinical trials, and internal research and development;

changes in the regulatory environment, including any announcement from FDA regarding a decision to regulate our activities;

the impact of seasonality on our business;

changes in recommendations of securities analysts or lack of analyst coverage;

failure to meet analyst expectations regarding our operating results;

additions or departures of key personnel; and

general market conditions

Variations in the timing of our future revenues and expenses could also cause significant fluctuations in our operating results from period to period and may result in unanticipated earning shortfalls or losses. In addition, the Nasdaq National Market in general, and the market for life science companies in particular, have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies.

In addition, future sales of common stock by our officers, including sales under Rule 10b5-1 sales plans, sales of substantial amounts of our common stock by insiders or other stockholders in the public market or otherwise or the awareness that a large number of shares is available for sale, could adversely affect the market price of our common stock.

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We must implement additional and expensive finance and accounting systems, procedures and controls as we grow our business and organization and to satisfy 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. We are required to comply as of December 31, 2006. Compliance with Section 404 of the Sarbanes-Oxley Act and other requirements will increase our costs and require additional management resources. We recently have been upgrading our finance and accounting systems, procedures and controls and will need to continue to implement additional finance and accounting systems, procedures and controls as we grow our business and organization and to satisfy new reporting requirements. If we are unable to complete the required Section 404 assessment as to the adequacy of our internal control over financial reporting, if we fail to maintain or implement adequate controls, 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 as of the date of our first Form 10-K for which compliance is required, our ability to obtain additional financing could be impaired. In addition, investors could lose confidence in the reliability of our internal control over financial reporting and in the accuracy of our periodic reports filed under the Exchange Act. A lack of investor confidence in the reliability and accuracy of our public reporting could cause our stock price to decline.

ITEM 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 SEC. The closing was October 4, 2005, the net offering proceeds to us were approximately $53.5 million. Through March 31, 2006, $9.5 million of the net proceeds were used to build our commercial capabilities in selling and marketing related to Onco*type* DX, $5.2 million were used to fund research and development programs for Onco*type* DX and in other cancers, $2.6 million to expand facilities and laboratory operations capacity and for information systems infrastructure and no funds were used for working capital and general corporate purposes. A portion of the net proceeds may also be used to acquire or invest in complementary businesses, technologies, services or products. Pending use for these or other purposes, net proceeds have been invested in interest bearing, investment grade securities.

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 purpose 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.

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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 15, 2006

By: /s/ Randal W. Scott

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

Date: May 15, 2006

By: /s/ G. Bradley Cole

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

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GENOMIC HEALTH, INC.
EXHIBIT INDEX

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