GENOMIC HEALTH INC
Form 10-Q
August 07, 2009

Table of Contents

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

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

For the quarterly period ended June 30, 2009

Or

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

For the transition period from _____ to _____

Commission File Number: 000-51541

GENOMIC HEALTH, INC.

(Exact name of registrant as specified in its charter)

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

301 Penobscot Drive
Redwood City, California 94063
(Address of principal executive offices, including Zip Code)

(650) 556-9300
(Registrant s telephone number, including area code)

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

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

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

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

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

The number of outstanding shares of the registrant s Common Stock, $0.0001 par value, was 28,558,428 as of July 31, 2009.

GENOMIC HEALTH, INC.
INDEX

Table of Contents

PART 1: FINANCIAL INFORMATION

Item 1. Financial Statements

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

	June 30, 2009 (Unaudited)	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,366	$ 11,171
Short-term investments	44,363	45,499
Accounts receivable (net of allowance for doubtful accounts; June 30, 2009 - $624, December 31, 2008 - $881)	7,938	8,807
Prepaid expenses and other current assets	5,195	4,781
Total current assets	68,862	70,258
Property and equipment, net	13,869	15,562
Restricted cash	500	500
Other assets	337	369
Total assets	$ 83,568	$ 86,689
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 2,531	$ 1,898
Accrued compensation	5,929	4,157
Accrued license fees	2,392	2,553
Accrued expenses and other current liabilities	5,126	4,398
Notes payable current portion	835	1,814
Deferred revenues current portion	1,492	2,381
Other current liabilities	364	364
Total current liabilities	18,669	17,565
Notes payable long-term portion	105	225
Deferred revenues long-term portion	476	1,417
Other liabilities	1,113	1,307
Commitments (Note 5)		
Stockholders equity:		
Preferred stock, $0.0001 par value per share, 5,000,000 shares authorized, none issued and outstanding at June 30, 2009 and December 31, 2008		
Common stock, $0.0001 par value per share, 100,000,000 shares authorized, 28,555,977 and 28,461,327 shares issued and outstanding at June 30, 2009 and December 31, 2008, respectively	2	2
Additional paid-in capital	240,165	234,412
Accumulated other comprehensive income	90	245
Accumulated deficit	(177,052)	(168,484)

Total stockholders equity	63,205	66,175
Total liabilities and stockholders equity	$ 83,568	$ 86,689

See accompanying notes.

Table of Contents

GENOMIC HEALTH, INC.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Revenues:				
Product revenues	$ 35,191	$ 26,327	$ 68,618	$ 49,682
Contract revenues	1,361	1,456	1,830	1,541
Total revenues	36,552	27,783	70,448	51,223
Operating expenses:				
Cost of product revenues	7,891	6,850	15,719	12,734
Research and development	9,243	7,322	17,888	13,728
Selling and marketing	15,709	11,827	30,406	24,194
General and administrative	7,651	6,225	14,989	12,130
Total operating expenses	40,494	32,224	79,002	62,786
Loss from operations	(3,942)	(4,441)	(8,554)	(11,563)
Interest and other income	213	448	462	1,069
Interest and other expense	(34)	(106)	(86)	(239)
Loss before income taxes	(3,763)	(4,099)	(8,178)	(10,733)
Provision for income taxes	(180)		(390)	
Net loss	$ (3,943)	$ (4,099)	$ (8,568)	$ (10,733)
Basic and diluted net loss per share	$ (0.14)	$ (0.15)	$ (0.30)	$ (0.38)
Shares used in computing basic and diluted net loss per share	28,540,832	28,262,407	28,518,518	28,239,908

See accompanying notes.

Table of Contents

GENOMIC HEALTH, INC.

Condensed Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Six Months Ended June 30,	
	2009	**2008**
Operating activities		
Net loss	$ (8,568)	$ (10,733)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	3,175	2,220
Employee stock-based compensation	5,056	4,541
Non-employee stock-based compensation	34	1
Gain on disposal of property and equipment	(43)	
Changes in assets and liabilities:		
Accounts receivable	869	(2,271)
Prepaid expenses and other assets	(409)	(1,518)
Accounts payable	633	(53)
Accrued expenses and other liabilities	555	1,617
Accrued compensation	1,772	482
Deferred revenues	(1,830)	3,160
Lease incentive obligations	(182)	508
Net cash provided by (used in) operating activities	1,062	(2,046)
Investing activities		
Purchases of property and equipment	(1,412)	(4,823)
Purchases of short-term investments	(31,319)	(73,569)
Maturities of short-term investments	32,300	59,299
Net cash used in investing activities	(431)	(19,093)
Financing activities		
Principal payments of notes payable	(1,099)	(1,381)
Proceeds from issuance of common stock under stock plans	663	578
Net cash used in financing activities	(436)	(803)
Net increase (decrease) in cash and cash equivalents	195	(21,942)
Cash and cash equivalents at the beginning of the period	11,171	39,164
Cash and cash equivalents at the end of the period	$ 11,366	$ 17,222
Cash paid for interest	$ 86	$ 230

See accompanying notes.

Table of Contents

GENOMIC HEALTH, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
June 30, 2009
(Unaudited)

Note 1. Organization and Summary of Significant Accounting Policies

The Company

Genomic Health, Inc. (the Company) is a life science company focused on the development and commercialization of genomic- based clinical diagnostic tests for cancer that allow physicians and patients to make individualized treatment decisions. In 2004, the Company launched its first test, the Onco*type* DX breast cancer test, which has been shown to predict the likelihood of breast cancer recurrence and the likelihood of chemotherapy benefit in a large portion of breast cancer patients. The Company was incorporated in Delaware in August 2000 and is located in Redwood City, California.

Principles of Consolidation

The condensed consolidated financial statements include all the accounts of the Company and its wholly-owned subsidiaries. The Company has two wholly-owned subsidiaries, Genomic Health Switzerland LLC, which was established in 2009 to support the Company s international sales and marketing efforts, and Onco*type* Laboratories, Inc., which was established in 2003 and is inactive. All significant intercompany balances and transactions have been eliminated.

Basis of Presentation and Use of Estimates

The accompanying interim period condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). The condensed consolidated balance sheet as of June 30, 2009, condensed consolidated statements of operations for the three and six months ended June 30, 2009 and 2008 and condensed consolidated statements of cash flows for the six months ended June 30, 2009 and 2008 are unaudited, but include all adjustments, consisting only of normal recurring adjustments, which the Company considers necessary for a fair presentation of its financial position, operating results and cash flows for the periods presented. The condensed consolidated balance sheet at December 31, 2008 has been derived from audited financial statements. However, it does not include certain information and notes required by GAAP for complete consolidated financial statements. In preparing these financial statements, the Company has evaluated events and transactions for potential recognition or disclosure through August 7, 2009, the date these financial statements were issued.

The preparation of financial statements in conformity with GAAP requires management to make judgments, assumptions and estimates that affect the amounts reported in the Company s condensed consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates.

Revenue Recognition

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

The Company s product revenues for tests performed are recognized when the following revenue recognition criteria are met: (1) persuasive evidence that an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectibility is reasonably assured. Criterion (1) is satisfied when the Company has an arrangement to pay or contract with the payor in place addressing reimbursement for the Onco*type* DX breast cancer test. In the absence of such arrangements, the Company considers that criterion (1) is satisfied when a third-party payor pays the Company for the test performed. In addition, the Company must receive a written request to perform the test from a physician. Criterion (2) is satisfied when the Company performs the test and generates and delivers to the physician, or makes available on its web portal, a Recurrence Score report.

Determination of criteria (3) and (4) is based on management s judgments regarding whether the fee charged for products or services delivered is fixed or determinable, contractual agreements entered into, and the collectibility of those fees under any contract or agreement. When

Table of Contents

evaluating collectibility, the Company considers whether it has sufficient history to reliably estimate a payor s individual payment patterns. Based upon at least several months of payment history, the Company reviews the number of tests paid against the number of tests billed and the payor s outstanding balance for unpaid tests to determine whether payments are being made at a consistently high percentage of tests billed and at appropriate amounts given the contracted payment amount. To the extent all criteria set forth above are not met when test results are delivered, product revenues are recognized when cash is received from the payor.

The Company recognizes a portion of its product revenues on an accrual basis when the criteria (3) and (4) described in the preceding paragraph are satisfied. For all periods presented, approximately half of total product revenue recognized was recorded on an accrual basis.

From time to time, Company receives requests for refunds. When it becomes aware of a request for a refund, Company ceases to record revenue for those payments until such time it determines whether or not a refund is due.

Contract revenues are generally derived from studies conducted with biopharmaceutical and pharmaceutical companies. The specific methodology for revenue recognition is determined on a case-by-case basis according to the facts and circumstances applicable to a given contract. Under certain contracts, the Company s input, measured in terms of full-time equivalent level of effort or running a set of assays through its clinical reference laboratory under a contractual protocol, triggers payment obligations, and revenues are recognized as costs are incurred or assays are processed. Certain contracts have payments that are triggered as milestones are completed, such as completion of a successful set of experiments. Milestones are assessed on an individual basis and revenue is recognized when these milestones are achieved, as evidenced by acknowledgment from collaborators, provided that (1) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement and (2) the milestone payment is non-refundable. Where separate milestones do not meet these criteria, the Company typically defaults to a performance-based model, such as revenue recognition following delivery of effort as compared to an estimate of total expected effort.

Advance payments received in excess of revenues recognized are classified as deferred revenue until such time as the revenue recognition criteria have been met.

Allowance for Doubtful Accounts

The Company accrues an allowance for doubtful accounts against its accounts receivable consistent with historical payment experience. Bad debt expense is included in general and administrative expense on the Company s condensed consolidated statements of operations. Accounts receivable are written off against the allowance when the appeals process is exhausted, when an unfavorable coverage decision is received or when there is other substantive evidence that the account will not be paid. As of June 30, 2009 and December 31, 2008, the Company s allowance for doubtful accounts was $624,000 and $881,000, respectively. Write-offs for doubtful accounts of $475,000 and $800,000 were recorded against the allowance during the three and six months ended June 30, 2009, respectively, and $7,000 and $138,000 during the three and six months ended June 30, 2008, respectively. Bad debt expense was $395,000 and $543,000 for the three and six months ended June 30, 2009, respectively and $273,000 and $357,000 for the three and six months ended June 30, 2008, respectively.

Research and Development Expenses

Research and development expenses are comprised of the following types of costs incurred in performing research and development activities: salaries and benefits, allocated overhead and facility occupancy costs, contract services, reagents and laboratory supplies, and costs to acquire in-process research and development projects and technologies that have no alternative future use. Research and development expenses also include costs related to activities performed under contracts with biopharmaceutical and pharmaceutical companies. Research and development costs are expensed as incurred.

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

Emerging Issues Task Force Issue No. 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1), was ratified by the Financial Accounting Standards Board (FASB) in November 2007 and adopted by the Company as of January 2009. EITF 07-1

Table of Contents

defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-1 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from, or made to, other collaborators based on applicable GAAP or, in the absence of applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. The adoption of EITF 07-1 did not have a material effect on the Company s condensed consolidated financial statements.

Recently Issued Accounting Pronouncements

In April 2009, FASB issued three related Staff Positions: (i) FASB Staff Position 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability have Significantly Decreased and Identifying Transactions That Are Not Orderly* (FSP 157-4), (ii) FASB Staff Position FAS 115-2 and FAS 124-2, *Recognition and Presentation of Other-Than-Temporary Impairment* (FSP FAS 115-2 and FAS 124-2), and (iii) FASB Staff Position FAS 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instrument*s (FSP FAS 107-1 and APB 28-1), which are effective for interim and annual periods ending after June 15, 2009. FSP 157-4 provides guidance on how to determine the fair value of assets and liabilities under Statement of Financial Accounting Standards No. 157, *Fair Value Measurements* (SFAS 157) in the current economic environment and reemphasizes that the objective of a fair value measurement remains an exit price. FSP FAS 115-2 and FAS 124-2 modifies the requirements for recognizing other-than-temporarily impaired debt securities and revises the existing impairment model for such securities. FSP FAS 107-1 and APB 28-1 enhances the disclosure of instruments under the scope of SFAS 157 for both interim and annual periods. The Company s adoption of these Staff Positions as of June 30, 2009 did not have a material impact on its financial condition or results of operations.

In May 2009, FASB issued Statement of Financial Accounting Standards No. 165, *Subsequent Events* (SFAS 165). SFAS 165 establishes general standards for accounting disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued and applies to both interim and annual financial statements. SFAS 165 is effective for interim or annual financial periods ending after June 15, 2009 and was adopted by the Company as of June 30, 2009. The adoption of SFAS 165 did not have a material impact on the Company s financial condition or results of operations.

In June 2009, FASB issued Statement of Financial Accounting Standards No. 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles*, a replacement of FASB Statement No. 162 (SFAS 168). SFAS 168 establishes the FASB Accounting Standards Codification (Codification) as the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in the preparation of financial statements in conformity with GAAP. Certain accounting standards have allowed for the continued application of superseded accounting standards for transactions that have an ongoing effect in an entity s financial statements. That superseded guidance has not been included in the Codification, shall be considered grandfathered, and shall continue to remain authoritative for those transactions after the effective date of this Statement, which is for financial statements issued for interim and annual periods ending after September 15, 2009. The Company does not expect the adoption of SFAS 168 to have a material impact on its financial condition or results of operations.

Table of Contents

Note 2. Net Loss Per Share

Basic net loss per share is calculated by dividing net loss for the period by the weighted-average number of common shares outstanding for the period without consideration for potential common shares. Diluted net loss per share is calculated by dividing net loss by the weighted-average number of common shares outstanding for the period and dilutive potential common shares for the period determined using the treasury-stock method. For purposes of this calculation, options to purchase common stock are considered to be potential common shares but are not included in the calculation of diluted net loss per share because their effect is anti-dilutive.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
	(In thousands, except share and per share amounts)			
Net loss	$ (3,943)	$ (4,099)	$ (8,568)	$ (10,733)
Weighted-average net common shares outstanding for basic and diluted loss per common share	28,540,832	28,262,407	28,518,518	28,239,908
Basic and diluted net loss per share	$ (0.14)	$ (0.15)	$ (0.30)	$ (0.38)
Outstanding dilutive securities not included in diluted net loss per share calculation (at end of period):				
Options to purchase common stock	4,730,556	3,931,216	4,730,556	3,931,216

Comprehensive Loss

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
	(In thousands)			
Net loss	$ (3,943)	$ (4,099)	$ (8,568)	$ (10,733)
Unrealized gain (loss) on available-for-sale securities	(23)	(121)	(155)	(60)
Comprehensive loss	$ (3,966)	$ (4,220)	$ (8,723)	$ (10,793)

Note 3. Fair Value Measurements

In September 2006, FASB issued SFAS 157, which defines fair value, establishes a framework for measuring fair value and requires expanded disclosures regarding fair value measurements. SFAS 157 applies whenever standards require (or permit) assets or liabilities to be measured at fair value, and does not expand the use of fair value in any new circumstances. The Company adopted SFAS 157 as of January 1, 2008 for financial assets and liabilities measured at fair value and as of January 1, 2009 for non-financial assets and liabilities measured at fair value. There was no financial statement impact as a result of these adoptions.

SFAS 157 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability, or an exit price, in the principal or most advantageous market for that asset or liability in an orderly transaction between market participants on the measurement date. SFAS 157 also establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

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

Table of Contents

Level 2: Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The following tables set forth the Company s financial instruments that were measured at fair value on a recurring basis at June 30, 2009 and December 31, 2008 by level within the fair value hierarchy. The Company did not have any non-financial assets or liabilities that were measured or disclosed at fair value on a recurring basis at June 30, 2009 or December 31, 2008. As required by SFAS 157, assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company s assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and considers factors specific to the asset or liability:

	Actively Quoted Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	Balance at June 30, 2009
		(In thousands)		
As of June 30, 2009				
Assets				
Money market deposits	$ 7,141	$	$	$ 7,141
Debt securities of U.S. Government-sponsored agencies		40,614		40,614
Commercial paper		3,749		3,749

	Actively Quoted Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	Balance at December 31, 2008
		(In thousands)		
As of December 31, 2008				
Assets				
Money market deposits	$ 5,926	$	$	$ 5,926
U.S. Treasury securities	1,004			1,004
Debt securities of U.S. Government-sponsored agencies		37,350		37,350
Commercial paper		8,149		8,149
Corporate bonds		1,000		1,000

Cash Equivalents and Short-term Investments

The Company considers all highly liquid investments with maturities of three months or less when purchased to be cash equivalents.

The Company invests in marketable securities, primarily money market securities, obligations of U.S. Government agencies and government-sponsored entities, corporate bonds and commercial paper. The Company considers all investments with a maturity date less than one year as of the balance sheet date to be short-term investments. These securities are carried at estimated fair value with unrealized gains and losses included in stockholders equity. Those investments with a maturity date greater than one year as of the balance sheet date are considered to be long-term investments. All investments are classified as available for sale.

Realized gains and losses and declines in value, if any, judged to be other than temporary on available-for-sale securities are reported in other income or expense. When securities are sold, any associated unrealized gain or loss recorded as a separate

Table of Contents

component of stockholders equity is reclassified out of stockholders equity on a specific-identification basis and recorded in earnings for the period.

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

	June 30, 2009			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
		(In thousands)		
Debt securities of U.S. Government-sponsored agencies	$ 40,724	$ 120	$ (229)	$ 40,614
Commercial paper	3,707	41		3,749
Total	$ 44,431	$ 161	$ (229)	$ 44,363

	December 31, 2008			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
		(In thousands)		
Debt securities of U.S. Government-sponsored agencies	$ 37,144	$ 209	$ (3)	$ 37,350
Corporate debt securities	8,110	42	(3)	8,149
Total	$ 45,254	$ 251	$ (6)	$ 45,499

The Company had no realized gains or losses on its available-for-sale securities for the three and six months ended June 30, 2009 and 2008, respectively.

The amortized cost and estimated fair value of available-for-sale securities by contractual maturity at June 30, 2009 was as follows:

	June 30, 2009	
	Cost	Market Value
	(In thousands)	
Due in one year or less	$44,431	$44,363

Note 4. Commercial Technology and Licensing Agreements

The Company is a party to various agreements under which it licenses technology on a nonexclusive basis in the field of human diagnostics. Access to these licenses enables the Company to process its Onco*type* DX breast cancer tests. While certain agreements contain provisions for fixed annual payments, license fees are generally calculated as a percentage of product revenues, with rates that vary by agreement and may be tiered, and payments that may be capped at annual minimum or maximum amounts. The Company recognized costs recorded under these agreements of $2.4 million and $4.7 million for the three and six months ended June 30, 2009, respectively and $1.9 million and $3.6 million for the three and six months ended June 30, 2008, respectively, which were included in cost of product revenues.

Note 5. Commitments

Notes Payable

In March 2005, the Company entered into an arrangement to finance the acquisition of laboratory and office equipment, computer hardware and software and leasehold improvements. In connection with this arrangement, the Company granted the lender a security

Table of Contents

interest in the assets purchased with the borrowed amounts. The Company can prepay all, but not part of, the amounts outstanding under the arrangement so long as the Company also pays a 4% premium on the outstanding principal balance. As of June 30, 2009, the outstanding notes payable principal balance under this arrangement was $940,000 at annual interest rates ranging from 11.01% to 11.30%, depending on the applicable note. According to the terms of the arrangement, the Company is required to notify the lender if there is a material adverse change in its financial condition, business or operations. The Company believes it has complied with all the material covenants of the financing arrangement as of June 30, 2009.

As of June 30, 2009, the Company s aggregate commitments under its financing arrangement were as follows:

	Annual Payments (In thousands) (Unaudited)
Years Ending December 31,	
2009 (remainder of the year)	$ 749
2010	238
Total minimum payments	987
Less: interest portion	(47)
Present value of net minimum payments	940
Less: current portion of obligations	(835)
Long-term obligations	$ 105

Lease Obligations

In September 2005, the Company entered into a non-cancelable lease for 48,000 square feet of laboratory and office space that the Company occupies in Redwood City, California. The lease expires in February 2012 and includes lease incentive obligations of $834,000 that are being amortized on a straight-line basis over the life of the lease. In connection with this lease, the Company was required to secure a $500,000 letter of credit, which is classified as restricted cash on the condensed consolidated balance sheets.

In January 2007, the Company entered into a non-cancelable lease for an additional 48,000 square feet of laboratory and office space in a nearby location. The lease expires in February 2012 and includes lease incentive obligations totaling $283,000 that are being amortized on a straight-line basis over the life of the lease. In connection with this lease, the Company paid a $151,000 cash security deposit, which is included in other assets on the condensed consolidated balance sheets.

Future non-cancelable commitments under these operating leases at June 30, 2009 were as follows:

	Annual Payments (In thousands) (Unaudited)
Years Ending December 31,	
2009 (remainder of the year)	$ 774
2010	1,634
2011	1,723
2012	290

Total minimum payments	$	4,421

Clinical Collaborator Costs

The Company has entered into a variety of collaboration and specimen transfer agreements relating to its development efforts. The Company recorded expenses of $891,000 and $1.5 million for the three and six months ended June 30, 2009, respectively, and $416,000 and $493,000 for the three and six months ended June 30, 2008, respectively, relating to services provided in connection with these agreements, which are included in research and development expenses. In addition to these expenses, certain agreements

Table of Contents

contain provisions for royalties from inventions resulting from these agreements. The Company has certain options and rights relating to joint inventions arising out of these agreements.

In addition to costs for research and development, under one of our collaboration agreements, we make fixed annual payments resulting from the launch and commercialization of the Onco*type* DX breast cancer test. At June 30, 2009, future payments remaining under this agreement totaled $950,000, of which $475,000 is payable in January 2010 and $475,000 is payable in January 2011. These payments are recorded in cost of product revenues as license fees. Expense is recorded ratably over the year before the relevant payment is made. If at any time the Company discontinues the sale of the Onco*type* DX breast cancer test, no future annual payments will be payable and the Company will have no further obligation under the agreement. If the Company s cash balance is less than $5.0 million on the due date of any of the annual payments, the Company may be able to defer any current annual payment due for a period of up to 12 months.

Note 6. Stock-Based Compensation

Stock Incentive Plan

On September 8, 2005, the Board of Directors approved the 2005 Stock Incentive Plan (the 2005 Plan), which was later approved by the Company s stockholders. The Company initially 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. On June 8, 2009, the Company s stockholders approved an amendment to the 2005 Plan to increase the shares reserved for issuance under the 2005 Plan by 3,980,000 shares. The amended and restated plan also extends the term under which awards may be granted under the 2005 Plan until January 27, 2019. As of June 30, 2009, the 2005 Plan provides for the issuance of a maximum of 8,980,000 shares, of which 4,874,939 shares of common stock were then available for future issuance.

Stock Options

The Company uses the Black-Scholes option valuation model to value stock options under Statement of Financial Accounting Standards No. 123 (Revised 2004), *Share-Based Payment* (SFAS 123R). The Company recorded stock-based compensation expense of $2.5 million and $5.1 million for the three and six months ended June 30, 2009, respectively, and $2.3 million and $4.5 million for the three and six months ended June 30, 2008, respectively. Stock-based compensation expense was calculated based on awards ultimately expected to vest and has been reduced for estimated forfeitures. SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The following table presents the impact of SFAS 123R on selected statements of operations line items for the three and six months ended June 30, 2009 and 2008:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
	(In thousands)			
Cost of product revenues	$ 88	$ 125	$ 181	$ 239
Research and development	770	720	1,540	1,455
Selling and marketing	798	648	1,595	1,278
General and administrative	880	792	1,740	1,569
Total stock-based compensation expense	$ 2,536	$ 2,285	$ 5,056	$ 4,541

Stock-based compensation expense resulting from the adoption of SFAS 123R represents expense related to stock options granted on or after January 1, 2006, as well as stock options granted prior to, but not yet vested as of, January 1, 2006. As of June 30, 2009, total unrecognized compensation expense related to unvested stock options, net of estimated forfeitures, was $20.6 million. The Company expects to recognize this expense over a weighted-average

period of 35 months.

Table of Contents

Valuation Assumptions

Option valuation models require the input of highly subjective assumptions that can vary over time. The Company s expected volatility is based on the historical volatility of the Company s common stock. The expected life of options granted is estimated based on historical option exercise data and assumptions related to unsettled options. The risk-free interest rate is estimated using published rates for U.S. Treasury securities with a remaining term approximating the expected life of the options granted. The Company uses a dividend yield of zero as it has never paid cash dividends and does not anticipate paying cash dividends in the foreseeable future. The Company granted options to purchase 80,350 and 207,550 shares of common stock to employees and directors during the three and six months ended June 30, 2009, respectively. The Company granted options to purchase 154,600 and 198,200 shares of common stock to employees and directors during the three and six months ended June 30, 2008, respectively. The weighted-average fair values and the assumptions used in calculating such values for stock options granted during these periods were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
	(Unaudited)			
Expected volatility	55%	60%	56%	60%
Risk-free interest rate	2.73%	3.22%	2.17%	3.14%
Expected life of options in years	5.60	5.74	5.76	5.77
Weighted-average fair value	$9.57	$10.95	$10.30	$11.19

Stock Options Exercised

For the three and six months ended June 30, 2009, the Company issued 34,360 and 94,650 shares of common stock in connection with the exercise of stock options with a weighted-average exercise price of $4.61 and $7.01 per share and total intrinsic value of $159,000 and $663,000, respectively. For the three and six months ended June 30, 2008, the Company issued 41,590 and 104,820 shares of common stock in connection with the exercise of stock options with a weighted-average exercise price of $5.12 and $5.51 per share and total intrinsic value of $213,000 and $578,000, respectively.

Note 7. Income Tax

For the three and six months ended June 30, 2009, the Company recorded a provision for income taxes of approximately $180,000 and $390,000, respectively, that is principally comprised of federal alternative minimum and California income tax. The tax provision for the three and six months ended June 30, 2009 was based on the Company s estimated taxable income for the year. The difference between the provision for income taxes that would be derived by applying the statutory rate to the Company s loss before tax and the income tax provision actually recorded is primarily due to the impact of non-deductible SFAS 123R stock-based compensation expenses and other currently non-deductible items, offset by the use of federal net operating loss carry-forwards that reduce the federal tax expense to the alternative minimum tax amount and California state income tax under their applicable statutes. For the six months ended June 30, 2008, the Company did not record a provision for income taxes because it estimated and incurred a taxable loss for the year ended December 31, 2008.

The Company intends to continue maintaining a full valuation allowance on its deferred tax assets until sufficient evidence exists to support the reversal of all or some portion of these allowances. Should the actual amounts differ from the Company s estimates, the amount of its valuation allowance could be materially impacted.

The Company had $575,000 and $413,000 of unrecognized tax benefits as of June 30, 2009 and 2008, respectively. The Company does not anticipate a material change in its unrecognized tax benefits over the next twelve months. Unrecognized tax benefits may change during the next twelve months for items that arise in the ordinary course of business.

The Company will recognize accrued interest and penalties related to unrecognized tax benefits in income tax expense when and if incurred. As of June 30, 2009, the Company had not recognized any tax-related penalties or interest in its consolidated balance sheets or statements of operations. All tax years from 2000 forward remain subject

to future examination by tax authorities.

Table of Contents

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

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. When used in this report, the words expects, anticipates, intends, estimates, plans, believes, and similar expressions are intended to identify forward-looking statements. These are statements that relate to future periods and include statements about our expectation that, for the foreseeable future, substantially all of our revenues will be derived from the Oncotype DX breast cancer test; the factors that may impact our financial results; the extent and duration of our net losses or when we may achieve profitability; our ability to recognize revenues other than on a cash basis; our business strategy and our ability to achieve our strategic goals; our expectations regarding product revenues; the amount of future revenues that we may derive from Medicare patients or categories of patients; our plans to pursue reimbursement on a case-by-case basis; our ability, and expectations as to the amount of time it will take, to achieve successful reimbursement from third-party payors and government insurance programs for new tests or markets, including for Oncotype DX for N+ breast cancer patients, our Oncotype DX colon cancer test, or for patients outside of the U.S.; our expectations regarding our international expansion and opportunities, and our expectations regarding revenues from international sales; our intent to enter into additional foreign distribution arrangements; the factors we believe to be driving demand for the Oncotype DX breast cancer test and our ability to sustain or increase such demand; our success in increasing patient and physician demand as a result of our direct sales approach; plans for enhancements of Oncotype DX to address different patient populations of breast cancer; plans for, and the timeframe for the development or commercial launch of, future tests addressing different patient populations or other cancers; the factors that we believe will drive the establishment of coverage policies; the capacity of our clinical reference laboratory to process tests and our expectations regarding capacity; our dependence on collaborative relationships and the success of those relationships; whether any tests will result from our collaborations; the applicability of clinical results to actual outcomes; our assumptions regarding commercialization of a test for colon cancer and the timing of commercial availability of any such test; our plans with respect to potential tests for ductal carcinoma in situ, or other cancers or for patients treated with specific treatments; the occurrence, timing, outcome or success of clinical trials or studies; our intention to plan additional development or clinical studies; the benefits of our technology platform; the economic benefits of our test to the healthcare system; the ability of our test to impact treatment decisions; our beliefs regarding our competitive benefits; our beliefs regarding the benefits of individual gene reporting; the level of investment in our sales force; our expectation that our general and administrative, sales and marketing and research and development expenses will increase and our anticipated uses of those funds; our expectations regarding capital expenditures; our ability to comply with the requirements of being a public company; our ability to attract and retain experienced personnel; the adequacy of our product liability insurance; how we intend to spend our existing cash and cash equivalents and how long we expect our existing cash to last; our anticipated cash needs and our estimates regarding our capital requirements and our needs for additional financing; our expected future sources of cash; our plans to borrow under existing or new financing arrangements; our belief that we are in material compliance with financial covenants; our expectations regarding repayment of debt or incurrence of additional debt; our compliance with federal, state and foreign regulatory requirements; the potential impact resulting from the regulation of Oncotype DX by the U.S. Food and Drug Administration, or FDA, and our belief that our Oncotype DX breast cancer test is properly regulated under the Clinical Laboratory Improvement Amendments of 1988, or CLIA; the impact of new or changing policies, regulation or legislation on our business; our belief that we have taken reasonable steps to protect our intellectual property; our strategies regarding filing additional patent applications to strengthen our intellectual property rights; the impact of changing interest rates; our beliefs regarding our unrecognized tax benefits; the impact of accounting pronouncements and our critical accounting policies, judgments, estimates, models and assumptions on our financial results; the impact of the economy on our business, patients and payors; our expectations regarding the impact of the economic environment on our liquidity and our investments; and anticipated trends and challenges in our business and the markets in which we operate.

Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those expected. These risks and uncertainties include, but are not limited to, those risks discussed in

Item 1A of this report, as well as our ability to develop and commercialize new products; the risk of unanticipated delays in research and development efforts; the risk that we may not obtain reimbursement for our existing test and any future tests we may develop; the risks and uncertainties associated with the regulation of our test by FDA; our ability to compete against third parties; our ability to obtain capital when needed; the economic environment; and our history of operating losses. These forward-looking statements speak only as of the date hereof. We expressly disclaim any obligation or undertaking to update any forward-looking statements contained herein to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based.

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

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

Table of Contents

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 Onco*type* DX diagnostic test is used for breast cancer patients to predict the likelihood of cancer recurrence and the likelihood of chemotherapy benefit and is conducted at our clinical reference laboratory in Redwood City, California. Effective July 1, 2009 the list price of our test increased from $3,820 to $3,975. Substantially all of our historical revenues have been derived from the sale of Onco*type* DX breast cancer tests ordered by physicians in the United States.

Oncotype DX Breast Cancer Test

For the three and six months ended June 30, 2009, we delivered more than 11,880 and 23,100 Onco*type* DX breast cancer test reports for use in treatment planning, compared to more than 9,690 and 18,850 test reports for the three and six months ended June 30, 2008. We believe increased demand resulted from our ongoing commercial efforts, continued publication of peer-reviewed articles on studies we sponsored, conducted or collaborated on that support the use and reimbursement of our Onco*type* DX breast cancer test, clinical presentations at major symposia, and the inclusion of our Onco*type* DX breast cancer test in clinical practice guidelines. However, this increased demand is not necessarily indicative of future growth rates, and we cannot assure you that this level of increased demand can be sustained or that publication of articles, future appearances or presentations at medical conferences or increased commercial efforts will have a similar impact on demand for our test in the future. We have in the past, and may in the future, experience slower sequential growth in demand for our test in the second and third calendar quarters, which we believe may be attributed to physicians, surgeons and patients scheduling vacations during this time. As of June 30, 2009, our clinical reference laboratory had the capacity to process up to 15,000 tests per calendar quarter.

We depend on third-party payors to provide reimbursement for our test. Accordingly, we have focused substantial resources on obtaining reimbursement coverage from third-party payors. Several large national third-party payors, a number of regional payors, and Palmetto Government Benefits Administrators, or Palmetto GBA, the local Medicare carrier for California with jurisdiction for claims submitted by us for Medicare patients, have issued positive coverage determinations for our Onco*type* DX breast cancer test for patients with node negative, or N-, estrogen receptor positive, or ER+, disease through contracts, agreements or policy decisions. Effective August 1, 2009, we negotiated a contracted rate of reimbursement with Anthem Insurance Companies, Inc., a subsidiary of one of the nation s largest health benefits companies.

Beginning in the second half of 2008 and continuing through the first half of 2009, we experienced an increase in usage of our Onco*type* DX breast cancer test for node positive, or N+, patients. While some payors provide policy coverage for the use of our test in patients with lymph node micro-metastasis (greater than 0.2mm, but not greater than 2.0 mm in size), a substantial portion of our existing reimbursement coverage has been limited to women with early-stage N-, ER+ breast cancer. Effective June 28, 2009, Palmetto GBA extended its coverage for the Onco*type* DX breast cancer test to include ER+ patients with N+ disease (up to three positive lymph nodes). However, we may not be able to obtain additional reimbursement coverage from other payors for our test for breast cancer patients with N+, ER+ disease.

Our domestic sales, marketing and reimbursement efforts are focused on direct interaction with medical and surgical oncologists, pathologists and payors. In January 2009, we hired an additional 20 U.S. sales representatives, increasing our domestic sales force to a total of 80 sales representatives. We have also continued to expand internationally. As of June 30, 2009, we had received test samples from over 40 countries and established exclusive distribution agreements for our Onco*type* DX breast cancer test with partners in over ten countries outside of the U.S. We established a European subsidiary in February 2009 and have lead executives with assignments in Europe and in Asia to support our international efforts. In June 2009, the St. Gallen International Consensus Panel on the Primary Therapy of Early Breast Cancer recommended for the first time that validated multigene assays should be considered as an adjunct to standard measures in helping determine chemotherapy benefit for early-stage breast cancer patients. We have completed or initiated multiple international clinical studies intended to support the adoption of our test outside of the U.S. For example, in April 2009, we announced results of a multi-center study in Japan demonstrating that our test had significant prognostic value in Japanese women with ER+ early-stage breast cancer. This was the first

study to examine the utility of our Onco*type* DX breast cancer test in a specific ethnic population. During the second quarter of 2009, we initiated our first Taiwanese Chinese population study in collaboration with the National Taiwan University. We do not expect international product revenues to comprise more than 10% of our total revenues for at least the next two years.

Table of Contents

Oncotype DX Colon Cancer Test Commercialization

At the May 2009 American Society of Clinical Oncology, or ASCO, meeting, we presented positive results from our independent clinical validation study in stage II colon cancer for our Onco*type* DX colon cancer test. The study, which utilized more than 1,400 patient samples from the international, multi-center QUASAR trial, demonstrated that the Onco*type* DX colon cancer test can independently predict the individual recurrence risk in stage II colon cancer patients following surgery, and indicated that the colon cancer Recurrence Score provided additional independent clinical value beyond standard measures of risk.

We are proceeding with commercialization plans to make our Onco*type* DX colon cancer test available to physicians and patients in early 2010. We expect to incur additional expenses, including infrastructure, sales and marketing and information technology costs, related to the commercial launch of our colon cancer test. Based upon our experience in obtaining adoption and reimbursement for our Onco*type* DX breast cancer test, we do not expect product revenues from our colon cancer test to comprise more than 10% of our total revenues for at least the next three years.

Product Pipeline

We continue to conduct research and development studies in breast cancer, colon cancer and other cancers. At the May 2009 ASCO meeting, we presented results from a clinical study that summarized the gene signatures of male patients for whom the Onco*type* DX breast cancer test was used to guide chemotherapy treatment, indicating that breast cancer in men displays similar gene signatures to female breast cancer. We also presented a separate study at the ASCO meeting demonstrating that there were significant differences in gene expression between hormone receptor negative, or triple negative, breast cancer compared with hormone receptor positive disease. We are investigating the utility of our Onco*type* DX breast cancer test in patients with ductal carcinoma in situ, or DCIS, which generally refers to a pre-invasive tumor with reduced risk of recurrence. We plan to evaluate the use of the Onco*type* DX breast cancer gene panel and also seek to identify other genes that may be used for treatment planning in DCIS.

We are planning additional studies in colon cancer for both stage II and stage III patients in order to provide additional information regarding treatment with agents such as oxaliplatin, epidermal growth factor, or EGFR, inhibitors and anti-angiogenesis agents. We completed processing samples related to gene discovery work under our contract research agreement for the development of a genomic test to estimate the risk of recurrence following surgery for patients with Stage I-III renal carcinoma, clear cell type. We have established agreements and identified sources of clinical samples in connection with our prostate and lung cancer programs.

Economic Environment

Continuing concerns over inflation, deflation, energy costs, geopolitical issues, the availability and cost of credit, the Federal stimulus plan, Federal budget proposals, the U.S. mortgage market and a declining real estate market in the U.S. have contributed to increased volatility and diminished expectations for the global economy and expectations of slower global economic growth going forward. These factors, combined with volatile oil prices, declining business and consumer confidence, a volatile stock market and increased unemployment, have precipitated an economic slowdown and recession. We continue to evaluate the impact of this environment on our cash management, cash collection activities and volume of tests delivered.

As of the date of this report, we have not experienced a loss of principal on any of our investments, and we expect that we will continue to be able to access or liquidate these investments as needed to support our business activities. From time to time, we monitor the financial position of our significant third-party payors, which include Medicare and managed care companies. As of the date of this report, we do not expect the current economic environment to have a material negative impact on our ability to collect payments from our third-party payors through the end of 2009. The economic slowdown could negatively impact the volume of tests we deliver in the future if patients lose healthcare coverage, delay medical checkups or are unable to pay for our test.

We intend to continue to assess the impact of the economic environment on our business activities. If the economic climate in the U.S. does not improve or continues to deteriorate, our cash position, cash collection activities and volume of tests delivered could be negatively impacted and we could experience lower revenues.

Critical Accounting Policies and Significant Judgments and Estimates

This discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, 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

Table of Contents

form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could therefore differ materially from those estimates under different assumptions or conditions.

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

Revenue Recognition

We exercise judgment in determining whether revenue is recognized on an accrual basis when test results are delivered or on a cash basis when cash is received from the payor. Our revenues for tests performed are recognized when the following criteria are met: (1) persuasive evidence that an arrangement exists; (2) delivery has occurred or services rendered; (3) the fee is fixed or determinable; and (4) collectibility is reasonably assured. We assess whether the fee is fixed or determinable based on the nature of the fee charged for the products or services delivered and existing contractual agreements. When evaluating collectibility, we consider whether we have sufficient history to reliably estimate a payor s individual payment patterns. Based upon at least several months of payment history, we review the number of tests paid against the number of tests billed and the payor s outstanding balance for unpaid tests to determine whether payments are being made at a consistently high percentage of tests billed and at appropriate amounts given the contracted payment amount. To the extent all criteria set forth above are not met, including where there is no evidence of payment history at the time test results are delivered, product revenues are recognized on a cash basis when cash is received from the payor.

Contract revenues are generally derived from studies conducted with biopharmaceutical and pharmaceutical companies and are recognized on a contract-specific basis. Under certain contracts, revenues are recognized as costs are incurred or assays are processed. We may exercise judgment when estimating full-time equivalent level of effort, costs incurred and time to project completion. For certain contracts, we utilize the performance-based method of revenue recognition, which requires that we estimate the total amount of costs to be expended for a project and recognize revenue equal to the portion of costs expended to date. The estimated total costs to be expended are necessarily subject to revision from time to time as the underlying facts and circumstances change.

Allowance for Doubtful Accounts

We accrue an allowance for doubtful accounts against our accounts receivable based on estimates consistent with historical payment experience. Our allowance for doubtful accounts is evaluated quarterly and adjusted when trends or significant events indicate that a change in estimate is appropriate. As of June 30, 2009 and December 31, 2008, our allowance for doubtful accounts was $624,000 and $881,000, respectively. The decrease in our allowance for doubtful accounts reflected the impact of writedowns and improved collections on our outstanding accounts receivable.

Research and Development Expenses

We enter into collaboration and clinical trial agreements with clinical collaborators and record these costs as research and development expenses. We record accruals for estimated study costs based on estimates of services received and effort expended by our collaborators pursuant to these agreements. The financial terms of these agreements are subject to negotiations, may vary from contract to contract, and may result in uneven payment flows. We determine our estimates through discussion with internal clinical development personnel and outside service providers as to the progress or stage of completion of services provided and the agreed upon fee to be paid for such services. Advance payments for goods or services that will be used or rendered for research and development activities are deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed.

All potential future product programs outside of breast and colon cancer are in the research or early development phase. The expected time frame in which a test for one of these other cancers can be brought to market is uncertain given the technical challenges and clinical variables that exist between different types of cancers. In 2008, we began maintaining information regarding costs incurred for activities performed under certain contracts with biopharmaceutical and pharmaceutical companies. However, we do not generally record or maintain information regarding costs incurred in research and development on a program-specific basis. Our research and development staff and associated infrastructure resources are deployed across several programs. Many of our costs are thus not attributable to individual programs. As a result, we are unable to determine the duration and completion costs of our

research and development programs or when, if ever, and to what extent we will receive cash inflows from the commercialization and sale of a product.

Table of Contents

Stock-based Compensation Expense

Under the provisions of Statement of Financial Accounting Standards No. 123 (Revised 2004), *Share-Based Payment*, or SFAS 123R, our employee stock-based compensation is estimated at the date of grant based on the fair value of the award using the Black-Scholes option-pricing model and is recognized as expense ratably over the requisite service period. The application of SFAS 123R requires significant judgment and the use of estimates, particularly surrounding assumptions used in determining fair value. The Black-Scholes valuation method requires the use of estimates such as stock price volatility and expected option lives, as well as expected option forfeiture rates, to value stock-based compensation. Our assumptions regarding expected volatility are based on the historical volatility of our common stock. The expected life of options is estimated based on historical option exercise data and assumptions related to unsettled options. Expected option forfeiture rates are based on historical data, and compensation expense is adjusted for actual results.

As required under SFAS 123R, we review our valuation assumptions on an ongoing basis, and, as a result, our valuation assumptions used to value employee stock-based awards granted in future periods may change. See Note 6, Stock-Based Compensation, in the Notes to Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for more information.

Results of Operations

Three and Six Months Ended June 30, 2009 and 2008

We recorded a net loss for the three and six months ended June 30, 2009 of $3.9 million and $8.6 million, respectively, compared to a net loss for the three and six months ended June 30, 2008 of $4.1 million and $10.7 million, respectively. On a basic and diluted per share basis, net loss was $0.14 and $0.30 for the three and six months ended June 30, 2009, respectively, compared to $0.15 and $0.38 for the three and six months ended June 30, 2008, respectively.

Revenues

We derive our revenues from product sales and, to a lesser extent, from contract research arrangements. We operate in one industry segment. All of our product revenues have been derived solely from the sale of our Onco*type* DX breast cancer test. Payors are billed upon generation and delivery of a breast cancer Recurrence Score report to the physician. Product revenues are recorded on a cash basis unless a contract or arrangement to pay is in place with the payor at the time of billing and collectibility is reasonably assured. Contract revenues are derived from studies conducted with biopharmaceutical and pharmaceutical companies and are recorded as contractual obligations are completed.

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2009	2008	2009	2008
	(In thousands)			
Product revenues	$ 35,191	$ 26,327	$ 68,618	$ 49,682
Contract revenues	1,361	1,456	1,830	1,541
Total revenues	$ 36,552	$ 27,783	$ 70,448	$ 51,223
Period over period dollar increase in product revenues	$ 8,864		$ 18,936	
Period over period percentage increase in product revenues	34%		38%	

The period over period increases in product revenues resulted from increased adoption, as evidenced by a 23% increase in test volume for both the three and six month comparative periods. We also experienced expanded reimbursement coverage and an increase in the amount of revenue recognized per test for both the three and six month

comparative periods. For all periods presented, approximately 50% of product revenues were recorded on an accrual basis and recognized at the time the test results were delivered. The balance of product revenues was recognized upon cash collection as payments were received.

Product revenues from Medicare payments were $6.4 million, or 18%, and $13.0 million, or 19%, of product revenues for the three and six months ended June 30, 2009, respectively compared to $5.7 million, or 22%, and $11.4 million, or 23%, of product revenues for the three and six months ended June 30, 2008, respectively. Product revenues from United HealthCare Insurance Company payments were $3.0 million, or 8%, and $5.8 million, or 8%, of product revenues for the three and six months ended June 30, 2009,

Table of Contents

respectively, compared to $3.3 million, or 12%, and $6.4 million, or 13%, of product revenues for the three and six months ended June 30, 2008, respectively.

Contract revenues were $1.4 million and $1.8 million for the three and six months ended June 30, 2009, respectively, compared to $1.5 million for each of the three and six months ended June 30, 2008. Contract revenues represented studies assessing our gene expression technology or work in gene selection and protocol design with our pharmaceutical partners. The period over period variances in contract revenues were due to project timing for ongoing contract research and development activities. We expect that our contract revenues will continue to fluctuate based on the number and timing of studies being conducted.

Cost of Product Revenues

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2009	2008	2009	2008
	(In thousands)			
Tissue sample processing costs	$ 5,381	$ 4,837	$ 10,808	$ 8,897
Stock-based compensation	88	125	181	240
Total tissue sample processing costs	5,469	4,962	10,989	9,137
License fees	2,422	1,888	4,730	3,597
Total cost of product revenues	$ 7,891	$ 6,850	$ 15,719	$ 12,734
Period over period dollar increase	$ 1,041		$ 2,985	
Period over period percentage increase	15%		23%	

Cost of product revenues represents the cost of materials, direct labor, equipment and infrastructure expenses associated with processing tissue samples (including histopathology, anatomical pathology, paraffin extraction, reverse transcription polymerase chain reaction, or RT-PCR, quality control analyses and shipping charges to transport tissue samples), stock-based compensation and license fees. Infrastructure expenses include allocated facility occupancy and information technology costs. Costs associated with performing our test are recorded as tests are processed. Costs recorded for tissue sample processing represent the cost of all the tests processed during the period regardless of whether revenue was recognized with respect to a specific test. Royalties for licensed technology calculated as a percentage of product revenues and fixed annual payments relating to the launch and commercialization of our Onco*type* DX breast cancer test are recorded as license fees in cost of product revenues at the time product revenues are recognized or in accordance with other contractual obligations. License fees represent a significant component of our cost of product revenues and are expected to remain so for the foreseeable future.

The $544,000, or 11%, increase in tissue sample processing costs for the three months ended June 30, 2009 compared to the three months ended June 30, 2008 reflected a 23% increase in test volume, partially offset by lower consulting expenses and other cost efficiencies. The $1.9 million, or 22%, increase in tissue sample processing costs for the six months ended June 30, 2009 compared to the six months ended June 30, 2008 reflected a 23% increase in test volume. The $534,000, or 28%, and $1.1 million, or 31%, increases in license fees for the three and six month comparative periods included higher royalties due to increases of $8.9 million, or 34%, and $18.9 million, or 38%, respectively, in product revenues recognized. We expect the cost of product revenues to increase to the extent we process more tests.

Table of Contents

Research and Development Expenses

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2009	2008	2009	2008
	(In thousands)			
Personnel-related expenses	$ 4,550	$ 4,037	$ 9,258	$ 7,788
Stock-based compensation	770	720	1,540	1,455
Collaboration expenses	891	416	1,495	493
Infrastructure and all other costs	3,032	2,149	5,595	3,992
Total research and development expenses	$ 9,243	$ 7,322	$ 17,888	$ 13,728
Period over period dollar increase	$ 1,921		$ 4,160	
Period over period percentage increase	26%		30%	

Research and development expenses represent costs incurred to develop our technology and carry out clinical studies and include personnel-related expenses, reagents and supplies used in research and development laboratory work, infrastructure expenses, including allocated overhead and facility occupancy costs, contract services and other outside costs. Research and development expenses also include costs related to activities performed under contracts with biopharmaceutical and pharmaceutical companies.

The $1.9 million, or 26%, increase in research and development expenses for the three months ended June 30, 2009 compared to the three months ended June 30, 2008 reflected a $513,000 increase in personnel-related expenses, an $883,000 increase in infrastructure and other expenses and a $475,000 increase in collaboration expenses related to clinical studies for a variety of cancers. The $4.2 million, or 30%, increase in research and development expenses for the six months ended June 30, 2009 compared to the six months ended June 30, 2008 reflected a $1.5 million increase in personnel-related expenses, a $1.6 million increase in infrastructure and other expenses and a $1.0 million increase in collaboration expenses. We expect our research and development expenses to increase as we continue to invest in our product pipeline for breast, colon and other cancers.

Selling and Marketing Expenses

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2009	2008	2009	2008
	(In thousands)			
Personnel-related expenses	$ 7,417	$ 5,334	$ 14,654	$ 11,192
Stock-based compensation	798	648	1,629	1,278
Promotional and marketing materials	3,439	2,960	5,949	5,841
Travel, meetings and seminars	1,927	1,621	3,985	3,297
Infrastructure and all other costs	2,128	1,264	4,188	2,586
Total sales and marketing expenses	$ 15,709	$ 11,827	$ 30,406	$ 24,194
Period over period dollar increase	$ 3,882		$ 6,212	
Period over period percentage increase	33%		26%	

Our selling and marketing expenses consist primarily of personnel-related expenses, education and promotional expenses, and infrastructure expenses, including allocated facility occupancy and information technology costs. These expenses include the costs of educating physicians, laboratory personnel and other healthcare professionals regarding our genomic technologies, how our Onco*type* DX breast cancer test was developed and validated and the value of the quantitative information that the test 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 our Onco*type* DX platform.

The $3.9 million, or 33%, increase in selling and marketing expenses for the three months ended June 30, 2009 compared to the three months ended June 30, 2008 was due to a $2.1 million increase in personnel-related expenses, due primarily to the addition of 20 domestic field sales representatives in January 2009, a $864,000 increase in infrastructure expenses, including allocations for

Table of Contents

information technology, recruiting and other expenses, $306,000 in higher travel-related expenses primarily associated with the increase in field sales personnel and our international expansion, a $150,000 increase in stock-based compensation, and a $479,000 increase in promotional field and marketing materials. The $6.2 million, or 26%, increase in selling and marketing expenses for the six months ended June 30, 2009 was due to a $3.5 million increase in personnel-related expenses, due primarily to the addition of field sales personnel, a $1.6 million increase in infrastructure expenses, $688,000 in higher travel-related expenses, and a $351,000 increase in stock-based compensation. We expect selling and marketing expenses to increase in future periods as we prepare for the commercialization of our Onco*type* DX colon cancer test and continue to expand our commercial efforts in international markets.

General and Administrative Expenses

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2009	2008	2009	2008
	(In thousands)			
Personnel-related expenses	$ 4,811	$ 3,736	$ 9,616	$ 7,126
Stock-based compensation	880	792	1,740	1,569
Professional fees and all other costs	1,960	1,697	3,633	3,435
Total general and administrative expenses	$ 7,651	$ 6,225	$ 14,989	$ 12,130
Period over period dollar increase	$ 1,426		$ 2,859	
Period over period percentage increase	23%		24%	

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

The $1.4 million, or 23%, and $2.9 million, or 24%, increases in general and administrative expenses for the three and six month comparative periods, respectively, were primarily due to increases in personnel-related expenses due to increases in headcount period over period. We expect general and administrative expenses to increase as we hire additional staff and incur other expenses to support the growth of our business and to the extent we spend more on fees for billing and collections as we process more tests.

Interest and Other Income

Interest and other income was $213,000 and $462,000 for the three and six months ended June 30, 2009, respectively, compared to $448,000 and $1.1 million for the three and six months ended June 30, 2008, respectively. The $235,000 and $607,000 decreases for the three and six month comparative periods were primarily due to lower market yields. We expect our interest income may continue to decrease if the overall decline in interest rates continues.

Interest and Other Expense

Interest and other expense was $34,000 and $86,000 for the three and six months ended June 30, 2009 compared to $106,000 and $239,000 for the three and six months ended June 30, 2008. The $72,000 and $153,000 decreases for the three and six month comparative periods were primarily due to lower average balances on our equipment financing notes as we paid them down. We expect our interest expense to decline as we continue to make payments on our equipment financing. We do not anticipate using additional equipment financing as a funding source in the next twelve months.

Income Tax Expense

For the three and six months ended June 30, 2009, we recorded income tax expense of approximately $180,000 and $390,000, respectively, which was principally comprised of federal alternative minimum tax and California income tax. The provision for income taxes for the three and six months ended June 30, 2009 was based on our estimated taxable income for the year. For the three and six months ended June 30, 2008, we did not record a provision for income taxes because we estimated and incurred a taxable loss for the year ended December 31, 2008.

Table of Contents

We intend to maintain a full valuation allowance on our deferred tax assets until sufficient evidence exists to support the reversal of all or some portion of these allowances. Should the actual amounts differ from our estimates, the amount of our valuation allowance could be materially impacted.

Liquidity and Capital Resources

As of June 30, 2009, we had an accumulated deficit of $177.1 million. We have not yet achieved profitability and anticipate that we will likely incur additional net losses. We cannot provide assurance as to when, if ever, we will achieve profitability. We expect that our research and development, selling and marketing and general and administrative expenses will continue to increase and, as a result, we will need to generate significant product revenues to achieve profitability.

	2009	2008 (In thousands)	$ Change
As of June 30:			
Cash, cash equivalents and short-term investments	$55,729	$ 60,627	$ (4,898)
Working capital	50,193	56,661	(6,468)
For the six months ended June 30:			
Cash provided by (used in):			
Operating activities	1,062	(2,046)	3,108
Investing activities	(431)	(19,093)	18,662
Financing activities	(436)	(803)	367
Capital expenditures (included in investing activities above)	(1,412)	(4,823)	3,411

Sources of Liquidity

At June 30, 2009, we had cash, cash equivalents and short-term investments of $55.7 million compared to $60.6 million at June 30, 2008. In accordance with our investment policy, available cash is invested in short-term, low-risk, investment-grade debt instruments. Our cash and short-term investments are held in a variety of interest-bearing instruments including money market accounts, obligations of U.S. government-sponsored entities, high-grade corporate bonds and commercial paper. At June 30, 2009, our holdings of obligations of U.S. government-sponsored entities consisted entirely of debt securities issued by the Federal Home Loan Bank, the Federal National Mortgage Association and the Federal Home Loan Mortgage Corporation.

Historically we have financed our operations primarily through sales of our equity securities and cash received in payment for our tests. At June 30, 2009, we had approximately $46.5 million of securities available for issuance under a shelf registration statement. Purchases of equipment and leasehold improvements have been partially financed through capital equipment financing arrangements. At June 30, 2009 and 2008, we had notes payable under these equipment financing arrangements of $940,000 and $3.3 million, respectively. Our existing notes payable under these arrangements are scheduled to be fully paid by November 2010.

Cash Flows

Net cash provided by operating activities was $1.1 million for the six months ended June 30, 2009 compared to net cash used in operating activities of $2.0 million for the six months ended June 30, 2008. Net cash provided by (used in) operating activities includes net loss adjusted for certain non-cash items and changes in assets and liabilities. Net cash provided by operating activities for the six months ended June 30, 2009 reflected a $1.8 million increase in accrued compensation expense and a $1.2 million increase in accounts payable, accrued expenses and other liabilities, partially offset by a $1.8 million decrease in deferred revenues reflecting the recognition of collaboration contract revenue. Net cash used in operating activities for the six months ended June 30, 2008 reflected a $4.0 million net loss excluding depreciation and stock-based compensation for the period, a $2.3 million increase in accounts receivable and a $1.5 million increase in prepaid expenses and other assets, partially offset by the receipt of $3.7 million in advance collaboration contract payments and a $2.1 million decrease in accrued expenses and other liabilities.

Net cash used in investing activities was $431,000 for the six months ended June 30, 2009, compared to $19.1 million for the six months ended June 30, 2008. Our investing activities have consisted predominately of

purchases and maturities of marketable securities and capital expenditures. Net cash used in investing activities for the six months ended June 30, 2009 included $1.4 million in capital expenditures, partially offset by $1.0 million in net maturities of short-term investments. Net cash used in investing activities for the six months ended June 30, 2008 included $14.3 million in net purchases of short-term investments, reflecting the investment of

Table of Contents

a portion of the cash proceeds from our May 2007 public offering of common stock, and $4.8 million in capital expenditures, primarily for facility expansion and improvements.

Net cash used in financing activities was $436,000 for the six months ended June 30, 2009, compared to $803,000 for the six months ended June 30, 2008. Our financing activities include proceeds from the sale of our common stock and payments on our capital equipment financing arrangements. Net cash used in financing activities for the six months ended June 30, 2009 included $1.1 million in principal payments on our debt, partially offset by $663,000 in proceeds from the issuance of our common stock upon the exercise of stock options. Net cash used in financing activities for the six months ended June 30, 2008 included $1.4 million in principal payments on our debt, partially offset by $578,000 in proceeds from the issuance of our common stock upon the exercise of stock options.

Contractual Obligations

The following summarizes our significant contractual obligations as of June 30, 2009 and the effect those obligations are expected to have on our liquidity and cash flows in future periods:

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
			(In thousands)		
Notes payable obligations	$ 987	$ 879	$ 108	$	$
Non-cancelable operating lease obligations	4,421	1,582	2,839		
Total	$ 5,408	$ 2,461	$ 2,947	$	$

Our notes payable obligations are for principal and interest payments on capital equipment financing. In March 2005, we entered into an arrangement to finance the acquisition of laboratory equipment, computer hardware and software, leasehold improvements and office equipment. In connection with this arrangement, we granted the lender a security interest in the assets purchased with these borrowings. We can prepay all, but not part, of the amounts owing under the arrangement so long as we also pay a 4% premium on the remaining payments. As of June 30, 2009, the outstanding notes payable principal balance under this arrangement totaled $940,000 at annual interest rates ranging from 11.01% to 11.30%, depending upon the applicable note.

Our non-cancelable operating lease obligations are for laboratory and office space. In September 2005, we entered into a non-cancelable lease for 48,000 square feet of laboratory and office space in Redwood City, California. In January 2007, we entered into a non-cancelable lease for an additional 48,000 square feet of office space in a nearby location. Both leases expire in February 2012.

We are required to make a series of annual payments under one of our collaboration agreements beginning on the date that we commercially launched our Onco*type* DX breast cancer test. At June 30, 2009, future annual payments due under this agreement totaled $950,000, of which $475,000 is due each of the years 2010 and 2011. However, because either party may terminate the agreement upon thirty days prior written notice, these payments are not included in the table above.

We have also committed to make potential future payments to third parties as part of our collaboration agreements. Payments under these agreements generally become due and payable only upon achievement of specific project milestones. Because the achievement of these milestones is generally neither probable nor reasonably estimable, such commitments have not been included in the table above.

Off-Balance Sheet Arrangements

As of June 30, 2009, we have no material off-balance sheet arrangements other than the lease obligations and payments under clinical study agreements discussed above.

24

Table of Contents

Operating Capital and Capital Expenditure Requirements

We expect to continue to incur net losses in the future and to make capital expenditures to keep pace with the expansion of our research and development programs, to scale our commercial operations, including the commercialization and launch of our Onco*type* DX colon cancer test and to support our international expansion efforts. We expect to spend approximately $6.2 million over the next twelve months for planned laboratory equipment and other expenditures to support the growth of our business. It may take years to move any one of a number of product candidates in research through development and validation to commercialization. We expect that our cash and cash equivalents will be used to fund working capital and for capital expenditures and other general corporate purposes, such as licensing technology rights, partnering arrangements for our tests outside the United States or reduction of debt obligations. We may also use cash to acquire or invest in complementary businesses, technologies, services or products. We have no current plans, agreements or commitments with respect to any such acquisition or investment, and we are not currently engaged in any negotiations with respect to any such transaction.

The amount and timing of actual expenditures may vary significantly depending upon a number of factors, such as the progress of our commercialization efforts, product development, regulatory requirements, the amount of cash used by operations and progress in reimbursement.

We currently anticipate that our cash, cash equivalents and short-term investments, together with collections from our Onco*type* DX breast cancer test, will be sufficient to fund our operations and facilities expansion plans for at least the next 12 months. We cannot be certain that our international expansion, the commercialization of our Onco*type* DX colon cancer test or the development of future tests will be successful or that we will be able to raise sufficient additional funds to see these activities through to a successful result.

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

- the rate of progress in establishing reimbursement arrangements with third-party payors;
- the cost of expanding our commercial and laboratory operations, including our selling and marketing efforts;
- the rate of progress and cost of research and development activities associated with expansion of Onco*type* DX for breast cancer;
- the rate of progress and cost of selling and marketing activities associated with commercialization of Onco*type* DX for colon cancer;
- the rate of progress and cost of research and development activities associated with products in the research and early development phase focused on cancers other than breast and colon cancer;
- the cost of acquiring or achieving access to tissue samples and technologies;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the effect of competing technological and market developments;
- costs related to international expansion;
- the cost and delays in product development as a result of any changes in regulatory oversight applicable to our products or operations; and
- the economic and other terms and timing of any contract research arrangements, clinical study agreements, licensing or other arrangements into which we may enter.

Until we can generate and maintain sufficient product revenues to finance our cash requirements, which we may never do, we expect to finance future cash needs primarily through public or private equity offerings, debt financings,

borrowings or strategic collaborations. The issuance of equity securities may result in dilution to stockholders, or may provide for rights, preferences or privileges senior to those of our holders of common stock. If we raise funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock. The terms of debt securities or borrowings could impose significant restrictions on our operations. We do not know whether additional funding will be available on acceptable terms, if at all. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs or selling and marketing initiatives. In addition, we may have to work with a partner on one or more of our product or market development programs, which would lower the economic value of those programs to our company.

Table of Contents

Recent Accounting Pronouncements

In April 2009, Financial Accounting Standards Board, or FASB, issued three related Staff Positions: (i) FASB Staff Position 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability have Significantly Decreased and Identifying Transactions That Are Not Orderly, or* FSP 157-4, (ii) FASB Staff Position FAS 115-2 and FAS 124-2, *Recognition and Presentation of Other-Than-Temporary Impairment*, or FSP FAS 115-2 and FAS 124-2, and (iii) FASB Staff Position FAS 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments*, or FSP FAS 107-1 and APB 28-1, which was effective for interim and annual periods ending after June 15, 2009. FSP 157-4 provides guidance on how to determine the fair value of assets and liabilities under Statement of Financial Accounting Standards No. 157, *Fair Value Measurements*, or SFAS 157, in the current economic environment and reemphasizes that the objective of a fair value measurement remains an exit price. FSP FAS 115-2 and FAS 124-2 modifies the requirements for recognizing other-than-temporarily impaired debt securities and revises the existing impairment model for such securities. FSP FAS 107-1 and APB 28-1 enhances the disclosure of instruments under the scope of SFAS 157 for both interim and annual periods. Our adoption of these Staff Positions as of June 30, 2009 did not have a material impact on our financial condition or results of operations.

In May 2009, FASB issued Statement of Financial Accounting Standards No. 165, *Subsequent Events* (SFAS 165). SFAS 165 establishes general standards for accounting disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued and applies to both interim and annual financial statements. SFAS 165 is effective for interim or annual financial periods ending after June 15, 2009. Our adoption of SFAS 165 as of June 30, 2009 did not have a material impact on our financial condition or results of operations.

In June 2009, FASB issued Statement of Financial Accounting Standards No. 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles*, a replacement of FASB Statement No. 162 (SFAS 168). SFAS 168 establishes the FASB Accounting Standards Codification (Codification) as the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in the preparation of financial statements in conformity with GAAP. Certain accounting standards have allowed for the continued application of superseded accounting standards for transactions that have an ongoing effect in an entity s financial statements. That superseded guidance has not been included in the Codification, shall be considered grandfathered, and shall continue to remain authoritative for those transactions after the effective date of this Statement, which is for financial statements issued for interim and annual periods ending after September 15, 2009. We do not expect the adoption of SFAS 168 to have a material impact on our financial condition or results of operations.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is confined to our cash equivalents and marketable securities. The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. Our investment policy provides for investments in short-term, low-risk, investment-grade debt instruments. Our investments in marketable securities, which are comprised primarily of money market funds, obligations of U.S. Government agencies and government-sponsored entities, high-grade corporate bonds and commercial paper, are subject to default, changes in credit rating and changes in market value. Due to recent financial and economic conditions, similar investments have experienced losses in value and liquidity constraints which differ from historical patterns. These investments are also subject to interest rate risk and will decrease in value if market rate interest rates increase.

Our cash, cash equivalents and marketable securities, totaling $55.7 million at June 30, 2009, did not include any auction preferred stock, auction rate securities or mortgage-backed investments. We currently do not hedge interest rate exposure, and we do not have any foreign currency or other derivative financial instruments. The securities in our investment portfolio are classified as available for sale and are, due to their short-term nature, subject to minimal interest rate risk. To date, we have not experienced a loss of principal on any of our investments. Although we currently expect that our ability to access or liquidate these investments as needed to support our business activities will continue, we cannot ensure that this will not change. We believe that, if market interest rates were to change immediately and uniformly by 10% from levels at June 30, 2009, the impact on the fair value of these securities or our cash flows or income would not be material.

ITEM 4. CONTROLS AND PROCEDURES.

(a) ***Evaluation of disclosure controls and procedures***. We maintain disclosure controls and procedures, as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, or Exchange Act, that are designed to ensure that information required

Table of Contents

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

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

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

Table of Contents

PART II. OTHER INFORMATION

ITEM 1A. RISK FACTORS.

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

We have incurred substantial net losses since our inception. For the six months ended June 30, 2009 and 2008, we incurred net losses of $8.6 million and $10.7 million, respectively. From our inception in August 2000 through June 30, 2009, we had an accumulated deficit of $177.1 million. To date, we have not, and we may never, achieve revenues sufficient to offset expenses. We expect to devote substantially all of our resources to continue to invest in our product pipeline, including our Onco*type* DX breast and colon cancer tests and future products, and our commercial and laboratory infrastructure. We expect to incur additional losses in the future and we may never achieve profitability.

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 our Onco*type* DX platform. Our research and development expenses were $17.9 million and $13.7 million, respectively, for the six months ended June 30, 2009 and 2008. We expect our research and development expense levels to remain high and to continue to increase for the foreseeable future as we seek to expand the clinical utility of our Onco*type* DX breast cancer test and develop new tests. As a result, we will need to generate significant revenues in order to achieve profitability. Our failure to achieve profitability in the future could cause the market price of our common stock to decline.

Declining general economic or business conditions may have a negative impact on our business.

Continuing concerns over inflation, deflation, energy costs, geopolitical issues, the availability and cost of credit, the Federal stimulus package, Federal budget proposals, the U.S. mortgage market and a declining real estate market in the U.S. have contributed to increased volatility and diminished expectations for the global economy and expectations of slower global economic growth going forward. These factors, combined with volatile oil prices, declining business and consumer confidence, a declining stock market and increased unemployment, have precipitated an economic slowdown and recession. If the economic climate in the U.S. does not improve or continues to deteriorate, our business, including our patient population, our suppliers and our third-party payors, could be negatively affected, resulting in a negative impact on our product revenues.

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

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

not experimental or investigational,

medically necessary,

appropriate for the specific patient,

cost-effective,

supported by peer-reviewed publications, and

included in clinical practice guidelines.

There is uncertainty concerning third-party payor reimbursement of any test incorporating new technology, including our Onco*type* DX platform. Several entities conduct technology assessments of new medical tests and

devices and provide the results of their assessments for informational purposes to other parties. These assessments may be used by third-party payors and health care providers as grounds to deny coverage for a test or procedure. Although there are a number of favorable assessments of our Onco*type* DX breast cancer test, the test has received negative assessments in the past and may receive additional negative assessments in the future.

Table of Contents

Since each payor makes its own decision as to whether to establish a policy to reimburse our test, seeking these approvals is a time-consuming and costly process. To date, we have secured policy-level reimbursement approval for our Onco*type* DX breast cancer test for N- patients from a number of third-party payors. We cannot be certain that coverage for this test will be provided in the future by additional third-party payors or that existing reimbursement policies will remain in place.

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

Insurers, including managed care organizations as well as government payors such as Medicare and Medicaid, have increased their efforts to control the cost, utilization and delivery of health care services. From time to time, Congress has considered and implemented changes in the Medicare fee schedules in conjunction with budgetary legislation. Further reductions of reimbursement for Medicare services may be implemented from time to time. Reductions in the reimbursement rates of other third-party payors have occurred and may occur in the future. These measures have resulted in reduced payment rates and decreased test utilization for the clinical laboratory industry.

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

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

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

For the three and six months ended June 30, 2009, payments from the administrator for Medicare accounted for 18% and 19% of our product revenues, respectively, compared to 22% and 23%, respectively, for the same periods in 2008. Payments from United HealthCare Insurance Company accounted for 8% of our product revenues for each of the three and six months ended June 30, 2009 compared to 12% and 13%, respectively, for the same periods in 2008. In the future, it is possible that these or other third-party payors that provide reimbursement for our test may suspend, revoke or discontinue coverage at any time, or may reduce the reimbursement rates payable to us. Any such actions could have a negative impact on our revenues.

If FDA were to begin regulating our test, we could incur substantial costs and time delays associated with meeting requirements for pre-market clearance or approval or we could experience decreased demand for or reimbursement of our tests.

Clinical laboratory tests like ours are regulated under CLIA, as administered through CMS, as well as by applicable state laws. Diagnostic kits that are sold and distributed through interstate commerce are regulated as

medical devices by FDA. Clinical laboratory tests that are developed and validated by a laboratory for its own use are called laboratory developed tests, or LDTs. Most LDTs are not currently subject to FDA regulation, although reagents or software provided by third parties and used to perform LDTs may be subject to regulation. We believe that Onco*type* DX is not a diagnostic kit and also believe that it is an LDT. As a result, we believe Onco*type* DX should not be subject to regulation under established FDA policies. The container we provide for collection and transport of tumor samples from a pathology laboratory to our laboratory may be a medical device subject to FDA regulation but is currently exempt from pre-market review by FDA.

Table of Contents

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

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

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

We cannot provide any assurance that FDA regulation, including pre-market review, will not be required in the future for our tests, either through new enforcement policies adopted by FDA or new legislation enacted by Congress. It is possible that legislation will be enacted into law and may result in increased regulatory burdens for us to continue to offer our tests.

If pre-market review is required, our business could be negatively impacted until such review is completed and clearance to market or approval is obtained, and FDA could require that we stop selling our test pending pre-market clearance or approval. If our test is allowed to remain on the market but there is uncertainty about our test, if it is labeled investigational by FDA, or if labeling claims FDA allows us to make are very limited, orders or reimbursement may decline. The regulatory approval process may involve, among other things, successfully completing additional clinical trials and submitting a pre-market clearance notice or filing a PMA application with FDA. If pre-market review is required by FDA, there can be no assurance that our test will be cleared or approved on a timely basis, if at all. Ongoing compliance with FDA regulations would increase the cost of conducting our business, and subject us to inspection by FDA and to the requirements of FDA and penalties for failure to comply with these requirements. We may also decide voluntarily to pursue FDA pre-market review of our tests if we determine that doing so would be appropriate.

Should any of the reagents obtained by us from vendors and used in conducting our test be affected by future regulatory actions, our business could be adversely affected by those actions, including increasing the cost of testing or delaying, limiting or prohibiting the purchase of reagents necessary to perform testing.

If we were required to conduct additional clinical trials prior to continuing to sell our Oncotype DX breast cancer test or marketing our colon cancer test or any other new test, those trials could lead to delays or failure to obtain necessary regulatory approval, which could cause significant delays in commercializing any future products and harm our ability to become profitable.

If FDA decides to regulate our tests, it may require additional pre-market clinical testing prior to submitting a regulatory notification or application for commercial sales. If we are required to conduct pre-market clinical trials, whether using prospectively acquired samples or archival samples, delays in the commencement or completion of clinical testing could significantly increase our test development costs and delay commercialization. Many of the

factors that may cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to delay or denial of regulatory clearance or approval. The commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the clinical trial.

Table of Contents

We may find it necessary to engage contract research organizations to perform data collection and analysis and other aspects of our clinical trials, which might increase the cost and complexity of our trials. We may also depend on clinical investigators, medical institutions and contract research organizations to perform the trials properly. If these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality, completeness or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, our clinical trials may have to be extended, delayed or terminated. Many of these factors would be beyond our control. We may not be able to enter into replacement arrangements without undue delays or considerable expenditures. If there are delays in testing or approvals as a result of the failure to perform by third parties, our research and development costs would increase, and we may not be able to obtain regulatory clearance or approval for our test. In addition, we may not be able to establish or maintain relationships with these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market our test, or to become profitable.

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

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

We are also required to maintain a license to conduct testing in California. California laws establish standards for day-to-day operation of our clinical reference laboratory, including the training and skills required of personnel and quality control. Because we receive specimens from New York State, our clinical reference laboratory is required to be licensed by New York. New York law also mandates proficiency testing for laboratories licensed under New York state law, regardless of whether or not such laboratories are located in New York. Moreover, several other states require that we hold licenses to test specimens from patients in those states. Other states may have similar requirements or may adopt similar requirements in the future. Finally, we may be subject to regulation in foreign jurisdictions as we seek to expand international distribution of our 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 our test, which would limit our revenues and harm our business. If we were to lose our license in New York or in other states where we are required to hold licenses, we would not be able to test specimens from those states.

We are subject to other regulation by both the federal government and the states in which we conduct our business, including:

Medicare billing and payment regulations applicable to clinical laboratories;

the federal Medicare and Medicaid Anti-kickback Law and state anti-kickback prohibitions;

the federal physician self-referral prohibition, commonly known as the Stark Law, and the state equivalents;

the federal Health Insurance Portability and Accountability Act of 1996;

the Medicare civil money penalty and exclusion requirements; and

the federal civil and criminal False Claims Act and state equivalents.

We have adopted policies and procedures designed to comply with these laws, including policies and procedures relating to financial arrangements between us and physicians who refer patients to us. In the ordinary course of our business, we conduct internal reviews of our compliance with these laws. Our compliance is also subject to

governmental review. The growth of our business and sales organization may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these laws and regulations is further increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management s attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including civil and criminal penalties, damages and fines, we could be required to refund payments received by us, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

Table of Contents

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

For the foreseeable future, we expect to derive substantially all of our revenues from sales of one test, our Onco*type* DX breast cancer test. We have been selling this test since January 2004. While we currently expect to commercialize a test for colon cancer in early 2010, there can be no assurance that we will be successful in doing so. We are in various stages of research and development for other tests that we may offer as well as for enhancements to our existing test. We are not currently able to estimate when we may be able to commercialize tests for other cancers or whether we will be successful in doing so. If we are unable to increase sales of our test or to successfully develop and commercialize other tests or enhancements, our revenues and our ability to achieve profitability would be impaired, and the market price of our common stock could decline.

Commercialization of our Oncotype DX colon cancer test will require significant effort and expense on our part, and our commercialization efforts may not be successful.

Commercialization of our Onco*type* DX colon cancer test will require significant effort and expense on our part. For example, we will need to expand our clinical reference laboratory capabilities, internal quality assurance and information technology systems and processes to accommodate processing of more than one type of test. In addition, we will need to obtain CLIA certification and some state permits before we may conduct a second type of test at our clinical reference laboratory. We will also need to educate physicians, patients and payors about the benefits and cost-effectiveness of our Onco*type* DX colon cancer test and to establish reimbursement arrangements for this test with payors. We will be required to implement additional customer service and billing processes and procedures to handle a second test, and we may need to hire additional scientific, technical and other personnel to support the commercialization process. We cannot assure you that our commercialization efforts will be successfully implemented, that our educational efforts will result in sufficient physician or patient demand or that we will be able to obtain adequate reimbursement for our colon cancer test. If we fail to successfully commercialize our Onco*type* colon cancer test, our reputation could be harmed and our future prospects and our business could suffer.

New test development involves a lengthy and complex process, and we may be unable to commercialize any of the tests we are currently developing.

We have multiple tests in early development and devote considerable resources to research and development. For example, we are conducting early development studies in colon cancer for stage III patients, prostate, renal cell and lung cancers. There can be no assurance that our technologies will be capable of reliably predicting the recurrence of cancers other than breast cancer with the sensitivity and specificity necessary to be clinically and commercially useful, or that our colon cancer test will result in a commercially successful product. In addition, before we can develop diagnostic tests for new cancers and commercialize any new products, we will need to:

conduct substantial research and development;

conduct validation studies;

expend significant funds; and

develop and scale our laboratory processes to accommodate different tests.

This product development process involves a high degree of risk and 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

32

Table of Contents

resources repeating clinical trials, which would adversely impact the timing for generating potential revenues from those product candidates. In addition, as we develop products, we will have to make significant investments in product development, marketing and selling resources. If a clinical validation study fails to demonstrate the prospectively defined endpoints of the study, we might choose to abandon the development of the product or product feature that was the subject of the clinical trial, which could harm our business.

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

We have added a second shift at our clinical laboratory facility and will need to ramp up our testing capacity as our test volume grows. We will need to continue to implement increases in scale and related processing, customer service, billing and systems process improvements, and to expand our internal quality assurance program to support testing on a larger scale. We will also need additional certified laboratory scientists and other scientific and technical personnel to process higher volumes of our tests. We cannot assure you that any increases in scale, related improvements and quality assurance will be successfully implemented or that appropriate personnel will be available. As our colon cancer test and additional products are commercialized, we will need to bring new equipment on-line, implement new systems, controls and procedures and hire personnel with different qualifications. Failure to implement necessary procedures or to hire the necessary personnel could result in higher cost of processing or an inability to meet market demand. There can be no assurance that we will be able to perform tests on a timely basis at a level consistent with demand, that our efforts to scale our commercial operations will not negatively affect the quality of our test results, or that we will be successful in responding to the growing complexity of our testing operations. If we encounter difficulty meeting market demand or quality standards for our tests, our reputation could be harmed and our future prospects and our business could suffer.

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

If medical practitioners do not order our Onco*type* DX breast cancer test, our colon cancer test once it is commercially available, 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 each type of test through published papers, presentations at scientific conferences and one-on-one education by our sales force. In addition, we will need to demonstrate our ability to obtain adequate reimbursement coverage from third-party payors.

Prior to the inclusion of our Onco*type* DX breast cancer test in clinical guidelines, guidelines and practices regarding the treatment of breast cancer often recommended that chemotherapy be considered in most cases, including many cases in which our test might indicate that, based on our clinical trial results, chemotherapy would be of little or no benefit. Accordingly, physicians may be reluctant to order a test that may suggest recommending against chemotherapy in treating breast cancer. Moreover, our test provides quantitative information not currently provided by pathologists and it is performed at our facility rather than by the pathologist in a local laboratory, so pathologists may be reluctant to support our test. These facts may make it difficult for us to convince medical practitioners to order our test for their patients, which could limit our ability to generate revenues and our ability to achieve profitability.

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

Some patients may decide not to use our Onco*type* DX breast cancer test due to its price, part or all of which may be payable directly by the patient if the applicable payor denies reimbursement in full or in part. Even if medical practitioners recommend that their patients use our test, patients may still decide not to use our test, either because they do not want to be made aware of the likelihood of recurrence or they wish to pursue a particular course of therapy regardless of test results. Additionally, the current economic slowdown could negatively impact patients, resulting in loss of healthcare coverage, delayed medical checkups or inability to pay for a relatively expensive test. 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.

Table of Contents

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

In recent years, there have been numerous advances in technologies relating to the diagnosis and treatment of cancer. For example, technologies in addition to ours now reportedly permit measurement of gene expression in fixed paraffin embedded, or FPE, tissue specimens. New chemotherapeutic or biologic strategies are being developed that may increase survival time and reduce toxic side effects. These advances require us to continuously develop new products and enhance existing products to keep pace with evolving standards of care. Our tests 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 test could decline, which would harm our revenues.

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

We license from third parties technology necessary to develop our products. For example, we license technology from Roche that we use to analyze genes for possible inclusion in our tests and that we use in our clinical reference laboratory to conduct our test. In return for the use of a third party s technology, we may agree to pay the licensor royalties based on sales of our products. Royalties are a component of cost of product revenues and impact the margin on our test. We may need to license other technologies to commercialize future products. Our business may suffer if these licenses terminate, if the licensors fail to abide by the terms of the license or fail to prevent infringement by third parties, if the licensed patents or other rights are found to be invalid or if we are unable to enter into necessary licenses on acceptable terms. Companies that attempt to replicate our tests could be set up in countries that do not recognize our intellectual property. Such companies could send test results into the United States and therefore reduce sales of our tests.

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

Our ability to compete and to achieve and maintain profitability is impacted by our ability to protect our proprietary discoveries and technologies. We currently rely on a combination of patent applications, copyrights, trademarks, and confidentiality, material data transfer, license and invention assignment agreements to protect our intellectual property rights. We also rely upon trade secret laws to protect unpatented know-how and continuing technological innovation. Our intellectual property strategy is intended to develop and maintain our competitive position. Patents may be granted to us jointly with other organizations, and while we may have a right of first refusal, we cannot guarantee that a joint owner will not license rights to another party, and cannot guarantee that a joint owner will cooperate with us in the enforcement of patent rights.

As of June 30, 2009, we had four issued patents in the U.S. covering genes and methods that are components of the Onco*type* DX breast cancer test, one of which was issued jointly to us and to the National Surgical Adjuvant Breast and Bowel Project, or NSABP, and one European patent for methods used to determine gene expression. Our pending patent applications may not result in issued patents, and we cannot assure you that our issued patents or any patents that might ultimately be issued by the U.S. Patent and Trademark Office will protect our technology. Any patents that may be issued to us might be challenged by third parties as being invalid or unenforceable, or third parties may independently develop similar or competing technology that avoids our patents. We cannot be certain that the steps we have taken will prevent the misappropriation and use of our intellectual property, particularly in foreign countries where the laws may not protect our proprietary rights as fully as in the United States.

From time to time, the United States Supreme Court, other federal courts, the U.S. Congress or the U.S. Patent and Trademark Office may change the standards of patentability and any such changes could have a negative impact on our business. In addition, competitors may develop their own versions of our test in countries where we did not apply for patents or where our patents have not issued and compete with us in those countries, including encouraging the use of their test by physicians or patients in other countries.

Table of Contents

We may face intellectual property infringement claims that could be time-consuming and costly to defend and could result in our loss of significant rights and the assessment of treble damages.

We have received notices of claims of infringement or misuse of other parties proprietary rights in the past and may from time to time receive additional notices. Some of these claims may lead to litigation. We cannot assure you that we will prevail in such actions, or that other actions alleging misappropriation or misuse by us of third-party trade secrets, infringement by us of third-party patents and trademarks or the validity of our patents, will not be asserted or prosecuted against us. We may also initiate claims to defend our intellectual property. Intellectual property litigation, regardless of outcome, is expensive and time-consuming, could divert management s attention from our business and have a material negative effect on our business, operating results or financial condition. If there is a successful claim of infringement against us, we may be required to pay substantial damages (including treble damages if we were to be found to have willfully infringed a third party s patent) to the party claiming infringement, develop non-infringing technology, stop selling our test or using technology that contains the allegedly infringing intellectual property or enter into royalty or license agreements that may not be available on acceptable or commercially practical terms, if at all. Our failure to develop non-infringing technologies or license the proprietary rights on a timely basis could harm our business. In addition, revising our test to include the non-infringing technologies would require us to re-validate our test, which would be costly and time-consuming. Also, we may be unaware of pending patent applications that relate to our test. Parties making infringement claims on future issued patents may be able to obtain an injunction that would prevent us from selling our test or using technology that contains the allegedly infringing intellectual property, which could harm our business.

It is possible that a third party or patent office might take the position that one or more patents or patent applications constitute prior art in the field of genomic-based diagnostics. In such a case, we might be required to pay royalties, damages and costs to firms who own the rights to these patents, or we might be restricted from using any of the inventions claimed in those patents.

If we are unable to compete successfully, we may be unable to increase or sustain our revenues or achieve profitability.

Our principal competition comes from existing diagnostic methods used by pathologists and oncologists. These methods have been used for many years and are therefore difficult to change or supplement. In addition, companies offering capital equipment and kits or reagents to local pathology laboratories represent another source of potential competition. These kits are used directly by the pathologist, which facilitates adoption more readily than tests like ours that are performed outside the pathology laboratory. In addition, few diagnostic methods are as expensive as our Onco*type* DX breast cancer test.

We also face competition from many public and private companies that offer products or have conducted research to profile genes, gene expression or protein expression in breast cancer, such as Celera Corporation, Clarient Diagnostic Services, Agendia B.V., Applied Genomics, bioTheranostics, Exagen Diagnostics and University Genomics. Commercial laboratories with strong distribution networks for diagnostic tests, such as Genzyme Corporation, Laboratory Corporation of America Holdings and Quest Diagnostics Incorporated, may become competitors. Other potential competitors include companies that develop diagnostic tests such as Bayer Diagnostics, a division of Siemens AG, Roche Diagnostics, a division of F. Hoffmann-La Roche Ltd, and Veridex LLC, a Johnson & Johnson company, as well as other companies and academic and research institutions. Our competitors may invent and commercialize technology platforms that compete with ours. In addition, in December 2005, the federal government allocated a significant amount of funding to The Cancer Genome Atlas, a project aimed at developing a comprehensive catalog of the genetic mutations and other genomic changes that occur in cancers and maintaining the information in a free public database. As more information regarding cancer genomics becomes available to the public, we anticipate that more products aimed at identifying targeted treatment options will be developed and these products may compete with ours. In addition, competitors may develop their own versions of our test in countries where we did not apply for patents or where our patents have not issued and compete with us in those countries, including encouraging the use of their test by physicians or patients in other countries.

Our Onco*type* DX breast cancer test is considered relatively expensive for a diagnostic test. Effective July 1, 2009, we increased the list price of our test from $3,820 to $3,975, and we may raise prices in the future. This could impact

reimbursement of and demand for our test. Many of our present and potential competitors have widespread brand recognition and substantially greater financial and technical resources and development, production and marketing capabilities than we do. Others may develop lower-priced, less complex tests that could be viewed by physicians and payors as functionally equivalent to our test, which could force us to lower the list price of our test and impact our operating margins and our ability to achieve profitability. Some competitors have developed tests cleared for marketing by FDA. There may be a marketing differentiation or perception that an FDA-cleared test is more desirable than Onco*type* DX tests, and that may discourage adoption and reimbursement of our test. If we are unable to compete successfully against current or future competitors, we may be unable to increase market acceptance for and sales of our test, which could prevent us from

Table of Contents

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 clinical partners, or if other laboratories or our competitors secure access to these samples before us, our ability to research, develop and commercialize future products will be limited or delayed.

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

We rely on and expect to continue to rely on clinical collaborators to perform a substantial portion of our clinical trial functions. If any of our collaborators were to breach or terminate its agreement with us or otherwise fail to conduct the contracted activities successfully and in a timely manner, the research, development or commercialization of the products contemplated by the collaboration could be delayed or terminated. If any of our collaboration agreements are terminated, or if we are unable to renew those agreements on acceptable terms, we would be required to seek alternatives. We may not be able to negotiate additional collaborations on acceptable terms, if at all, and these collaborations may not be successful.

In the past, we have entered into clinical trial collaborations with highly regarded organizations in the cancer field including, for example, NSABP. Our success in the future depends in part on our ability to enter into agreements with other leading cancer organizations. This can be difficult due to internal and external constraints placed on these organizations. Some organizations may limit the number of collaborations they have with any one company so as to not be perceived as biased or conflicted. Organizations may also have insufficient administrative and related infrastructure to enable collaborations with many companies at once, which can extend the time it takes to develop, negotiate and implement a collaboration. Additionally, organizations often insist on retaining the rights to publish the clinical data resulting from the collaboration. The publication of clinical data in peer-reviewed journals is a crucial step in commercializing and obtaining reimbursement for a test such as ours, and our inability to control when, if ever, results are published may delay or limit our ability to derive sufficient revenues from any product that may result from a collaboration.

From time to time we expect to engage in discussions with potential clinical collaborators which may or may not lead to collaborations. However, we cannot guarantee that any discussions will result in clinical collaborations or that any clinical studies which may result will be enrolled or completed in a reasonable time frame or with successful outcomes. Once news of discussions regarding possible collaborations are known in the medical community, regardless of whether the news is accurate, failure to announce a collaboration agreement or the entity s announcement of a collaboration with an entity other than us may result in adverse speculation about us, our product or our technology, resulting in harm to our reputation and our business.

The loss of key members of our senior management team or our inability to retain highly skilled scientists, clinicians and salespeople could adversely affect our business.

Our success depends largely on the skills, experience and performance of key members of our executive management team and others in key management positions. The efforts of each of these persons together will be critical to us as we continue to develop our technologies and testing processes and as we attempt to transition to a company with more than one commercialized product. If we were to lose one or more of these key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategies.

Our research and development programs and commercial laboratory operations depend on our ability to attract and retain highly skilled scientists and technicians, including geneticists, licensed laboratory technicians, chemists, biostatisticians and engineers. We may not be able to attract or retain qualified scientists and technicians in the future due to the 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

Table of Contents

discovery, development and sales programs. All of our employees are at-will employees, which means that either we or the employee may terminate their employment at any time.

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

We do not have redundant clinical reference laboratory facilities outside of Redwood City, California. Redwood City is situated near earthquake fault lines. Our facility and the equipment we use to perform our tests would be costly to replace and could require substantial lead time to repair or replace. The facility may be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, flooding and power outages, which may render it difficult or impossible for us to perform our tests for some period of time. The inability to perform our tests or the backlog of tests that could develop if our facility is inoperable for even a short period of time may result in the loss of customers or harm our reputation, and we may be unable to regain those customers in the future. Although we possess insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all.

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

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

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

Changes in healthcare policy could increase our costs and impact sales of and reimbursement for our tests.

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 our tests based on existing healthcare policies. Changes in healthcare policy, such as changes in the FDA regulatory policy for LDTs, the creation of broad limits for diagnostic products in general or requirements that Medicare patients pay for portions of clinical laboratory tests or services received, could substantially impact the sales of our tests, increase costs and divert management s attention. For example, in 1989, the U.S. Congress passed federal self-referral prohibitions commonly known as the Stark Law, significantly restricting, regulating and changing laboratories relationships with physicians. In addition, sales of our tests outside of the U.S. makes us subject to foreign regulatory requirements, which may also change over time. We cannot predict what changes, if any, will be proposed or adopted or the effect that such proposals or adoption may have on our business, financial condition and results of operations.

Several proposals to reform the system of health care delivery in the U.S. are currently being considered by the federal and state governments. Some of the reforms call for a government sponsored health plan. A number of states are also contemplating significant reform of their healthcare policies. A proposal for additional government-funded health care could subject expenditures for health care to governmental budget constraints and limits on spending. We cannot predict what healthcare policy reforms, if any, will be adopted or the effect that such adoption may have on our business, financial condition and results of operations.

Table of Contents

We rely on a limited number of suppliers or, in some cases, a sole supplier, for some of our laboratory instruments and materials and may not be able to find replacements in the event our suppliers no longer supply that equipment or those materials.

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

We also rely on several sole suppliers for certain laboratory materials which we use to perform our tests. While we have developed alternate sourcing strategies for these materials, we cannot be certain that these strategies will be effective. If we should encounter delays or difficulties in securing these laboratory materials, delays in commercialization or an interruption in sales could occur.

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

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

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

The marketing, sale and use of our tests could lead to the filing of product liability claims if someone were to allege that our tests failed to perform as it was designed. We may also be subject to liability for errors in the test results we provide to physicians or for a misunderstanding of, or inappropriate reliance upon, the information we provide. For example, physicians sometimes order our Onco*type* DX breast cancer test for patients who do not have the same specific clinical attributes indicated on the report form as those for which the test provides clinical experience information from validation studies. It is our practice to offer medical consultation to physicians ordering our test for such patients, including ER- breast cancer patients. A product liability or professional liability claim could result in substantial damages and be costly and time consuming for us to defend. Although we believe that our existing product and professional liability insurance is adequate, we cannot assure you that our insurance would fully protect us from the financial impact of defending against product liability or professional liability claims. Any product liability or professional liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability lawsuit could cause injury to our reputation, result in the recall of our products, or cause current clinical partners to terminate existing agreements and potential clinical partners to seek other partners, any of which could impact our results of operations.

If we use biological and hazardous materials in a manner that causes injury, we could be liable for damages.

Our activities currently require the controlled use of potentially harmful biological materials, hazardous materials and chemicals and may in the future require the use of radioactive compounds. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability

could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject on an ongoing basis to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations may become significant and could negatively affect our operating results.

Table of Contents

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

Our business strategy contemplates international expansion, including establishing direct sales and physician outreach and education capabilities outside of the United States and expanding our relationship with distributors. In February 2009, we established a subsidiary in Geneva, Switzerland and we may establish operations in other countries in the future. Doing business internationally involves a number of risks, including:

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

failure by us or our distributors to obtain regulatory approvals for the use of our test in various countries;

difficulties in staffing and managing foreign operations;

complexities associated with managing multiple payor reimbursement regimes or self-pay systems;

logistics and regulations associated with shipping tissue samples, including infrastructure conditions and transportation delays;

limits in our ability to penetrate international markets if we are not able to process tests locally;

financial risks, such as longer payment cycles, difficulty collecting accounts receivable and exposure to foreign currency exchange rate fluctuations;

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

regulatory and compliance risks that relate to maintaining accurate information and control over sales and distributors activities that may fall within the purview of the Foreign Corrupt Practice Act, its books and records provisions or its anti-bribery provisions.

Any of these factors could significantly harm our future international expansion and operations and, consequently, our revenues and results of operations.

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

As of June 30, 2009, we had exclusive distribution agreements for our Onco*type* DX breast cancer test in over ten countries outside of the U.S., and we may enter into other similar arrangements in other countries in the future. We intend to grow our business internationally, and to do so we may need to attract additional distributors to expand the territories in which we sell our test. Distributors may not commit the necessary resources to market and sell our test to the level of our expectations. If current or future distributors do not perform adequately, or we are unable to locate distributors in particular geographic areas, we may not realize long-term international revenue growth. Regulatory requirements, costs of doing business outside of the United States and the reimbursement process in foreign markets may also impact our revenues from international sales or impact our ability to increase international sales in the future.

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

As part of our business strategy, we may pursue acquisitions of complementary businesses and assets, as well as technology licensing arrangements. We also may pursue strategic alliances that leverage our core technology and industry experience to expand our product offerings or distribution. We have no experience with respect to acquiring other companies and limited experience with respect to the formation of strategic alliances and joint ventures. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions by us also could result in significant

write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. Integration of an acquired company also may require management resources that otherwise would be available for ongoing development of our existing business. We may not identify or complete these transactions in a timely manner, on a cost-

Table of Contents

effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance or joint venture.

To finance any acquisitions, we may choose to issue shares of our common stock as consideration, which would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other companies for stock. The market price of our common stock has been particularly volatile during the recent period of upheaval in the capital markets and world economy, and this excessive volatility may continue for an extended period of time. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

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

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

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

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

sustain commercialization of our breast cancer test and enhancements to that test

fund commercialization of our colon cancer test, enhancements to that test or any future tests we may develop;

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

further expand our clinical laboratory operations;

expand our technologies into other areas of cancer;

expand our research and development activities;

acquire or license technologies; and

finance capital expenditures and general and administrative expenses.

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

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

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

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

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

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

competing technological and market developments;

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

changes in regulatory policies or laws that affect our operations.

Table of Contents

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. The credit markets and the financial services industry have been experiencing a period of unprecedented turmoil and upheaval characterized by the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the United States federal government. These events have generally made equity and debt financing more difficult to obtain. Accordingly, additional equity or debt financing might not be available on reasonable terms, if at all. If adequate funds are not available, we may have to scale back our operations or limit our research and development activities.

We must implement additional and expensive finance and accounting systems, procedures and controls as we grow our business and organization and to satisfy public company reporting requirements, which will increase our costs and require additional management resources.

As a public reporting company, we are required to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the Securities and Exchange Commission. Compliance with Section 404 of the Sarbanes-Oxley Act and other requirements has increased our costs and required additional management resources. We will need to continue to implement additional finance and accounting systems, procedures and controls as we grow our business and organization and to satisfy existing reporting requirements. If we fail to maintain or implement adequate controls, if we are unable to complete the required Section 404 assessment as to the adequacy of our internal control over financial reporting in future Form 10-K filings, or if our independent registered public accounting firm is unable to provide us with an unqualified report as to the effectiveness of our internal control over financial reporting in future Form 10-K filings, our ability to obtain additional financing could be impaired. In addition, investors could lose confidence in the reliability of our internal control over financial reporting and in the accuracy of our periodic reports filed under the Exchange Act. A lack of investor confidence in the reliability and accuracy of our public reporting could cause our stock price to decline.

Table of Contents

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

At our Annual Meeting of Stockholders held on June 8, 2009, the stockholders:

1. Elected the persons listed below to serve as directors of Genomic Health, each for a one-year term or until their successors are elected and qualified.

2. Approved the Amended and Restated Genomic Health, Inc. 2005 Stock Incentive Plan.

3. Ratified the selection of Ernst & Young LLP as the Company s independent registered public accounting firm for the year ending December 31, 2009.

The following sets forth information regarding the results of the voting at the Annual Meeting:

Proposal 1. Election of Directors

	Votes	
Nominee	For	Withheld
Randal W. Scott, Ph.D.	26,615,460	82,497
Kimberly J. Popovits	26,637,532	60,425
Julian C. Baker	26,111,291	586,666
Brook H. Byers	26,152,419	545,538
Fred E. Cohen, M.D., D. Phil.	26,641,591	56,366
Samuel D. Colella	26,638,591	59,366
Ginger L. Graham	26,639,078	58,879
Randall S. Livingston	26,639,077	58,880
Woodrow A. Myers, Jr., M.D.	26,144,548	553,409

Proposal 2. Approval of the Amended and Restated Genomic Health, Inc. 2005 Stock Incentive Plan

	Votes		
For	Against	Abstain	Non Votes
17,248,123	7,157,944	7,676	2,284,214

Proposal 3. Appointment of Ernst & Young LLP as the Company s independent registered public accounting firm

	Votes	
For	Against	Abstain
26,640,991	46,177	10,789

Table of Contents

ITEM 6. EXHIBITS

Exhibit Number	Description
10.1#	Amended and Restated Genomic Health, Inc. 2005 Stock Incentive Plan.
10.2#	Form of Stock Option Agreement.
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).

# Indicates management contract or compensatory plan or arrangement.

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

Table of Contents

SIGNATURES

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

GENOMIC HEALTH, INC.

Date: August 7, 2009

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

Date: August 7, 2009

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

Table of Contents

GENOMIC HEALTH, INC.
EXHIBIT INDEX

Exhibit Number	Description
10.1#	Amended and Restated Genomic Health, Inc. 2005 Stock Incentive Plan.
10.2#	Form of Stock Option Agreement.
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).

# Indicates management contract or compensatory plan or arrangement.

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