

GENOMIC HEALTH INC  
Form 10-Q/A  
November 09, 2015  
Table of Contents

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q/A

(Amendment No. 1)

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

For the quarterly period ended September 30, 2015

Or

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)

Edgar Filing: GENOMIC HEALTH INC - Form 10-Q/A

Delaware  
(State or other jurisdiction of  
incorporation or organization)

77-0552594  
(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 NO

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 NO

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

Accelerated filer

Non-accelerated filer  
(Do not check if a smaller reporting company)

Smaller reporting company

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

The number of outstanding shares of the registrant's Common Stock, \$0.0001 par value, was 32,542,356 as of October 31, 2015.

---

Table of Contents

EXPLANATORY NOTE

Genomic Health, Inc. (“we”, “us” or the “Company”) is filing this Amendment No. 1 to its Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2015 filed with the Securities and Exchange Commission on November 5, 2015 (the “Original Filing”) to include the correct Exhibit 31.2, which Exhibit was incorrect in the Original Filing.

Table of Contents

GENOMIC HEALTH, INC.

INDEX

	Page
<u>PART I:</u>	<u>FINANCIAL INFORMATION</u>
<u>Item 1.</u>	<u>Financial Statements</u>
	<u>Condensed Consolidated Balance Sheets</u> 3
	<u>Condensed Consolidated Statements of Operations</u> 4
	<u>Condensed Consolidated Statements of Comprehensive Income (Loss)</u> 5
	<u>Condensed Consolidated Statements of Cash Flows</u> 6
	<u>Notes to Condensed Consolidated Financial Statements</u> 7
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> 17
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures about Market Risk</u> 37
<u>Item 4.</u>	<u>Controls and Procedures</u> 38
<u>PART II:</u>	<u>OTHER INFORMATION</u> 39
<u>Item 1A.</u>	<u>Risk Factors</u> 39
<u>Item 6.</u>	<u>Exhibits</u> 59
<u>Signatures</u>	60

Table of Contents

## PART 1: FINANCIAL INFORMATION

## Item 1. Financial Statements

## GENOMIC HEALTH, INC.

## Condensed Consolidated Balance Sheets

(In thousands)

(Unaudited)

	September 30, 2015	December 31, 2014
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 28,010	\$ 29,726
Short-term marketable securities (see Note 3)	70,003	73,934
Accounts receivable (net of allowance for doubtful accounts; 2015—\$3,926, 2014—\$3,628)	33,754	34,916
Prepaid expenses and other current assets	10,238	9,944
Total current assets	142,005	148,520
Property and equipment, net	34,682	21,860
Other assets	1,656	15,541
Total assets	\$ 178,343	\$ 185,921
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 5,595	\$ 6,987
Accrued compensation and employee benefits	20,804	17,708
Accrued license fees	2,197	2,656
Accrued expenses and other current liabilities	14,465	10,444
Deferred revenues	251	335
Other current liabilities	208	208
Total current liabilities	43,520	38,338
Other liabilities	2,294	2,070
Commitments (see Note 5)		

Edgar Filing: GENOMIC HEALTH INC - Form 10-Q/A

Stockholders' equity:		
Common stock	3	3
Additional paid-in capital	386,738	370,496
Accumulated other comprehensive income (loss)	1,332	(15)
Accumulated deficit	(225,434)	(194,861)
Treasury stock, at cost	(30,110)	(30,110)
Total stockholders' equity	132,529	145,513
Total liabilities and stockholders' equity	\$ 178,343	\$ 185,921

See accompanying notes.

Table of Contents

GENOMIC HEALTH, INC.

Condensed Consolidated Statements of Operations

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Product revenues	\$ 73,554	\$ 69,101	\$ 212,325	\$ 206,580
Operating expenses:				
Cost of product revenues	13,718	11,979	39,513	36,241
Research and development	13,480	13,891	47,193	40,527
Selling and marketing	35,369	34,059	107,964	102,702
General and administrative	16,425	15,007	48,594	44,750
Total operating expenses	78,992	74,936	243,264	224,220
Loss from operations	(5,438)	(5,835)	(30,939)	(17,640)
Interest income	54	47	163	144
Other income (expense), net	(158)	(345)	(207)	(537)
Loss before income taxes	(5,542)	(6,133)	(30,983)	(18,033)
Income tax (benefit) expense	6,301	129	(410)	292
Net loss	\$ (11,843)	\$ (6,262)	\$ (30,573)	\$ (18,325)
Basic and diluted net loss per share	\$ (0.36)	\$ (0.20)	\$ (0.95)	\$ (0.58)
Shares used in computing basic and diluted net loss per share	32,498	31,590	32,294	31,339

See accompanying notes.



Table of Contents

GENOMIC HEALTH, INC.

Condensed Consolidated Statements of Comprehensive Income (Loss)

(In thousands)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Net loss	\$ (11,843)	\$ (6,262)	\$ (30,573)	\$ (18,325)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale marketable securities, net of tax expense (benefit) of \$6,206 and \$(765) for the three and nine months ended September 30, 2015, respectively, and \$0 for the three and nine months ended September 30, 2014	(10,696)	(5)	1,347	(14)
Comprehensive loss	\$ (22,539)	\$ (6,267)	\$ (29,226)	\$ (18,339)

See accompanying notes.

Table of Contents

GENOMIC HEALTH, INC.

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2015	2014
Operating activities		
Net loss	\$ (30,573)	\$ (18,325)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization	5,076	5,197
Employee stock-based compensation	12,055	12,596
Write-off of previously capitalized software costs	635	—
Impairment of assets held for sale and long-lived assets	—	414
Outside director restricted stock awarded in lieu of fees	150	170
Gain on disposal of property and equipment	(61)	(72)
Deferred tax benefit from unrealized gain on available-for-sale marketable securities	(765)	—
Changes in assets and liabilities:		
Accounts receivable	1,162	(1,521)
Prepaid expenses and other assets	(383)	242
Accounts payable	(1,816)	672
Accrued compensation and employee benefits	3,096	650
Accrued expenses and other liabilities	1,863	2,979
Deferred revenues	(84)	(397)
Net cash (used in) provided by operating activities	(9,645)	2,605
Investing activities		
Purchases of property and equipment	(16,056)	(5,588)
Proceeds from sale of property and equipment	42	117
Purchases of marketable securities	(54,605)	(72,221)
Maturities of marketable securities	74,505	76,826
Purchase of other investments	—	(2,000)
Net cash provided by (used in) investing activities	3,886	(2,866)
Financing activities		
Net proceeds from issuance of common stock under stock plans	7,766	7,703
Withholding taxes related to restricted stock units net share settlement	(3,723)	(3,483)
Net cash provided by financing activities	4,043	4,220
Net (decrease) increase in cash and cash equivalents	(1,716)	3,959
Cash and cash equivalents at the beginning of period	29,726	33,279
Cash and cash equivalents at the end of period	\$ 28,010	\$ 37,238
Non-cash investing and financing activities		

Edgar Filing: GENOMIC HEALTH INC - Form 10-Q/A

Accrued purchase of property and equipment	\$ 4,128	\$ 874
Change in fair value of equity investment	\$ 2,083	\$ —

See accompanying notes.

6

---

Table of Contents

GENOMIC HEALTH, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2015

(Unaudited)

Note 1. Organization and Summary of Significant Accounting Policies

The Company

Genomic Health, Inc. (the “Company”) is a global healthcare company that provides clinically-actionable genomic information to personalize cancer treatment. The Company develops and globally commercializes genomic based clinical laboratory services that analyze the underlying biology of cancer, allowing physicians and patients to make individualized treatment decisions. The Company is translating significant amounts of genomic data that will be useful for treatment planning throughout the cancer patient’s journey, from diagnosis to treatment selection and monitoring. The Company was incorporated in Delaware in August 2000. The Company’s first product, the Oncotype DX invasive breast cancer test, was launched in 2004 and is used for early stage invasive breast cancer patients to predict the likelihood of breast cancer recurrence and the likelihood of chemotherapy benefit. In January 2010, the Company launched its second product, the Oncotype DX colon cancer test, which is used to predict the likelihood of colon cancer recurrence in patients with stage II disease. In December 2011, the Company made Oncotype DX available for patients with ductal carcinoma in situ (“DCIS”), a pre invasive form of breast cancer. This test provides a DCIS score that is used to predict the likelihood of local recurrence. In June 2012, the Company began offering the Oncotype DX colon cancer test for use in patients with stage III disease treated with oxaliplatin containing adjuvant therapy. In May 2013, the Company launched the Oncotype DX prostate cancer test. The test provides a Genomic Prostate Score, or GPS, to predict disease aggressiveness in men with low risk disease. This test is used to improve treatment decisions for prostate cancer patients, in conjunction with the Gleason score, or tumor grading.

Principles of Consolidation

The accompanying condensed consolidated financial statements include all the accounts of the Company and its wholly-owned subsidiaries. The Company had two wholly-owned subsidiaries at September 30, 2015: Genomic Health International Holdings, LLC, which was established in Delaware in 2010 and supports the Company’s international sales and marketing efforts; and Oncotype Laboratories, Inc., which was established in 2012, and is inactive. Genomic Health International Holdings, LLC has 10 wholly-owned subsidiaries. The functional currency for the Company’s wholly-owned subsidiaries incorporated outside the United States is the U.S. dollar. All significant intercompany balances and transactions have been eliminated.

## Basis of Presentation and Use of Estimates

The accompanying interim period condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (“GAAP”). The condensed consolidated balance sheet as of September 30, 2015, condensed consolidated statements of operations and comprehensive income (loss) for the three and nine months ended September 30, 2015 and 2014, and condensed consolidated statements of cash flows for the nine months ended September 30, 2015 and 2014 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, 2014 has been derived from audited financial statements, but it does not include certain information and notes required by GAAP for complete consolidated financial statements.

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

## Table of Contents

The accompanying interim period condensed consolidated financial statements and related financial information should be read in conjunction with the audited consolidated financial statements and the related notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2014.

Certain reclassifications have been made to prior period amounts to conform to the current period presentation. For the three and nine months ended September 30, 2014, a reclassification of certain expenses from research and development to selling and marketing was made in the condensed consolidated statements of operations to conform to the current period presentation.

## Revenue Recognition

The Company derives its revenues from product sales. The majority of the Company's historical product revenues have been derived from the sale of the Oncotype DX breast cancer test. The Company generally bills third party payors upon generation and delivery of a patient report to the physician. As such, the Company takes assignment of benefits and the risk of collection with the third party payor. The Company generally 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 medical 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) collectability is reasonably assured. Criterion (1) is satisfied when the Company has an arrangement to pay or a contract with the payor in place addressing reimbursement for the Oncotype DX 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. 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 patient report. When evaluating whether the fee is fixed or determinable and collectible, the Company considers whether it has sufficient history to reliably estimate the total fee that will be received from a payor and a payor's individual payment patterns. Determination of criteria (3) and (4) are based on management's judgments regarding whether the fee charged for products or services delivered is fixed or determinable, and the collectability of those fees under any contract or arrangement. 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 arrangement or contracted payment amount. The estimated accrual amounts per test, recorded upon delivery of a patient report, are calculated for each accrual payor and are based on the arrangement or contracted price adjusted for individual payment patterns resulting from co-payment amounts and excluded services in healthcare plans. The Company also reduces sales for an estimate of amounts that qualify as patient assistance and related deductions that do not qualify for revenue recognition. When a payment received for an individual test is either higher or lower than the estimated accrual amount, the Company recognizes the difference as either cash revenue, in the case of higher payments, or in the case of lower payments, a charge against either the patient assistance program and related deductions reserve or the allowance for doubtful accounts, as applicable.

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 has exclusive distribution agreements for one or more of its Oncotype DX tests with distributors covering more than 90 countries. The distributor generally provides certain marketing and administrative services to the Company within its territory. As a condition of these agreements, the distributor generally pays the Company an agreed upon fee per test and the Company processes the tests. The same revenue recognition criteria described above generally apply to tests received through distributors. To the extent all criteria set forth above are not met when test results are delivered, product revenues are generally recognized when cash is received from the distributor.

From time to time, the Company receives requests for refunds of payments, generally due to overpayments made by third-party payors. Upon becoming aware of a refund request, the Company establishes an accrued liability for tests covered by the refund request until such time as the Company determines whether or not a refund is due. Accrued

## Table of Contents

refunds were \$532,000 and \$944,000 at September 30, 2015 and December 31, 2014, respectively, and are included in accrued expenses and other current liabilities.

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

### Allowance for Doubtful Accounts

The Company accrues an allowance for doubtful accounts against its accounts receivable based on estimates consistent with historical payment experience. Bad debt expense is included in general and administrative expense on the Company's condensed consolidated statements of operations. Accounts receivable are written off against the allowance when the appeals process is exhausted, when an unfavorable coverage decision is received or when there is other substantive evidence that the account will not be paid. The Company's allowance for doubtful accounts as of September 30, 2015 and December 31, 2014 was \$3.9 million and \$3.6 million, respectively. Write-offs for doubtful accounts of \$1.7 million and \$4.0 million were recorded against the allowance during the three and nine months ended September 30, 2015, respectively, and write-offs of \$1.0 million and \$4.0 million were recorded against the allowance during the three and nine months ended September 30, 2014, respectively. Bad debt expense was \$2.1 million and \$4.7 million for the three and nine months ended September 30, 2015, respectively, and \$1.7 million and \$4.8 million for the three and nine months ended September 30, 2014, respectively.

### Investments in Equity Securities

Beginning in 2011, the Company made investments in various tranches of the preferred stock of Invitae Corporation ("Invitae"), which at the time was a privately-held company, such that the carrying value of this investment was \$13.9 million at December 31, 2014. On February 18, 2015, Invitae completed an initial public offering of its common stock and the Company's preferred stock investment automatically converted into 2,207,793 shares of Invitae common stock. This investment is accounted for under the cost method as an available-for-sale marketable security and valued at \$15.9 million at September 30, 2015. Unrealized gains or losses resulting from changes in the fair value of this investment will be recorded in other comprehensive income until the securities are sold. These securities were subject to a lock-up agreement that expired in August 2015 and continue to be subject to the resale limitations of Rule 144 under the Securities Act of 1933.

### Property and Equipment



Property and equipment, including purchased and internally developed software are stated at cost. Depreciation is calculated using the straight line method over the estimated useful lives of the assets, which generally range from three to seven years. Leasehold improvements are amortized using the straight line method over the estimated useful lives of the assets or the remaining term of the lease, whichever is shorter. The Company wrote off \$57,000 and \$635,000 of previously capitalized software costs for the three and nine months ended September 30, 2015, respectively.

#### Recently Issued Accounting Pronouncements

In April 2015, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update No. 2015-05, Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Customer’s Accounting for Fees Paid in a Cloud Computing Arrangement (“ASU 2015-05”). This amendment provides guidance to help entities determine whether a cloud computing arrangement contains a software license that should be accounted for as internal-use software or as a service contract. ASU 2015-05 is effective for interim and annual reporting periods beginning after December 15, 2015, with early adoption permitted. Upon adoption, an entity has the option to apply the provisions of ASU 2015-05 either prospectively to all arrangements entered into or materially modified, or retrospectively. The Company does not expect the impact of the adoption of ASU 2015-05 to be material to its consolidated financial statements.

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers (“ASU 2014-09”) to provide guidance on revenue recognition. ASU 2014-09 requires a company to recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the

Table of Contents

company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under current guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. In July 2015, the FASB deferred the effective date for annual reporting periods beginning after December 15, 2017 (including interim reporting periods within those periods). Early adoption is permitted to the original effective date of December 15, 2016 (including interim reporting periods within those periods). The amendments may be applied retrospectively to each prior period presented or retrospectively with the cumulative effect recognized as of the date of initial application. The Company is currently evaluating the impact of adopting ASU 2014-09 on its consolidated financial statements.

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 of 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 and restricted stock unit (“RSU”) awards are considered to be potential common shares and are not included in the calculation of diluted net loss per share because their effect is anti-dilutive.

Options to purchase 671,000 and 853,000 shares of the Company’s common stock were outstanding during the three and nine months ended September 30, 2015, respectively, and 106,000 and 116,000 RSUs were outstanding during the three and nine months ended September 30, 2015, respectively, but were not included in the computation of diluted net loss per share because their effect is anti-dilutive. Options to purchase 1.0 million shares of the Company’s common stock were outstanding during the three and nine months ended September 30, 2014, respectively, and 139,000 and 109,000 RSUs were outstanding during the three and nine months ended September 30, 2014, respectively, but were not included in the computation of diluted net loss per share because their effect is anti-dilutive.

Note 3. Fair Value Measurements

The Company measures certain financial assets, including cash equivalents and marketable securities, at their fair value on a recurring basis. The fair value of these financial assets was determined based on a hierarchy of three levels of inputs, of which the first two are considered observable and the last unobservable, as follows:

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

Level 2: Observable inputs other than Level 1 inputs, 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; and

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.

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 consider factors specific to the asset or liability. The Company did not have any non-financial assets or liabilities that were measured or disclosed at fair value on a recurring basis at either September 30, 2015 or December 31, 2014, respectively. The following tables set forth the

Table of Contents

Company's financial instruments that were measured at fair value on a recurring basis at September 30, 2015 and December 31, 2014 by level within the fair value hierarchy:

	Actively Quoted Markets for Identical Assets Level 1 (In thousands)	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	Balance at September 30, 2015
As of September 30, 2015:				
Assets				
Money market deposits	\$ 19,130	\$ —	\$ —	\$ 19,130
Commercial paper	—	18,749	—	18,749
Corporate debt securities	—	36,065	—	36,065
Corporate equity securities	—	15,940	—	15,940
Total	\$ 19,130	\$ 70,754	\$ —	\$ 89,884
	Actively Quoted Markets for Identical Assets Level 1 (In thousands)	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	Balance at December 31, 2014
As of December 31, 2014:				
Assets				
Money market deposits	\$ 12,397	\$ —	\$ —	\$ 12,397
Commercial paper	—	29,749	—	29,749
Corporate debt securities	—	46,435	—	46,435
Total	\$ 12,397	\$ 76,184	\$ —	\$ 88,581

The Company's commercial paper and corporate bonds are classified as Level 2 as they are valued using multi-dimensional relational pricing models that use observable market inputs, including benchmark yields, reported trades, broker-dealer quotes, issuer spreads, benchmark securities, bids, offers and reference data. Not all inputs listed are available for use in the evaluation process on any given day for each security evaluation. In addition, market

indicators and industry and economic events are monitored and may serve as a trigger to acquire further corroborating market data. The Company's corporate equity securities are classified as Level 2 while subject to certain restrictions on sale. The Company's corporate equity securities at September 30, 2015 were previously recorded as investments in a privately held company and included in other assets as of December 31, 2014. There were no transfers between Level 1 and Level 2 categories during the three or nine months ended September 30, 2015 and 2014, respectively.

All of the Company's marketable securities are classified as available-for-sale. The following tables illustrate the Company's available-for-sale marketable securities as of the dates indicated:

	September 30, 2015			
	Amortized	Unrealized	Unrealized	Estimated
	Cost	Gains	Losses	Fair Value
	(In thousands)			
Commercial paper	\$ 18,732	\$ 17	\$ —	\$ 18,749
Corporate debt securities	35,317	1	(4)	35,314
Corporate equity securities	13,857	2,083	—	15,940
Total	\$ 67,906	\$ 2,101	\$ (4)	\$ 70,003

Table of Contents

	December 31, 2014			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
	(In thousands)			
Commercial paper	\$ 29,730	\$ 19	\$ —	\$ 29,749
Corporate debt securities	44,219	—	(34)	44,185
Total	\$ 73,949	\$ 19	\$ (34)	\$ 73,934

The Company had no realized gains or losses on available-for-sale marketable securities for the three and nine months ended September 30, 2015 and 2014, respectively.

All of the Company's available-for-sale marketable securities had contractual maturities of one year or less as of September 30, 2015 and December 31, 2014.

#### Note 4. Collaboration and Commercial Technology Licensing Agreements

The Company has entered into a variety of collaboration and specimen transfer agreements relating to its development efforts. The Company recorded collaboration expenses of \$1.4 million and \$10.8 million for the three and nine months ended September 30, 2015, respectively, and \$1.9 million and \$4.1 million for the three and nine months ended September 30, 2014, respectively, relating to services provided in connection with these agreements. The \$10.8 million of collaboration expense for the nine months ended September 30, 2015 includes a one-time \$5.5 million expense for the wind-down of a license agreement and development program as described below. In addition to these expenses, some of the agreements contain provisions for royalties from inventions resulting from the collaborations. The Company has specified options and rights relating to joint inventions arising out of the collaborations.

The Company is a party to various agreements under which it licenses technology on a non-exclusive basis in the field of human diagnostics. Access to these licenses enables the Company to process its Oncotype DX tests. While certain agreements contain provisions for fixed annual payments, license fees are generally calculated as a percentage of product revenues, with rates that vary by agreement and may be tiered, and payments that may be capped at annual minimum or maximum amounts. The Company recognized costs recorded under these agreements totaling \$2.3 million and \$6.9 million for the three and nine months ended September 30, 2015, respectively, and \$2.4 million and \$7.2 million for the three and nine months ended September 30, 2014, respectively, which were included in cost of product revenues.

In November 2013, the Company entered into an exclusive license agreement to develop and commercialize a test to predict benefit from DNA damage-based chemotherapy drugs, such as anthracycline-based regimens, in high risk breast cancer. The Company made an up-front payment of \$9.0 million, which was recognized in research and

development expense in the fourth quarter of 2013, and milestone payments would have been required if certain clinical and commercial endpoints were achieved in the future. With successful commercialization of a test, the Company would have been obligated to pay royalties. During the quarter ended March 31, 2015, the Company accrued \$5.5 million in anticipation of the wind-down of this license agreement and development program, which was recognized as research and development expense in the accompanying condensed consolidated statements of operations. The license agreement was terminated in May 2015 and, as a result, the Company has no future obligations under this agreement.

The Company is required to make a series of fixed annual payments under a collaboration agreement beginning with the one year anniversary of achieving a key milestone for the Company's DCIS clinical study in June 2014. As of September 30, 2015, future annual payments under this agreement totaled \$1.7 million, including payments of \$604,000, \$604,000, and \$504,000 due in 2015, 2016, and 2017, respectively.

Table of Contents

Note 5. Commitments

Lease Obligations

In September 2005, the Company entered into a non-cancelable lease for 48,000 square feet of laboratory and office space that the Company currently occupies in Redwood City, California. In November 2010, the Company executed an amendment to extend the term of the lease through March 2019, with an option for the Company to extend the term of the lease for an additional five years. The agreement included lease incentive obligations of \$834,000 that are being amortized on a straight line basis over the life of the lease.

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. In November 2010, the Company executed an amendment to extend the term of the lease through March 2018, with an option for the Company to extend the lease for an additional five years. The agreement included lease incentive obligations totaling \$283,000 that are being amortized on a straight line basis over the life of the lease.

In October 2009, the Company entered into a non-cancelable agreement to lease an additional 30,500 square feet of office space near the locations the Company occupies. The lease expires in March 2018, with an option for the Company to extend the term of the lease for an additional five years. The agreement includes lease incentive obligations of \$307,000 that are being amortized on a straight line basis over the life of the lease.

In August 2013, the Company entered into a non-cancelable agreement to lease an additional 18,400 square feet of laboratory and office space near the locations the Company currently occupies. The lease expires in March 2019, with an option for the Company to extend the term of the lease for an additional five years. In July 2014, the Company leased an additional 5,500 square feet in the same location on the same terms. The agreements include lease incentive obligations of \$358,000 that are being amortized on a straight line basis over the life of the lease.

In May 2010, the Company's European subsidiary entered into a non-cancelable lease for approximately 2,500 square feet of office space in Geneva, Switzerland. In May 2014, the Company executed an amendment to extend the terms of the lease and executed a new lease for approximately 5,000 square feet of additional space in the same location. Both leases expire in May 2016.

Future non-cancelable commitments under these operating leases at September 30, 2015 were as follows:



Years Ending December 31,	Annual Payments (In thousands)
2015 (remainder of year)	\$ 986
2016	3,871
2017	3,867
2018	2,476
2019	504
Total minimum payments	\$ 11,704

#### Note 6. Stock-Based Compensation

##### Stock Options

The Company granted options to purchase 17,000 and 449,667 shares of common stock to employees during the three and nine months ended September 30, 2015, respectively, and options to purchase 442,010 shares of common stock to employees during nine months ended September 30, 2014. There were no options granted during the three months ended September 30, 2014. For the three and nine months ended September 30, 2015, the Company issued 69,123 and 335,192 shares of common stock in connection with the exercise of stock options with a weighted-average exercise price

## Table of Contents

of \$12.62 and \$15.70 per share, respectively. For the three and nine months ended September 30, 2014, the Company issued 166,090 and 424,840 shares of common stock in connection with the exercise of stock options with a weighted-average exercise price of \$15.47 and \$12.85 per share, respectively.

### Performance-Based Vesting Stock Options

During the nine months ended September 30, 2015, the Company granted performance-based vesting stock options (“PV stock options”) to purchase 148,100 shares of common stock. There were no PV stock options granted during the three months ended September 30, 2015 or the three and nine months ended September 30, 2014. The number of shares potentially issuable under PV stock options is subject to the attainment of pre-established, objective performance goals over a specified period. In addition, the awards have a service vesting criteria following the achievement of performance criteria through February 2019.

The Company recognizes the fair value of these awards to the extent the achievement of the related performance criteria is estimated to be probable. If a performance criterion is subsequently determined to not be probable of achievement, any related expense is reversed in the period such determination is made. Conversely, if a performance criterion is not currently expected to be achieved but is later determined to be probable of achievement, a “catch-up” entry is recorded in the period such determination is made for the expense that would have been recognized had the performance criterion been probable of achievement since the grant of the award. As of September 30, 2015, the achievement of the performance criteria was not estimated to be probable. Changes in the Company’s assessment of the probability of achievement of performance criteria could result in expense being accrued or reversed in future periods.

### Restricted Stock Units

During the three and nine months ended September 30, 2015, the Company awarded 19,319 and 403,825 RSUs with a grant-date fair value of \$530,000 and \$12.5 million, or \$27.46 and \$30.85 per share, respectively. During the three and nine months ended September 30, 2014, the Company awarded 21,970 and 367,157 RSUs with a grant-date fair value of \$607,000 and \$10.7 million, or \$27.64 and \$29.07 per share, respectively. Each RSU entitles the recipient to receive one share of the Company’s common stock upon vesting. RSUs awarded to employees generally vest as to one-third of the total number of shares awarded annually over a three-year period. During the three and nine months ended September 30, 2015, the Company issued 9,780 and 174,997 shares of common stock in connection with the vesting of RSUs with a weighted-average grant date fair value of \$31.72 and \$29.79 per share, respectively. During the three and nine months ended September 30, 2014, the Company issued 9,901 and 182,574 shares of common stock in connection with the vesting of RSUs with a weighted-average grant date fair value of \$30.69 and \$28.30 per share, respectively.

Performance-Based Vesting Restricted Stock Units

During the nine months ended September 30, 2015, the Company awarded 22,980 performance-based vesting restricted stock units (“PVRSUs”) with a grant-date fair value of \$715,000, or \$31.12 per share. The amount potentially available under a PVRSU is subject to the attainment of pre-established, objective performance goals over a specified period. In addition, the awards have a service vesting criteria following the achievement of performance criteria through February 2018. During the nine months ended September 30, 2014, the Company awarded 44,630 PVRSUs with a grant-date fair value of \$1.2 million or \$27.21 per share. In addition, these awards have a service vesting criteria following the achievement of performance criteria through February 2016. During the nine months ended September 30, 2015, the Company issued 4,227 shares of common stock in connection with the vesting of PVRSUs with a weighted-average grant date fair value of \$27.21 per share. As of September 30, 2015, there were 29,133 PVRSUs outstanding with a grant date fair value of \$883,000.

The Company recognizes the fair value of these awards to the extent the achievement of the related performance criteria is estimated to be probable. If a performance criterion is subsequently determined to not be probable of achievement, any related expense is reversed in the period such determination is made. Conversely, if a performance criterion is not currently expected to be achieved but is later determined to be probable of achievement, a “catch-up” entry is recorded in the period such determination is made for the expense that would have been recognized had the performance criterion been probable of achievement since the grant of the award. As of September 30, 2015, the

## Table of Contents

achievement of the performance criteria was not estimated to be probable. Changes in the Company's assessment of the probability of achievement of performance criteria could result in expense being accrued or reversed in future periods.

### Restricted Stock in Lieu of Directors' Fees

Outside members of the Company's Board of Directors may elect to receive fully-vested restricted stock in lieu of cash compensation for services as a director. During the three and nine months ended September 30, 2015, the Company issued 1,825 and 5,025 shares of restricted stock to outside directors, with a grant date fair value of \$50,000 and \$150,000, and a weighted-average grant date fair value of \$27.34 and \$29.79 per share, respectively. During the three and nine months ended September 30, 2014, the Company issued 2,148 and 6,109 shares of restricted stock to outside directors, with a grant date fair value of \$60,000 and \$170,000, and a weighted-average grant date fair value of \$27.86 and \$27.78 per share, respectively.

### Employee Stock Purchase Plan

During the nine months ended September 30, 2015, 108,674 shares of common stock were issued under the Company's Employee Stock Purchase Plan ("ESPP"). There were no shares issued during the three months ended September 30, 2014. A total of 1,250,000 shares of common stock have been reserved for issuance under the ESPP, of which 651,064 shares were available for issuance as of September 30, 2015. As of September 30, 2015, there was \$222,000 of unrecognized compensation expense related to the ESPP, which is expected to be recognized over a period of two months.

### Employee Stock-Based Compensation Expense

The Company recognized employee stock-based compensation expense of \$3.9 million and \$12.1 million for the three and nine months ended September 30, 2015, respectively, and \$4.0 million and \$12.6 million for the three and nine months ended September 30, 2014, respectively. Employee stock-based compensation expense includes expense related to stock option grants, RSU awards, PVRSU awards and stock purchased under the ESPP. Employee stock-based compensation expense is calculated based on awards expected to vest and has been reduced for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Employee stock-based compensation expense also includes expense related to stock options granted to outside directors of the Company.

### Valuation Assumptions

The Company values its stock option grants using the Black-Scholes option valuation model. Option valuation models require the input of highly subjective assumptions that can vary over time. The Company's assumptions regarding expected volatility are based on the historical volatility of the Company's common stock. The expected life of options granted is estimated based on historical option exercise data and assumptions related to unsettled options. The risk-free interest rate is estimated using published rates for U.S. Treasury securities with a remaining term approximating the expected life of the options granted. The Company uses a dividend yield of zero as it has never paid cash dividends and does not anticipate paying cash dividends in the foreseeable future.

Note 7. Segment Information

The Company operates in one business segment, which primarily focuses on the development and global commercialization of genomic based clinical laboratory services that analyze the underlying biology of cancer, allowing physicians and patients to make individualized treatment decisions. As of September 30, 2015, the majority of the Company's product revenues have been derived from sales of one product, the Oncotype DX breast cancer test.

Table of Contents

The following table summarizes total revenue from customers by geographic region. Product revenues are attributed to countries based on ship-to location.

	Three Months		Nine Months Ended	
	Ended		September 30,	
	September 30,	September 30,	September 30,	September 30,
	2015	2014	2015	2014
	(In thousands)		(In thousands)	
United States	\$ 63,051	\$ 57,777	\$ 181,459	\$ 171,863
Outside of the United States	10,503	11,324	30,866	34,717
Total revenues	\$ 73,554	\$ 69,101	\$ 212,325	\$ 206,580

## Note 8. Income Taxes

The Company recorded income tax expense of \$6.3 million and an income tax benefit of \$410,000 for the three and nine months ended September 30, 2015, respectively, which was computed using the “discrete” (or “cut-off”) method. The income tax expense and benefit for the three and nine months ended September 30, 2015 are principally comprised of a deferred tax expense and a deferred tax benefit generated by the unrealized gain recognized during the period on available-for-sale marketable securities, which is included in other comprehensive income. The intraperiod tax allocation rules limit the amount of benefit recognized to the lesser of year-to-date pre-tax loss or year-to-date unrealized gain recognized on available-for-sale marketable securities included in other comprehensive income. Therefore, the tax benefit will change accordingly in subsequent periods. The deferred tax expense of \$6.2 million recorded in the three months ended September 30, 2015 was increased by \$96,000 of miscellaneous state income tax and foreign income tax expense. The deferred tax benefit of \$765,000 recorded in the nine months ended September 30, 2015 was offset by \$355,000 of miscellaneous state income tax and foreign income tax expense. Income tax expense for the three and nine months ended September 30, 2014 was \$129,000 and \$292,000, respectively, which was computed using the same method and was principally comprised of state income taxes and foreign taxes.

Based on all available objective evidence, the Company believes that it is more likely than not that its net deferred tax assets will not be fully realized. Accordingly, the Company maintained a valuation allowance against all of its net deferred tax assets as of each of September 30, 2015 and December 31, 2014. The Company will continue to maintain a full valuation allowance until there is sufficient evidence to support recoverability of its deferred tax assets.

The Company had \$1.6 million of unrecognized tax benefits at each of September 30, 2015 and December 31, 2014. The Company does not anticipate a material change to its unrecognized tax benefits over the next 12 months that would affect its effective tax rate. Unrecognized tax benefits may change during the next 12 months for items that arise in the ordinary course of business.

Accrued interest and penalties related to unrecognized tax benefits are recognized as part of the Company's income tax provision in its condensed consolidated statements of operations. The statute of limitations remain open for the years 2000 through 2015 in U.S. federal and state jurisdictions, and for the years 2010 through 2015 in foreign jurisdictions.

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, a significant amount of our revenues will be derived from Oncotype DX for invasive breast cancer; the factors that may impact our financial results; our ability to achieve sustained profitability; our business strategy and our ability to achieve our strategic goals; our expectations regarding product revenues and the sources of those revenues; the amount of future revenues that we may derive from Medicare patients or categories of patients; our belief that we may become more dependent on Medicare reimbursement in the future; 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 reimbursement from third-party payors and government insurance programs for new indications of tests, new tests or in new markets; the potential impact of changes in reimbursement levels for our tests; our expectations regarding our international expansion and opportunities; our expectations for reimbursement in international markets; our intent to enter into additional foreign distribution arrangements; the potential effects of foreign currency exchange rate fluctuations; our beliefs with respect to the benefits and attributes of our tests or tests we may seek to develop in the future; the factors we believe drive demand for our tests and our ability to sustain or increase such demand; our success in increasing patient and physician demand as a result of our direct sales approach and our sales forces' capacity to sell our tests; plans for, and the timeframe for the development or commercial launch of, future tests or enhancements to address different patient populations of breast, colon or prostate cancer, other types of cancer or specific cancer treatments; our ability to compete with new or existing market participants; the factors that we believe will drive reimbursement and the establishment of coverage policies; the capacity of our clinical reference laboratory to process tests and our expectations regarding capacity; our expectations regarding expansion of our clinical reference laboratory; our dependence on collaborative relationships to develop tests and the success of those relationships; whether any tests will result from our collaborations or license agreements; the applicability of clinical results to actual outcomes; our estimates and assumptions with respect to disease incidence and potential market opportunities; the occurrence, timing, outcome or success of clinical trials or studies; our plans with respect to additional studies; our expectations regarding timing of the announcement or publication of research results; the benefits of our technology platform; the economic benefits of our tests to the healthcare system; the ability of our tests to impact treatment decisions; our beliefs regarding our competitive position; our expectations regarding new and future technologies, including non-invasive test technology, and their potential benefits; our beliefs regarding the benefits of genomic analysis in various patient populations; our expectations regarding clinical development processes future tests may follow; our expectation that our research and development, general and administrative and sales and marketing 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 expectations regarding future levels of bad debt expense and billing and collections fees; our ability to attract and retain experienced personnel; our plans to implement new enterprise software; the adequacy of our product liability insurance; our anticipated cash needs and our estimates regarding our capital requirements; our need for additional financing; our expected future sources of cash; our compliance with federal, state and foreign regulatory requirements; the potential impact resulting from the regulation of our tests by the U.S. Food and Drug Administration, or FDA, and other similar non-U.S. regulators; our belief that our tests are properly regulated under the Clinical Laboratory Improvement Amendments of 1988, or CLIA; the impact of new or changing policies, regulation or legislation, or of judicial decisions, on our business and reimbursement for our tests; the impact of seasonal fluctuations and economic conditions on our business; our belief that we have taken reasonable steps to protect our intellectual property; the impact of changing interest rates; our beliefs regarding our unrecognized tax benefits or our valuation allowance; 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; 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 and product enhancements; the risk of unanticipated delays in research and development efforts; the risk that we may not obtain or maintain reimbursement for

## Table of Contents

our existing tests or any future tests we may develop; the risk that reimbursement pricing or coverage may change; the risks and uncertainties associated with the regulation of our tests by the FDA or regulatory agencies outside of the U.S.; the success of our new technology; the results of clinical studies; the applicability of clinical results to actual outcomes; the impact of new legislation or regulations, or of judicial decisions, on our business; our ability to compete against third parties; our ability to obtain capital when needed; the economic environment; and our history of operating losses. These forward-looking statements speak only as of the date hereof. We expressly disclaim any obligation or undertaking to update any forward-looking statements contained herein to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based.

This report contains statistical data attributable to both the Kantar Health, Inc.'s CancerMPact database (February 2013) and the Globocan 2008 Data published by the International Agency for Research on Cancer (IARC) 2008, or data that we derived from these sources. These sources generally indicate that they believe their information is reliable but do not guarantee the accuracy and completeness of their information. Although we believe that the sources are reliable, we have not independently verified their data.

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

## Business Overview

We are a global healthcare company that provides clinically-actionable genomic information to personalize cancer treatment. We develop and globally commercialize genomic-based clinical laboratory services that analyze the underlying biology of cancer, allowing physicians and patients to make individualized treatment decisions. We are translating significant amounts of genomic data that will be useful for treatment planning throughout the cancer patient's journey, from diagnosis to treatment selection and monitoring. We offer our Oncotype DX tests as a clinical laboratory service, where we analyze the expression levels of genes in tumor tissue samples and provide physicians with a quantitative gene expression profile expressed as a single quantitative score, which we call a Recurrence Score for invasive breast cancer and colon cancer, a DCIS Score for ductal carcinoma in situ, or DCIS, and a Genomic Prostate Score, or GPS, for prostate cancer.

In January 2004, we launched our first Oncotype DX test, which is used to predict the likelihood of cancer recurrence and the likelihood of chemotherapy benefit in early stage invasive breast cancer patients. In January 2010, we launched our second Oncotype DX test, the first multigene expression test developed to assess risk of recurrence in

stage II colon cancer patients. In late December 2011, we made Oncotype DX available for patients with DCIS, a pre-invasive form of breast cancer. In June 2012, we extended our offering of the Oncotype DX colon cancer test to patients with stage III disease treated with oxaliplatin-containing adjuvant therapy. In May 2013, we launched our Oncotype DX prostate cancer test, which is used to predict disease aggressiveness in men with low risk disease. Effective August 1, 2015, the list price of our Oncotype DX breast cancer tests in the United States increased from \$4,510 to \$4,620, the list price of our Oncotype DX colon cancer test increased from \$4,330 to \$4,420 and the list price of our Oncotype DX prostate cancer test increased from \$4,180 to \$4,520. The substantial majority of our historical revenues have been derived from the sale of Oncotype DX breast cancer tests ordered by physicians in the United States.

For the three and nine months ended September 30, 2015, we delivered more than 27,820 and 79,340 Oncotype DX test reports for use in treatment planning, respectively, an increase of 17% and 12%, respectively, from the more than 23,700 and 70,850 reports delivered for the same periods in 2014. All of our tests are conducted at our clinical reference laboratory in Redwood City, California. Our clinical reference laboratory processing capacity is currently approximately 115,000 tests annually, and has significant expansion capacity with incremental increases in laboratory personnel and equipment. The Oncotype DX breast, colon, and prostate cancer tests analyze different genes. However, all of the tests are based on a similar Oncotype DX reverse transcription polymerase chain reaction, or RT-PCR platform. We believe that we currently have sufficient capacity to process current demand for our tests.

## Table of Contents

In connection with the May 2013 launch of our prostate cancer test, we have expanded our clinical laboratory processing capacity. We expect our continued commercialization efforts of our prostate cancer test will result in increased costs for laboratory testing, including staffing-related costs, incremental sales and marketing personnel to introduce our product to a new group of physicians and patients, costs for clinical utility studies and costs associated with obtaining reimbursement coverage.

We depend upon third-party payors, both public and private, to provide reimbursement for our tests. Accordingly, we have and expect to continue to focus substantial resources on obtaining and maintaining reimbursement coverage from third-party payors.

We have continued to expand our business, both in the United States and internationally. We currently plan to continue to use essentially the same business model internationally as we use in the United States, however, there are significant differences between countries that need to be considered. For example, operational requirements generally vary from country to country, and different countries may have a public healthcare system, a combination of public and private healthcare system or a cash-based payment system. We have a direct commercial presence with employees in Canada, Japan and certain European countries, including our European headquarters in Geneva, Switzerland. Additionally, we have exclusive distribution agreements for the sale of our breast and colon cancer tests with distributors covering more than 90 countries outside of the United States.

As our international business expands, our financial results become more sensitive to the effect of fluctuations in foreign currency exchange rates. For example, in countries where we have a direct commercial presence, our tests are sold in local currency, which results in foreign currency exchange rate fluctuations affecting our U.S.-dollar reported revenues. In other markets where we sell our tests in U.S. dollars to distribution partners, the demand for our tests may be impacted by the change in U.S. dollar exchange rates affecting partners' costs or local market price adjustments.

We expect that international sales of our Oncotype DX tests will be heavily dependent on the availability of reimbursement and sample access. In many countries, governments are primarily responsible for reimbursing diagnostic tests. Governments often have significant discretion in determining whether a test will be reimbursed at all, and if so, how much will be paid. In addition, certain countries, such as China, have prohibitions against exporting tissue samples which will limit our ability to offer our tests in those countries without local laboratories or a method of test delivery which does not require samples to be transported to our U.S. laboratory.

The majority of our international Oncotype DX breast and colon cancer test revenues come from direct payor reimbursement, payments from our distributors, patient self-pay, and clinical collaborations in various countries. We have obtained some coverage, which varies substantially from country to country, for our breast cancer test outside of the United States, including in Argentina, Canada, the Czech Republic, Germany, Greece, Ireland, Israel, Saudi Arabia, Spain, Switzerland and the United Kingdom. In September 2013, we announced that the National Institute for Health and Care Excellence (NICE) in the United Kingdom issued its final guidance recommending Oncotype DX as the only multi-gene breast cancer test for use in clinical practice to guide chemotherapy treatment decisions for patients with early-stage, hormone receptor-positive, lymph node negative, human epidermal growth factor receptor 2 negative, invasive breast cancer. We have established reimbursement with NHS England following NICE's recommendation for our breast cancer test, similar to our contracting process with U.S. insurers, and in April 2015, we began experiencing an increase in test orders from the United Kingdom. We are in the process of completing contractual arrangements with more than 100 NHS England trusts, which is necessary to begin to receive payment from each trust and recognize revenue on these tests. During the quarter ended September 30, 2015, we began to receive payments from NHS England trusts with whom we have completed contractual arrangements. In April 2014, we announced that the Gynecologic Oncology Working Group (AGO) in Germany updated their guidelines to recommend Oncotype DX as the only breast cancer gene expression test to predict chemotherapy benefit in early-stage, hormone receptor-positive invasive breast cancer. We expect that it will take several years to establish

broad coverage and reimbursement for our Oncotype DX breast, colon and prostate cancer tests with payors in countries outside of the United States and there can be no assurance that our efforts will be successful.

#### Oncotype DX Breast Cancer Test

We expect to continue to focus substantial resources on pursuing global adoption of and reimbursement for our Oncotype DX breast cancer test. We believe increased demand for our Oncotype DX breast cancer test resulted from our

19

---

## Table of Contents

ongoing commercial efforts, expanded utility for new breast cancer patient groups, continued publication of peer-reviewed articles on studies we sponsored, conducted or collaborated on that support the use of and reimbursement for the test, clinical presentations at major symposia, and the inclusion of our breast cancer test in clinical practice guidelines for node negative, or N-, estrogen receptor positive, or ER+, invasive disease. However, this increased demand is not necessarily indicative of future growth rates, and we cannot provide assurance that this level of increased demand can be sustained or that publication of articles, future appearances or presentations at medical conferences, increased commercial efforts or expansion of utility to new breast cancer patient groups will have a similar impact on demand for our breast cancer test in the future. Sequential quarterly demand for our breast cancer test may also be impacted by other factors, including the economic environment and seasonal variations that have historically impacted physician office visits, our shift in commercial focus to our Oncotype DX colon and prostate cancer tests or any future products we may develop, patient enrollment in Oncotype DX clinical studies and the number of clinical trials in process by cooperative groups or makers of other tests conducting experience studies.

Most national and regional third-party payors in the United States, along with the designated regional Medicare contractor for our tests, have issued positive coverage determinations for our Oncotype DX breast cancer test for patients with N-, ER+, invasive disease through contracts, agreements or policy decisions. The local carrier with jurisdiction for claims submitted by us for Medicare patients also provides coverage for our breast cancer test for ER+ patients with node positive, or N+, disease (up to three positive lymph nodes) and invasive breast cancer patients where a lymph node status is unknown or not accessible due to a prior surgical procedure, or when the test is used to guide a neoadjuvant treatment decision. Additionally, some payors provide policy coverage for the use of our test in ER+ patients with N+ disease, including lymph node micro-metastasis. In July 2011, the American Journal of Managed Care published results of an economic assessment suggesting use of Oncotype DX in breast cancer patients with 1-3 positive nodes may improve health outcomes without adding incremental cost. However, we may not be able to obtain reimbursement coverage from other payors for our test for breast cancer patients with N+, ER+ disease.

In September 2015, initial results from the Trial Assigning Individual Options for Treatment (Rx), or TAILORx, a multi-center, prospectively conducted trial of more than 10,000 women with early stage breast cancer were published in The New England Journal of Medicine. The trial demonstrated that a group of trial participants with an Oncotype DX breast cancer score of 10 or less who received hormonal therapy alone without chemotherapy had less than 1% chance of recurrence at 5 years.

In December 2011, we made the Oncotype DX breast cancer test available for patients with DCIS, a pre-invasive form of breast cancer. The launch of Oncotype DX for DCIS patients was based upon presented positive results from a clinical validation study of the Oncotype DX breast cancer test in patients with DCIS, conducted by the Eastern Cooperative Oncology Group, or ECOG, a clinical trials cooperative group supported by the National Cancer Institute. The study met its primary endpoint by demonstrating that a pre-specified Oncotype DX DCIS Score derived from the Oncotype DX breast cancer test outperforms traditional clinical and pathologic measures to predict the risk of local recurrence, defined as either the development of a new invasive breast cancer or the recurrence of DCIS in the same breast. In May 2013, our Oncotype DX DCIS clinical validation study was published online in the Journal of the National Cancer Institute. Following the publication of the results of this study, the Medicare contractor for our Oncotype DX breast cancer test expanded coverage to include patients with DCIS.

In June 2014, we announced positive top line results of another clinical validation study to confirm and extend the observations of the published DCIS clinical validation study, conducted in collaboration with the Ontario DCIS Study Group. The results were presented at the San Antonio Breast Cancer Symposium in December 2014. The results from this clinical validation study were published by Breast Cancer Research and Treatment in July 2015. A second clinical validation study, conducted by the Ontario DCIS Study Group, was also published in August 2015 in Breast Cancer Research and Treatment. Each of these studies reconfirm that the Oncotype DX DCIS score is a strong predictor of local recurrence, which could be either invasive breast cancer or DCIS.

In June 2015, the Journal of Surgical Oncology published results from a clinical utility study which demonstrated the results from our Oncotype DX DCIS test resulted in treatment recommendation changes for 31% of patients.

The Veterans Administration, Department of Defense hospital facilities and some private payors provide coverage for the Oncotype DX DCIS test. We expect that it may take several years to establish coverage with a majority of public and private payors for use of our test in DCIS patients and we may not be able to obtain such coverage.

## Table of Contents

### Oncotype DX Colon Cancer Test

In January 2010, we launched our Oncotype DX colon cancer test, the first multigene expression test developed to assess the risk of recurrence in patients with stage II disease. We collaborated with the National Surgical Adjuvant Breast and Bowel Project, or NSABP, and the Cleveland Clinic on a total of four development studies in more than 1,800 patient samples to analyze patients with stage II colon cancer. The test was then independently evaluated in more than 1,400 stage II colon cancer patients in the QUASAR validation study which demonstrated that the Oncotype DX colon cancer test can independently predict individual recurrence risk in stage II colon cancer patients following surgery. The QUASAR study results were published in the Journal of Clinical Oncology in November 2011. In November 2013, the Journal of Clinical Oncology published positive results of the third successful validation of the Oncotype DX colon cancer test in patients with stage II disease and the first validation study in patients with stage III disease. Also in November 2013, the Current Medical Research & Opinion published positive results from the Partnership for Health Analytic Research clinical utility analysis of the Oncotype DX colon cancer test, demonstrating that use of the test changes treatment recommendations in 29% of stage II colon cancer patients.

Medicare, the Veterans Administration, Department of Defense hospital facilities and some private payors provide coverage for the Oncotype DX colon cancer test. We are working with additional public and private payors and health plans to secure additional coverage for our colon cancer test based upon published clinical evidence showing the utility of the test. However, we cannot predict whether, at what rate, or under what circumstances, payors will reimburse for this test.

We believe the key factors that will drive further global adoption of our colon cancer test include results from additional studies we sponsor, conduct or collaborate on that support the use of and increased coverage and reimbursement for the test, clinical presentations at major symposia, publications, inclusion of the test in clinical guidelines and our ongoing commercial efforts.

### Oncotype DX Prostate Cancer Test

In June 2012, we presented results of our first development study in prostate tissue obtained from needle biopsies. The study, an analysis of biopsy samples from men with conventionally defined low/intermediate risk prostate cancer, showed that genes and biological pathways associated with clinically-aggressive prostate cancer in radical prostatectomy specimens can be reliably measured by quantitative RT-PCR from fixed prostate needle biopsies.

In September 2012, we announced positive top line results from the clinical validation study of our biopsy-based prostate cancer test. As a result of this clinical validation study meeting its primary end point, we launched our Oncotype DX prostate cancer test in May 2013 and made the test commercially available worldwide. The test provides a Genomic Prostate Score, or GPS, that predicts disease aggressiveness in men with low risk disease. This test may be used to improve treatment decisions for prostate cancer patients, in conjunction with the Gleason score, or tumor grading. In May 2014, European Urology published the positive results from our two development studies, as



well as our clinical validation study of diagnostic biopsies from 395 men who were candidates for active surveillance, demonstrating that the use of GPS can potentially increase the number of men who could confidently choose active surveillance by 20 to 30%.

In August 2014, we announced positive top line results of a second clinical study, demonstrating the ability of our test's GPS to predict multiple clinical endpoints related to disease aggressiveness among low/intermediate risk patients. The study also confirmed the earlier validation study published in May 2014. The results from the clinical validation study were presented at the European Society for Medical Oncology in September 2014, and at the Society of Urologic Oncology meeting in December 2014.

In April 2015, Urology Practice published the positive results of our decision impact study of our prostate cancer test. This prospective study involving 158 newly diagnosed prostate cancer patients showed that incorporation of our test's GPS changed modality and/or intensity of treatment recommendations in 26% of patients across multiple urology practice settings. Additionally, 85% of urologists were more confident in their treatment recommendation following review of the patient's GPS.

## Table of Contents

In May 2015, multiple abstracts focused on our Oncotype DX prostate cancer test were presented at the American Urological Association annual meeting, including an abstract from investigators at University of California San Francisco demonstrating a wide distribution of test results within each MRI category. This suggests that MRI and GPS provide complementary information about the aggressiveness of an individual's prostate cancer.

Also in May 2015, the MoIDX program of Palmetto, GBA, or Palmetto, released a draft local coverage determination, or LCD, supporting reimbursement for the Oncotype DX prostate cancer test for men with very low and low risk disease, as defined by NCCN guidelines, who are considering treatment. In August 2015, Palmetto issued its final LCD, approving nationwide coverage of our prostate cancer test for qualified Medicare patients throughout the United States and effective October 13, 2015, Palmetto initiated reimbursement coverage of the Oncotype DX prostate cancer test.

In July 2015, a second utility study focused on the Oncotype DX prostate cancer test was published in Urology Practice. This study analyzed the medical charts from 211 men diagnosed with prostate cancer across 10 different sites and compared physician recommendations and the actual treatment received between patients who received the Oncotype DX prostate cancer test and those who did not. The observed net increase in physicians recommending active surveillance was very consistent with the previously published prospective clinical study in Urology Practice. In addition, when actual treatment received was determined, patients who received an Oncotype DX GPS had an absolute increase of 24% and a relative increase of 56% in use of active surveillance when compared to patients in the same practices with similar traditional risk factors but without an Oncotype DX GPS.

We expect to continue to invest substantial resources related to continued clinical studies and the global adoption of and reimbursement for our prostate cancer test. We expect our commercialization efforts for our prostate cancer test will result in further increased costs for laboratory testing, including staffing-related costs, incremental sales and marketing personnel to introduce this product to a new group of physicians and patients, costs for clinical utility studies and costs associated with obtaining reimbursement coverage.

## Product Development Opportunities

In addition to developing products to address new cancer areas, we continually look to expand the clinical utility and addressable patient populations for our existing cancer tests. These developments efforts may lead to a wide variety of possible new products covering various treatment decisions, including:

- Risk assessment;
- Screening and prevention;
- Early disease diagnosis;
- Adjuvant and/or neoadjuvant disease treatment;
- Metastatic disease treatment selection; and
- Treatment monitoring.

Potential new products may address a specific clinical need or guide a targeted therapy decision and may also leverage our next generation sequencing, or NGS, capabilities to expand our product opportunities. Additionally, potential new products may use non-invasive tests that can be performed on blood and urine to quantify the presence and burden of cancer as well as the sensitivity or resistance to specific drug therapies.

#### Technology

Our commercially available tests utilize RT-PCR technology to quantify gene expression in patient tumor samples. We are also incorporating new technologies, such as high-throughput NGS, in our research and development laboratory. NGS is typically used to sequence the deoxyribonucleic acids, or DNAs, in the cellular genome of the host tumor. With this technology, we can also sequence millions of ribonucleic acid chains, or RNAs, map them back to their respective genes based on their sequence and then count the number of copies and compare the relative expression between different genes.

## Table of Contents

We have selected NGS to be our primary technology for future biomarker discovery and have begun using NGS for future clinical development in tandem with our existing RT-PCR based approach. NGS technologies parallelize the sequencing process, producing thousands or millions of sequences at once, and are intended to provide nucleic acid sequence information at lower cost than standard methods. We have created proprietary methods for NGS analysis of fixed paraffin embedded, or FPE, tissue nucleic acids, created bioinformatics programs, and infrastructure for data storage and analysis and plan to rely on NGS as the technology source of new biomarkers in the future.

We have begun to further advance our research and development pipeline with proprietary platforms that incorporate emerging molecular technologies in order to develop non-invasive liquid biopsy tests that can be performed on blood or urine. While early-stage cancer continues to represent a significant opportunity with near-term potential, we believe this technology will provide an opportunity to expand our business further along the patient's cancer journey. Expanding our focus beyond early-stage treatment decision support toward later-stage disease includes opportunities to monitor progression and response to therapeutics for patients who are diagnosed with later stage or recurrent disease who can also benefit from precision medicine.

In June 2015, we announced positive results from a liquid biopsy proof-of-concept study demonstrating the ability to more conveniently detect disease recurrence with a level of accuracy comparable to cystoscopy, an invasive procedure for surveillance of early-stage bladder cancer. These results may lead to our development of a urine test that may offer physicians and patients a non-invasive alternative for monitoring bladder cancer.

## Economic Environment

Continuing concerns over entitlement and health care reform efforts, regulatory changes and taxation issues, and geopolitical issues have contributed to uncertain expectations both for the U.S. and global economies. These factors, combined with uncertainties in business and consumer confidence and continued concerns regarding the stability of some European Union member countries, have contributed to the expectations of slower domestic and global economic growth in the near term. We periodically evaluate the impact of the economic 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 short-term marketable securities, and we expect that we will continue to be able to access or liquidate these investments as needed to support our business activities. We periodically monitor the financial position of our significant third-party payors, which include Medicare and managed care companies. As of the date of this report, we do not expect the current economic environment to have a material negative impact on our ability to collect payments from third-party payors in the foreseeable future. We believe the economic environment and changes in the healthcare system continued to impact product payment cycles, growth in tests delivered and product revenue generated during the three and nine months ended September 30, 2015. We intend to continue to assess the impact of the economic environment on our business activities. If the economic environment does not improve or deteriorates, our business including our patient population, government and third-party payors and our distributors and suppliers could be negatively affected, resulting in a negative impact on our product revenues.

## U.S. Healthcare Environment

Healthcare reform proposals and medical cost containment measures are being adopted in the U.S. and in many foreign countries. These reforms and measures, including those envisioned by the adoption in 2010 of the Affordable Care Act, or ACA, could among other things limit the use of our tests and reduce reimbursement. We also expect that pricing of medical products and services will remain under pressure as alternative payment models such as bundling, value-based purchasing and accountable care organizations develop in the United States.

Sales of our tests in the United States and other countries are dependent upon the coverage decisions and reimbursement policies established by government healthcare programs and private health insurers. Market acceptance of our tests has and will continue to depend upon the ability to obtain an appropriate level of coverage for, and reimbursement from, third-party payors for our tests. We have had Medicare coverage for our Oncotype DX breast cancer test since 2006 and for our Oncotype DX colon cancer test since 2011. In October 2015, we obtained Medicare

Table of Contents

coverage for our Oncotype DX prostate cancer test. Under the terms of the coverage determination for our prostate cancer test, reimbursement is limited to tests ordered by physicians who agree to participate in a Certification Training Registry and to provide certain information about Medicare beneficiaries who receive our test.

The healthcare industry has undergone significant change driven by various efforts to reduce costs. The effect of the implementation of the ACA on our business is uncertain. Among other things, the law requires medical device manufacturers to pay a 2.3% excise tax on U.S. sales of certain medical devices that are listed with the FDA starting in January 2013. Although the FDA has issued draft guidance that, if finalized, would regulate certain clinical laboratory tests that are developed and validated by a laboratory for its own use, referred to as LDTs, as medical devices, none of our LDTs, such as our Oncotype DX breast, colon and prostate cancer tests, are currently listed with the FDA. We cannot assure you that the tax will not apply to services such as ours in the future.

In September 2015, the Centers for Medicare and Medicaid Services, or CMS released a final payment determination, subject to reconsideration, for the Clinical Laboratory Fee Schedule, or CLFS, for the Oncotype DX breast cancer test, representing a 15% reduction from the current Medicare payment rate. A review of the calculation of this new rate revealed the omission of the rate paid by Noridian Healthcare Solutions, or Noridian, the Medicare Administrative Contractor, or MAC, that processes our claims. This omission resulted in a lower price calculation. In October 2015, CMS reversed its earlier reduced payment determination and reinstated the Medicare payment rate that has been in effect since 2006.

Also in September 2015, CMS published preliminary determinations for 2016 for payment for new and revised codes under the CLFS. This included a preliminary determination to establish payment for our Oncotype DX colon cancer test by “crosswalk”, or reference to a pricing determination made based on an equivalent or similar but unrelated molecular diagnostic test. If finalized, this would result in a reduction in payment of 79% from the rate currently in effect. CMS also proposed similar reductions for seven similar tests with new codes. Since the publication of the preliminary determination, we have had multiple discussions with CMS, the Department of Health & Human Services and representatives from congressional offices. We understand that the CMS preliminary determination was based, in part, on a misunderstanding of recommendations made by laboratories, including us. We believe CMS now understands our recommendation to maintain the contractor amount currently in effect. In addition, an advisory panel established under the Protecting Access to Medicare Act of 2014, or PAMA, has since twice recommended to CMS that they not proceed with the rate proposed in the preliminary determination but instead leave rate-setting to the local Medicare contractors. The final determination is expected to be published in November or December 2015. We cannot be sure that the reductions proposed in the preliminary determination will not be maintained in the final determination.

In addition, PAMA includes a substantial new payment system for certain clinical laboratory tests that is scheduled to be effective starting January 1, 2017. Under PAMA, laboratories that receive the majority of their Medicare revenues from payments made under the CLFS or the Physician Fee Schedule would report, beginning January 1, 2016, and then every three years thereafter (or annually for “advanced diagnostic laboratory tests”), private payor payment rates and volumes for their tests. CMS will use the rates and volumes reported by laboratories to develop Medicare payment rates for the tests equal to the volume-weighted median of the private payor payment rates for the tests.

In September 2015, CMS issued a proposed rule that outlines how the agency intends to implement the PAMA payment system. With respect to reporting, we believe the policy articulated in the proposed rule would require us to report information annually on rates paid by private payors for each of our Oncotype DX tests. Under the criteria outlined in the proposed rule, we believe all of our Oncotype DX tests would be considered advanced diagnostic laboratory tests. The proposed rule does not disclose the reporting format or plan at this time, instead indicating that guidance regarding the mechanism for reporting will be forthcoming. The proposed rule does, however, clarify that payment rates and the reporting period will coincide with the calendar year. CMS also proposes that the data collection period be immediately followed by a 90-day period during which we may verify and validate our private payor rate data before the data is due to CMS by the final day of the 90-day reporting period.

With respect to pricing of existing tests, CMS further defines the rate-setting methodology in the proposed rule by proposing to assess every payment rate, by payor, submitted by laboratories and to determine the median of the payment rates. CMS indicates that it intends to list each distinct private payor rate the same number of times in the array as its

## Table of Contents

volume. CMS proposes that the PAMA rate-setting process follow the current timeline for CLFS rate-setting (i.e., publication of preliminary rates in September with final rates published in November to become effective the following January), and will update the payment rates every three years, or annually for advanced diagnostic laboratory tests. Any reductions to payment rates resulting from the new methodology are limited to 10% per test per year in each of the years 2017 through 2019 and to 15% per test per year in each of 2020 through 2022.

With respect to pricing of new advanced diagnostic laboratory tests, the initial payment rate (for a period not to exceed nine months) will be set at the “actual list charge” for the test as reported by the laboratory. CMS proposes that the “actual list charge” be the lowest publicly available price at which the test is available according to sources such as websites, tests registries or price listing for a patient. If the actual list charge substantially exceeds private payor rates by more than 30%, CMS will have the ability to recoup excess payments made during the initial nine-month payment period.

There have also been recent and substantial changes to the payment structure for physicians, including those passed as part of the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, which was signed into law on April 16, 2015. MACRA created the Merit-Based Incentive Payment System which, beginning in 2019, more closely aligns physician payments with composite performance on three existing incentive programs (i.e., the Physician Quality Reporting System, the Value-based modifier program and the Electronic Health Record Meaningful Use program) and incentivizes physicians to enroll in alternative payment methods. At this time, we do not know whether these changes to the physician payment systems will have any impact on orders or payments for our tests.

### Changes in Medicare Administrative Contractor services

On a five year rotational basis, Medicare requests bids for its regional MAC services. In September 2013, the claims processing function for our jurisdiction transitioned from Palmetto GBA, to our current MAC, Noridian. Palmetto GBA under their MolDx Program is continuing to establish coverage, coding and reimbursement policies for molecular diagnostic tests performed in our jurisdiction, including our tests. The elimination of the MolDx Program or a change in the administrator of that program could impact the current coverage or payment rates for our existing tests and our ability to obtain Medicare coverage for products for which we do not yet have coverage or any products we may launch in the future, or delay payments for our tests.

### Critical Accounting Policies and Significant Judgments and Estimates

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



financial statements, as well as revenues and expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could therefore differ materially from those estimates under different assumptions or conditions.

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

#### Revenue Recognition

We determine whether revenue is recognized on an accrual basis when test results are delivered or on a cash basis when cash is received from the payor. Our revenues for tests performed are recognized on an accrual basis when the following criteria are met: (1) persuasive evidence that an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. When evaluating whether the fee is fixed or determinable and collectible, we consider whether we have sufficient history to reliably estimate the total fee that will be received from a payor and a payor's individual payment patterns. Based upon at least several

Table of Contents

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 arrangement or contracted payment amount. The estimated accrual amounts per test, recorded upon delivery of a patient report, are calculated for each accrual payor and are based on the arrangement or contracted price adjusted for individual payment patterns resulting from co-payment amounts and excluded services in healthcare plans.

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.

We enter into exclusive distribution agreements for the sale of one or more of our Oncotype DX tests with distributors outside of the United States. In these countries, the distributor generally provides us with certain marketing and administrative services within its territory. As a condition of these agreements, the distributor generally pays us an agreed upon fee per test and we process the tests. The same revenue recognition criteria described above generally apply to tests received through distributors. To the extent all criteria set forth above are not met when test results are delivered, product revenues are generally recognized when cash is received from the distributor.

Test revenue recognized on an accrual basis is recorded upon delivery of each test performed, net of any contractual discount, at the amount that we expect to collect. We determine the amount we expect to collect on a per payor, per contract or arrangement basis, based on our analysis of historical average payments. This average amount is typically lower than the agreed upon amount due to several factors, such as the amount of patient co-payments, the existence of secondary payors and claim denials. We typically review our analysis annually, or at the time a contractual price change is implemented or when information comes to our attention that leads us to believe an adjustment may be warranted.

As of September 30, 2015, amounts outstanding for tests delivered, net of write-downs and adjustments, which were not recognized as revenue upon delivery because our accrual revenue recognition criteria were not met and which had not been collected totaled approximately \$66.3 million. We cannot provide any assurance as to when, if ever, and to what extent these amounts will be collected.

From time to time, we receive requests for refunds of payments, generally due to overpayments made by third party payors. Upon becoming aware of a refund request, we establish an accrued liability for tests covered by the refund request until such time as we determine whether or not a refund is due. If we determine that a refund is due, we credit cash and reduce the accrued liability. Accrued refunds were \$532,000 and \$944,000 at September 30, 2015 and December 31, 2014, respectively.

Accounts Receivable

We accrue an allowance for doubtful accounts against our accounts receivable based on estimates consistent with historical payment experience. Our allowance for doubtful accounts is evaluated quarterly and adjusted when trends or significant events indicate that a change in estimate is appropriate. Historically, the amounts of uncollectible accounts receivable that have been written off have been consistent with management's expectations. We cannot assure you that we will not experience higher than expected write-offs in the future. As of September 30, 2015 and December 31, 2014, our allowance for doubtful accounts was \$3.9 million and \$3.6 million, respectively. See "Liquidity and Capital Resources" for additional information, including a summary of accounts receivable aging by payor mix.

#### Research and Development Expenses

We enter into collaboration and clinical trial agreements with clinical collaborators and record these costs as research and development expenses. We record accruals for estimated study costs comprised of work performed by our collaborators under contract terms. The financial terms of these agreements are subject to negotiation, 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

## Table of Contents

be used or rendered for future research and development activities are deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed.

All potential future product programs outside of breast, colon and prostate cancer are in the research or development phase. Although we have estimated the time frame in which some of these products may be brought to market, the timing is uncertain given the technical challenges and clinical variables that exist between different types of cancers. We maintain information regarding costs incurred for activities performed under certain contracts with biopharmaceutical and pharmaceutical companies. However, we do not generally record or maintain information regarding costs incurred in research and development on a program-specific basis. Our research and development staff and associated infrastructure resources are deployed across several programs. Many of our costs are thus not attributable to individual programs. As a result, we are unable to determine the duration and completion costs of our research and development programs or when, if ever, and to what extent we will receive cash inflows from the commercialization and sale of a product.

### Stock-based Compensation Expense

We measure all stock-based payments to employees and directors, including grants of stock options, based on their relative fair values. Fair values of awards granted under our stock option plans and Employee Stock Purchase Plan, or ESPP, were estimated at grant or purchase rights offering dates using a Black Scholes option valuation model. Stock-based compensation expense related to stock option grants is estimated at the date of grant and stock-based compensation expense related to ESPP purchases is estimated at the beginning of each offering period based on these fair value calculations. The expense is recognized ratably over the requisite service period. The application of option valuation models requires significant judgment and the use of estimates, particularly surrounding assumptions used in determining fair value. The Black Scholes option valuation model requires the use of estimates such as stock price volatility and expected option lives 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. The expected life of stock issuable pursuant to the ESPP is six months, or the duration of the purchase period. Expected forfeiture rates for stock option grants are based on historical data, and compensation expense is adjusted for actual results. We do not include expected forfeiture rates when calculating stock-based compensation expense for stock issuable pursuant to the ESPP due to the short duration of the purchase period; however, we do adjust the expense for actual results.

Stock-based compensation expense related to restricted stock unit, or RSU, awards is based on the market value of our common stock at the date of grant and is recognized as expense ratably over the requisite service period. Expected forfeiture rates for RSUs are based on historical data, and compensation expense is adjusted for actual results.

We review our valuation assumptions on an ongoing basis, and, as a result, our assumptions used to value stock 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.

## Deferred Tax Assets

We are required to reduce our deferred tax assets by a valuation allowance if it is more likely than not that some or all of our deferred tax assets will not be realized. We must use judgment in assessing the potential need for a valuation allowance, which requires an evaluation of both negative and positive evidence. The weight given to the potential effect of negative and positive evidence should be commensurate with the extent to which it can be objectively verified. In determining the need for and amount of our valuation allowance, if any, we assess the likelihood that we will be able to recover our deferred tax assets using historical levels of income, estimates of future income and tax planning strategies. As a result of historical cumulative losses and, based on all available evidence, we believe it is more likely than not that our recorded net deferred tax assets will not be realized. Accordingly, we recorded a valuation allowance against all of our net deferred tax assets at both September 30, 2015 and December 31, 2014. We will continue to maintain a full valuation allowance on our deferred tax assets until there is sufficient evidence to support the reversal of all or some portion of this allowance.

Table of Contents

## Results of Operations

## Three and Nine Months Ended September 30, 2015 and 2014

We recognized net losses of \$11.8 million and \$30.6 million for the three and nine months ended September 30, 2015 compared to net losses of \$6.3 million and \$18.3 million for the three and nine months ended September 30, 2014. On a basic and diluted per share basis, net loss per share was \$0.36 and \$0.95 for the three and nine months ended September 30, 2015 compared to net loss per share of \$0.20 and \$0.58 for the three and nine months ended September 30, 2014. We may incur net losses in future periods due to future spending and fluctuations in our business, and we may not achieve or maintain sustained profitability in the future.

## Revenues

We derive our revenues primarily from product sales and, in some periods, from contract research arrangements. We operate in one industry segment. As of September 30, 2015, substantially all of our product revenues have been derived from the sale of our Oncotype DX breast cancer test. Payors are billed upon generation and delivery of test results 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 collectability is reasonably assured.

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2015	2014	2015	2014
	(In thousands)		(In thousands)	
Product revenues	\$ 73,554	\$ 69,101	\$ 212,325	\$ 206,580
Period over period dollar increase in product revenues	\$ 4,453		\$ 5,745	
Period over period percentage increase in product revenues	6	%	3	%

Test volume increased by 17% and 12% for the three and nine months ended September 30, 2015 compared to the three and nine months ended September 30, 2014, respectively, of which approximately 4% and 5%, respectively, of the growth was from prostate cancer tests delivered and 13% and 7%, respectively, of the growth was from breast cancer tests delivered worldwide. As of September 30, 2015, we had not yet obtained reimbursement coverage from third-party payors for our prostate cancer test. In addition, the stronger U.S. dollar in the three and nine months ended September 30, 2015 as compared with the corresponding prior year periods resulted in a negative impact on total product revenues of \$855,000 and \$2.5 million, respectively, or approximately 1% in both periods. Approximately \$54.1 million, or 74%, and \$156.5 million, or 74%, of product revenues for the three and nine months ended September 30, 2015, respectively, were recorded on an accrual basis and recognized at the time the test results were

delivered, compared to \$49.5 million, or 72%, and \$149.5 million, or 72%, of product revenues for the three and nine months ended September 30, 2014, respectively. For all periods, the balance of product revenues was recognized upon cash collection as payments were received. The timing of recognition of revenues related to third-party payments may cause fluctuations in product revenues from period to period.

Product revenues related to Medicare patients for the three and nine months ended September 30, 2015 were \$15.1 million, or 20%, and \$43.2 million, or 20%, of product revenues, respectively, compared to \$13.8 million, or 20%, and \$41.8 million, or 20%, of product revenues for the three and nine months ended September 30, 2014, respectively. There were no other third-party payors comprising product revenues of 10% or more for those periods. International product revenues decreased to \$10.5 million, or 14%, of product revenues, for the three months ended September 30, 2015 from \$11.3 million, or 16%, of product revenues, for the three months ended September 30, 2014 primarily due to foreign exchange rate differences. International product revenues decreased to \$30.9 million, or 15%, of product revenues, for the nine months ended September 30, 2015, from \$34.7 million, or 17%, of product revenues, for the nine months ended September 30, 2014 primarily due to foreign exchange rate differences which accounted for \$2.5 million of the decrease, as well as the recognition in the same period in 2014 of revenue resulting from a temporary access program in the United Kingdom.

Table of Contents

## Cost of Product Revenues

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2015	2014	2015	2014
	(In thousands)		(In thousands)	
Tissue sample processing costs	\$ 11,246	\$ 9,478	\$ 32,261	\$ 28,676
Stock-based compensation	129	131	401	405
Total tissue sample processing costs	11,375	9,609	32,662	29,081
License fees	2,343	2,370	6,851	7,160
Total cost of product revenues	\$ 13,718	\$ 11,979	\$ 39,513	\$ 36,241
Period over period dollar increase in tissue sample processing costs	\$ 1,768		\$ 3,585	
Period over period percentage increase in tissue sample processing costs	19 %		13 %	

Cost of product revenues represents the cost of materials, direct labor, equipment and infrastructure expenses associated with processing tissue samples (including sample accessioning, histopathology, anatomical pathology, paraffin extraction, RT PCR, quality control analyses and shipping charges to transport tissue samples) and license fees. Infrastructure expenses include allocated facility occupancy and information technology costs. Costs associated with performing our tests are recorded as tests are processed. Costs recorded for tissue sample processing represent the cost of all the tests processed during the period regardless of whether revenue was recognized with respect to that test. Royalties for licensed technology calculated as a percentage of product revenues and fixed annual payments relating to the launch and commercialization of Oncotype DX tests are recorded as license fees in cost of product revenues at the time product revenues are recognized or in accordance with other contractual obligations. While license fees are generally calculated as a percentage of product revenues, the percentage increase in license fees does not correlate exactly to the percentage increase in product revenues because certain agreements contain provisions for fixed annual payments and other agreements have tiered rates and payments that may be capped at annual minimum or maximum amounts. License fees represent a significant component of our cost of product revenues and are expected to remain so for the foreseeable future.

Tissue sample processing costs increased \$1.8 million, or 19%, for the three months ended September 30, 2015 compared to the three months ended September 30, 2014. Tissue sample processing costs increased \$3.6 million, or 13%, for the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014. These increases were driven primarily by increase in test volume of 17% and 12% for the three and nine months ended September 30, 2015, respectively. We expect the cost of product revenues to increase in future periods to the extent we process more tests.





Table of Contents

## Research and Development Expenses

	For the Three Months Ended		For the Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
	(In thousands)		(In thousands)	
Personnel-related expenses	\$ 7,598	\$ 6,749	\$ 22,744	\$ 21,001
Stock-based compensation	996	1,024	3,149	3,131
Collaboration expenses	411	1,062	8,138	2,203
Reagents and laboratory supplies	981	195	2,071	1,831
Allocated information technology, facilities and other costs	1,953	2,286	6,136	6,823
Other costs	1,541	2,575	4,955	5,538
Total research and development expenses	\$ 13,480	\$ 13,891	\$ 47,193	\$ 40,527
Period over period dollar increase (decrease)	\$ (411)		\$ 6,666	
Period over period percentage increase (decrease)	(3)	%	16	%

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

The \$411,000, or 3%, decrease in research and development expenses for the three months ended September 30, 2015 compared to the three months ended September 30, 2014 was primarily due to a \$651,000 decrease in collaboration expenses, a \$333,000 decrease in allocated information technology, facilities and other costs and a \$1.0 million decrease in other costs partially offset by a \$849,000 increase in personnel-related expenses and a \$786,000 increase in reagents and laboratory supplies.

The \$6.7 million, or 16%, increase in research and development expenses for the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014 was primarily due to a one-time \$5.5 million expense for the wind-down of a license agreement and development program. Exclusive of this one-time expense, research and development expenses for the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014 increased by \$1.2 million primarily due to a \$1.7 million increase in personnel-related expenses and a \$435,000 increase in a collaboration expenses partially offset by a \$687,000 decrease in allocated information technology, facilities and other costs and a \$583,000 decrease in other costs. The \$1.7 million increase in personnel-related expenses was primarily attributable to a \$2.0 million increase in salaries, benefits and related expenses due to increased headcount. The decrease in allocated information technology, facilities and other costs is primarily due to capitalization of certain costs of project work from our various information technology groups, allocated based on specific development projects for the nine months ended September 30, 2015.

We expect our research and development expenses, exclusive of the one-time expense described above, to increase in future periods due to increased investment in our new product pipeline for breast, colon, prostate and other cancers, along with increased investment in our proprietary liquid platforms.

Table of Contents

## Selling and Marketing Expenses

	For the Three Months Ended September 30, 2015		For the Nine Months Ended September 30, 2015	
	2014		2014	
	(In thousands)		(In thousands)	
Personnel-related expenses	\$ 18,965	\$ 19,090	\$ 58,214	\$ 55,623
Stock-based compensation	1,132	1,220	3,406	3,730
Promotional and marketing materials	4,005	3,790	13,397	14,240
Travel, meetings and seminars	3,770	3,414	12,111	10,975
Collaboration expenses	964	841	2,634	1,932
Allocated information technology, facilities and other costs	5,462	4,734	14,506	13,382
Other costs	1,071	970	3,696	2,820
Total selling and marketing expenses	\$ 35,369	\$ 34,059	\$ 107,964	\$ 102,702
Period over period dollar increase	\$ 1,310		\$ 5,262	
Period over period percentage increase	4	%	5	%

Our selling and marketing expenses consist primarily of personnel-related expenses, education and promotional expenses, market analysis and development 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 tests are developed and validated and the value of the quantitative information that our tests provide. Selling and marketing expenses also include the costs of sponsoring continuing medical education, medical meeting participation and dissemination of scientific and economic publications related to our tests. Our sales force compensation includes annual salaries and eligibility for quarterly commissions based on the achievement of predetermined sales goals and other management objectives.

The \$1.3 million, or 4%, increase in selling and marketing expenses for the three months ended September 30, 2015 compared to the three months ended September 30, 2014 was primarily due to a \$728,000 increase in allocated information technology, facilities and other costs, a \$356,000 increase in travel, meetings and seminars and a \$215,000 increase in promotional and marketing materials.

The \$5.3 million, or 5%, increase in selling and marketing expenses for the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014 was primarily due to a \$2.6 million increase in personnel-related expenses, a \$1.1 million increase in travel, meetings and seminars, \$1.1 million increase in allocated information technology, facilities and other costs and an \$876,000 increase in other costs partially offset by an \$843,000 decrease in promotional and marketing materials. The \$2.6 million increase in personnel-related expenses was attributable to a \$1.5 million increase in salaries, benefits and related expenses due primarily to increased headcount, including new hires related to our international growth, prostate expansion and annual salary increases and a \$1.0 million increase in bonus.

We expect selling and marketing expenses will continue to increase in future periods due to our efforts to establish adoption of and reimbursement for our new products, continued investment in our global commercial infrastructure and increases in our sales force and incurring other expenses to support the growth of our business.

Table of Contents

## General and Administrative Expenses

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2015	2014	2015	2014
	(In thousands)		(In thousands)	
Personnel-related expenses	\$ 11,015	\$ 10,872	\$ 33,257	\$ 31,545
Stock-based compensation	1,671	1,611	5,099	5,330
Occupancy and equipment expenses	6,511	5,062	16,942	15,348
Billing and collection fees	2,448	2,273	7,745	7,081
Bad debt expense	2,056	1,671	4,727	4,821
Professional fees and other expenses	2,413	2,233	7,520	6,337
Information technology, facilities and other cost allocations	(9,689)	(8,715)	(26,696)	(25,712)
Total general and administrative expenses	\$ 16,425	\$ 15,007	\$ 48,594	\$ 44,750
Period over period dollar increase	\$ 1,418		\$ 3,844	
Period over period percentage increase	9	%	9	%

Our general and administrative expenses consist primarily of personnel-related expenses, occupancy and equipment expenses, including rent and depreciation expenses, billing and collection fees, bad debt expense, professional fees and other expenses, including intellectual property defense and prosecution costs, and other administrative costs, partially offset by cost allocations to our commercial laboratory operations, research and development, and sales and marketing functions, including allocated information technology and facility occupancy costs.

The \$1.4 million, or 9%, increase in general and administrative expenses for the three months ended September 30, 2015 compared to the three months ended September 30, 2014 was primarily due to a \$1.4 million increase in occupancy and equipment expenses, a \$385,000 increase in bad debt expense, a \$180,000 increase in professional fees and other expenses and a \$175,000 increase in billing and collection fees partially offset by a \$1.0 million increase in information technology, facilities and other costs allocated to other functional areas.

The \$3.8 million, or 9%, increase in general and administrative expenses for the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014 was primarily due to a \$1.7 million increase in personnel-related expenses, a \$1.6 million increase in occupancy and equipment expense, a \$1.2 million increase in professional fees and other expenses and a \$664,000 increase in billing and collection fees partially offset by a \$1.0 million increase in information technology, facilities and other costs allocated to other functional areas and a \$231,000 decrease in stock-based compensation. Of the \$1.7 million increase in personnel-related expenses, \$2.8 million was attributable to higher contract labor and consulting expenses to support growth of our business and a \$170,000 increase in bonus expense partially offset by a \$1.2 million decrease in salaries and benefits expenses.

We expect general and administrative expenses to increase in future periods as we hire additional staff and incur other expenses to support the growth of our business, and to the extent we spend more on billing and collections fees and bad debt expense.

#### Interest Income

Interest income was \$54,000 and \$163,000 for the three and nine months ended September 30, 2015, respectively, compared to \$47,000 and \$144,000 for the three and nine months ended September 30, 2014, respectively. We expect our interest income will remain nominal if the current low interest rate environment continues.

#### Other Income (Expense), Net

Other expense, net was \$158,000 and \$207,000 for the three and nine months ended September 30, 2015, respectively, compared to \$345,000 and \$537,000 for the three and nine months ended September 30, 2014, respectively. Other expense, net for the three and nine months ended September 30, 2015 was primarily related to \$197,000 and \$259,000 of net foreign currency losses, respectively, resulting from valuation adjustments to our international accounts

Table of Contents

receivable balance. We expect other income (expense), net to continue to fluctuate based on fluctuations in exchange rates that impact our foreign currency transaction gains and losses.

## Income Tax Expense (Benefit)

We recorded income tax expense of \$6.3 million and an income tax benefit of \$410,000 for the three and nine months ended September 30, 2015, respectively, which was computed using the “discrete” (or “cut-off”) method. The income tax expense and benefit for the three and nine months ended September 30, 2015, respectively, is principally comprised of a deferred tax expense and a deferred tax benefit generated by the unrealized gain recognized during this period on available-for-sale marketable securities, which is included in other comprehensive income. The intraperiod tax allocation rules limit the amount of benefit recognized to the lesser of year-to-date pre-tax loss or year-to-date unrealized gain recognized on available-for-sale marketable securities included in other comprehensive income. Therefore, the tax benefit will change accordingly in subsequent periods. The deferred tax expense of \$6.2 million recorded in the three months ended September 30, 2015 was increased by \$96,000 of miscellaneous state income tax and foreign income tax expense. The deferred tax benefit of \$765,000 recorded in the nine months ended September 30, 2015 was offset by \$355,000 of miscellaneous state income tax and foreign income tax expenses. The income tax expense for the three and nine months ended September 30, 2014 was \$129,000 and \$292,000, respectively, which was computed using the same method and was principally comprised of state income taxes and foreign taxes.

Based on all available objective evidence, management believes that it is more likely than not that our net deferred tax assets will not be fully realized. Accordingly, we maintained a valuation allowance against all of our net deferred tax assets as of both September 30, 2015 and December 31, 2014. We will continue to maintain a full valuation allowance until there is sufficient evidence to support recoverability of our deferred tax assets.

## Liquidity and Capital Resources

As of September 30, 2015, we had an accumulated deficit of \$225.4 million. We may incur net losses in the future, and we cannot provide assurance as to when, if ever, we will achieve sustained profitability. We expect that our research and development, selling and marketing and general and administrative expenses will increase in future periods and, as a result, we will need to continue to generate significant product revenues to achieve sustained profitability.

2015	2014
(In thousands)	



As of September 30,		
Cash, cash equivalents and marketable securities	\$ 98,013	\$ 104,690
Working capital	98,485	111,621
For the nine months ended September 30,		
Cash provided by (used in):		
Operating activities	(9,645)	2,605
Investing activities	3,886	(2,866)
Financing activities	4,043	4,220
Capital expenditures (included in investing activities above)	(16,056)	(5,588)

### Sources of Liquidity

Historically we have financed our operations primarily through sales of our equity securities and cash received in payment for our tests. At September 30, 2015, we had cash, cash equivalents and short-term marketable securities of \$98.0 million compared to \$104.7 million at September 30, 2014. The \$6.7 million decrease was attributable to investments in the growth of our business, including research and development, global expansion, and activities related to reimbursement coverage of our tests partially offset by a \$15.9 million investment in Invitae Corporation, or Invitae, reclassified from non-marketable securities upon Invitae's initial public offering, or IPO, in February 2015. As a newly issued public security, the market price of Invitae's common stock may be subject to high volatility. For example, the price of Invitae's common stock fluctuated between \$6.58 per share and \$22.35 per share since the IPO in February 2015 through October 2015. In accordance with our investment policy, available cash is invested in short-term and long-term,

Table of Contents

low-risk, investment-grade debt instruments. Other than our equity investment in Invitae, our cash and marketable securities are held in a variety of interest-bearing instruments including money market accounts and high-grade commercial paper and corporate bonds.

## Accounts Receivable

At September 30, 2015 and December 31, 2014, \$33.8 million, or 19%, and \$34.9 million, or 19%, respectively, of our total assets consisted of accounts receivable. The \$1.1 million decrease in accounts receivable from December 31, 2014 to September 30, 2015 was attributable to increased cash collections partially offset by increased revenues. Days sales outstanding, or DSO, is a measure of the average number of days it takes for us to collect our accounts receivable, calculated from the date that tests are billed. At both September 30, 2015 and December 31, 2014, our weighted average DSOs was 80 days. The timing of our billing and cash collections may also causes fluctuations in our monthly DSOs and accounts receivable. With a new unique CPT code in place, it was necessary for payors to update their billing systems to reflect this change, which resulted and may continue to result in payment delays and a related increase in accounts receivable balances.

The following tables summarize accounts receivable by payor mix at September 30, 2015 and December 31, 2014:

	September 30, 2015			Current	31 - 60 Days	61 - 90 Days	91 - 120 Days	121 to 180 Days	Over 180 Days
	Total	% of Total	%						
	(In thousands)								
Managed care and other	\$ 31,907	85	%	\$ 11,624	\$ 5,060	\$ 3,454	\$ 2,403	\$ 2,767	\$ 6,599
Medicare	5,773	15		4,467	136	138	117	176	739
Total	37,680	100	%	\$ 16,091	\$ 5,196	\$ 3,592	\$ 2,520	\$ 2,943	\$ 7,338
Allowance for doubtful accounts	(3,926)								
Net accounts receivable	\$ 33,754								
	December 31, 2014								
		% of			31 - 60	61 - 90	91 - 120	121 to 180	Over 180

Edgar Filing: GENOMIC HEALTH INC - Form 10-Q/A

	Total	Total	Current	Days	Days	Days	Days	Days	
	(In thousands)								
Managed care and other	\$ 28,303	73	%	\$ 11,469	\$ 3,637	\$ 2,649	\$ 2,085	\$ 2,485	\$ 5,978
Medicare	10,241	27		5,187	3,621	469	190	231	543
Total	38,544	100	%	\$ 16,656	\$ 7,258	\$ 3,118	\$ 2,275	\$ 2,716	\$ 6,521
Allowance for doubtful accounts	(3,628)								
Net accounts receivable	\$ 34,916								

Cash Flows

Net cash used in operating activities was \$9.6 million for the nine months ended September 30, 2015, compared to net cash provided by operating activities of \$2.6 million for the nine months ended September 30, 2014. 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 used in operating activities for the nine months ended September 30, 2015 reflect net loss of \$30.6 million, adjusted for \$17.1 million of stock-based compensation and depreciation and amortization expense, a \$3.1 million increase in accrued compensation, a \$1.9 million increase in accrued expenses and other liabilities, a \$1.2 million decrease in accounts receivable and a \$765,000 deferred tax benefit generated from unrealized gain recognized on available-for-sale marketable securities. Net cash provided by operating activities for the nine months ended September 30, 2014 reflected a net loss of \$18.3 million, adjusted for \$17.8 million of stock-based compensation and depreciation and amortization expense, a \$3.0 million increase in accrued expenses and other liabilities, a \$672,000 increase in accounts payable, a \$650,000 increase in accrued compensation, a \$414,000 impairment of assets held for

## Table of Contents

sale and long-lived assets and a \$242,000 decrease in prepaid expenses and other assets offset by a \$1.5 million increase in accounts receivable and a \$397,000 decrease in deferred revenues.

Net cash provided by investing activities was \$3.9 million for the nine months ended September 30, 2015, compared to net cash used in investing activities of \$2.9 million for the nine months ended September 30, 2014. Our investing activities have consisted predominately of purchases and maturities of marketable securities and capital expenditures. Net cash provided by investing activities for the nine months ended September 30, 2015 included \$19.9 million in net maturities of marketable securities offset by \$16.1 million in capital expenditures. Net cash used in investing activities of \$2.9 million for the nine months ended September 30, 2014 included \$5.6 million in capital expenditures and \$2.0 million invested in a privately held company, partially offset by \$4.6 million in net maturities of marketable securities.

Net cash provided by financing activities was \$4.0 million for the nine months ended September 30, 2015, compared to \$4.2 million for the nine months ended September 30, 2014. Our financing activities have historically included sales of our equity securities. Net cash provided by financing activities for the nine months ended September 30, 2015 included \$7.8 million in proceeds from the issuance of our common stock upon the exercise of employee stock options partially offset by cash paid for tax withholdings of \$3.7 million related to net share settlements of RSUs. Net cash provided by financing activities for the nine months ended September 30, 2014 included \$7.7 million in proceeds from the issuance of our common stock upon the exercise of employee stock options and stock purchased pursuant to our ESPP, partially offset by cash paid for tax withholdings of \$3.5 million related to net share settlements of RSUs.

## Contractual Obligations

There were no material changes during the interim period in the contractual obligations presented in the latest annual report for the year ended December 31, 2014.

## Operating Capital and Capital Expenditure Requirements

We currently anticipate that our cash, cash equivalents and short-term marketable securities, together with payments for our tests, will be sufficient to fund our operations and facilities expansion plans for at least the next 12 months, including the expansion of our research and development programs, our proprietary liquid platforms development efforts, our efforts to expand adoption of and reimbursement for our tests and our international expansion efforts. We expect to spend approximately \$24 million over the next 12 months for planned laboratory equipment, information technology and facilities expansion. We may also use cash to acquire or invest in complementary businesses, technologies, services or products. We expect that our cash, cash equivalents and short term marketable securities will also be used to fund working capital and for other general corporate purposes, such as licensing technology rights, distribution arrangements for our tests both within and outside of the United States or expanding our direct sales

capabilities worldwide.

The amount and timing of actual expenditures may vary significantly depending upon a number of factors, such as the amount of cash provided by our operations, the progress of our commercialization efforts, product development, regulatory requirements, progress in reimbursement for our tests and available strategic opportunities for acquisition of or investment in complementary businesses, technologies, services or products.

We cannot be certain that our international expansion plans, efforts to expand adoption of and reimbursement for our tests or the development of future products will be successful or that we will be able to raise sufficient additional funds to see these activities through to a successful result. It may take years to move any one of a number of product candidates in research through development and validation to commercialization.

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

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

Table of Contents

- costs associated with expanding our commercial and laboratory operations, including our selling and marketing efforts;
- the rate of progress and cost of research and development activities associated with expansion of our current tests and the development of new tests;
- the rate of progress and cost of selling and marketing activities associated with expanding adoption of our Oncotype DX colon and prostate cancer and DCIS tests;
- the rate of progress and cost of research and development activities associated with NGS and our proprietary liquid platform;
- costs associated with acquiring, licensing or investing in technologies, including NGS and our proprietary liquid platform;
- costs associated with acquiring or investing in complementary businesses or assets;
- costs related to future product launches;
- costs related to acquiring or achieving access to tissue samples and technologies;
- costs related to 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;
- costs and delays in product development as a result of any changes in regulatory oversight applicable to our products or operations;
- the impact of changes in Federal, state and international taxation; and
- the economic and other terms and timing of any collaborations, licensing or other arrangements into which we may enter or investments or acquisitions we might seek to effect.

If we are not able to generate and maintain sustained product revenues to finance our cash requirements, we will need to finance future cash needs primarily through public or private equity offerings, debt financings, borrowings or strategic collaborations or licensing arrangements. If we raise funds by issuing equity securities, dilution to stockholders may result. Any equity securities issued may also provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock. The terms of debt securities or borrowings could impose significant restrictions on our operations. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or products, or grant licenses on terms that are not favorable to us. The credit market and financial services industry have in the past, and may in the future, experience periods of upheaval that could impact the availability and cost of equity and debt financing. If we are not able to secure additional funding when needed, on acceptable terms, we may have to delay, reduce the scope of or eliminate one or more research and development programs or selling and marketing initiatives. In addition, we may have to work with a partner on one or more of our product or market development programs, which could lower the economic value of those programs to us.

## Table of Contents

### Off-Balance Sheet Arrangements

As of September 30, 2015, we had no material off-balance sheet arrangements.

### Recently Issued Accounting Pronouncements

In April 2015, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update No. 2015-05, Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Customer's Accounting for Fees Paid in a Cloud Computing Arrangement ("ASU 2015-05"). This amendment provides guidance to help entities determine whether a cloud computing arrangement contains a software license that should be accounted for as internal-use software or as a service contract. ASU 2015-05 is effective for interim and annual reporting periods beginning after December 15, 2015, with early adoption permitted. Upon adoption, an entity has the option to apply the provisions of ASU 2015-05 either prospectively to all arrangements entered into or materially modified, or retrospectively. We do not expect the impact of the adoption of the ASU 2015-05 to have a material effect on our consolidated financial statements.

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers ("ASU 2014-09") to provide guidance on revenue recognition. ASU 2014-09 requires a company to recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under current guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. In July 2015, the FASB deferred the effective date for annual reporting periods beginning after December 15, 2017 (including interim reporting periods within those periods). Early adoption is permitted to the original effective date of December 15, 2016 (including interim reporting periods within those periods). The amendments may be applied retrospectively to each prior period presented or retrospectively with the cumulative effect recognized as of the date of initial application. We are currently evaluating the impact of adopting ASU 2014-09 on our consolidated financial statements.

## ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

### Interest Rate Risk

Our exposure to market risk for changes in interest rates relates primarily to interest earned on our cash equivalents and marketable securities. The primary objective of our investment activities is to preserve our capital to fund



operations. We also seek to maximize income from our investments without assuming significant risk. Our investment policy provides for investments in short-term, low-risk, investment-grade debt instruments. Our investments in marketable securities, which are comprised primarily of money market funds, commercial paper and corporate bonds, are subject to default, changes in credit rating and changes in market value. These investments are subject to interest rate risk and will decrease in value if market interest rates increase.

At September 30, 2015, we had cash, cash equivalents and short-term marketable securities of \$98.0 million. We currently do not hedge interest rate exposure, and we do not have any foreign currency or other derivative financial instruments. The securities in our investment portfolio are classified as available for sale and are, due to their short-term nature, subject to minimal interest rate risk. To date, we have not experienced a loss of principal on any of our investments. Although we currently expect that our ability to access or liquidate these investments as needed to support our business activities will continue, we cannot ensure that this will not change. We believe that, if market interest rates were to change immediately and uniformly by 10% from levels at September 30, 2015, the impact on the fair value of these securities or our cash flows or income would not be material.

#### Foreign Currency Exchange Risk

Substantially all of our revenues are recognized in U.S. dollars, although a growing percentage is denominated in foreign currency as we expand into markets outside of the United States. Certain expenses related to our international activities are payable in foreign currencies. As a result, factors such as changes in foreign currency exchange rates or

Table of Contents

weak economic conditions in foreign markets will affect our financial results. We recognized net foreign currency losses of \$197,000 and \$259,000 for the three and nine months ended September 30, 2015, respectively, compared to net foreign exchange transaction losses of \$345,000 and \$562,000 for the three and nine months ended September 30, 2014, respectively. The functional currency of our wholly-owned subsidiaries is the U.S. dollar, so we are not currently subject to gains and losses from foreign currency translation of the subsidiary financial statements. We currently do not hedge foreign currency exchange rate exposure. Although the impact of currency fluctuations on our financial results has been immaterial in the past, there can be no guarantee that the impact of currency fluctuations related to our international activities will not be material in the future.

ITEM 4. CONTROLS AND PROCEDURES.

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

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 the third quarter of 2015 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 have a history of net losses, we may incur net losses in the future, and we expect to continue to incur significant expenses to develop and market our tests, which may make it difficult for us to achieve sustained profitability.

We have historically incurred substantial net losses. From our inception in August 2000 through September 30, 2015, we had an accumulated deficit of \$225.4 million. We expect to continue to invest in our product pipeline, including our current Oncotype DX tests and future products, and in our global commercial infrastructure, our laboratory operations and next generation sequencing and other technology, including liquid biopsy. For the three and nine months ended September 30, 2015, our research and development expenses were \$13.5 million and \$47.2 million, respectively, and our selling and marketing expenses were \$35.4 million and \$108.0 million, respectively. We expect our expense levels to continue to increase for the foreseeable future as we seek to globally expand the clinical utility of our Oncotype DX breast cancer test, drive adoption of and reimbursement for our Oncotype DX colon cancer and prostate cancer tests and develop and commercialize new tests. As a result, we will need to generate significant growth in revenues in order to achieve sustained profitability. Our failure to achieve sustained profitability in the future could cause the market price of our common stock to decline.

Continued weak general economic or business conditions could have a negative impact on our business.

Continuing concerns over entitlement and healthcare reform efforts, regulatory changes and taxation issues, and geopolitical issues have contributed to continued volatility and uncertain expectations for both the U.S. and global economies. These factors, combined with uncertainties in business and consumer confidence and continued concerns regarding the stability of some European Union member countries, have contributed to the expectations of slower domestic and global economic growth in the near term. These economic conditions continued to impact product payment cycles, growth in tests delivered and product revenues generated during three and nine months ended September 30, 2015. If the economic environment does not improve or deteriorates, our business, including our patient population, our suppliers and our third party payors, could be negatively affected, resulting in a negative impact on our product revenues.

Healthcare policy changes, including recently enacted legislation reforming the U.S. healthcare system, may have a material adverse effect on our financial condition and results of operations.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, collectively, the Affordable Care Act, or ACA, enacted in March 2010, makes changes that are expected to significantly impact the pharmaceutical and medical device industries and clinical laboratories. For example, beginning in 2013, each medical device manufacturer must pay sales tax in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices that are listed with the FDA. Although the FDA has issued draft guidance that, if finalized, would regulate certain LDTs as medical devices, none of our LDTs, such as our Oncotype DX breast, colon and prostate cancer tests, are currently listed with the FDA. We cannot assure you that the tax will not apply to services such as ours in the future.

Other significant measures contained in the ACA include, for example, coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures, initiatives to revise Medicare payment methodologies, such as bundling of payments across the continuum of care by providers and physicians, and initiatives to promote quality indicators in payment methodologies. The ACA also includes significant new fraud and abuse measures, including required disclosures of financial arrangements with physician customers, lower thresholds for violations and increasing potential penalties for such violations. In addition, the ACA establishes an Independent Payment Advisory Board, or IPAB, to reduce the per capita rate of growth in Medicare spending if expenditures exceed certain targets. At this point, the triggers for IPAB proposals have not been met; it is unclear when such triggers may be made met in the future and when any IPAB-proposed reductions to payments could take effect. In addition to the ACA, various healthcare reform proposals have also emerged from federal and state governments. We are monitoring the

Table of Contents

impact of the ACA and these healthcare reform proposals in order to enable us to determine the trends and changes that may potentially impact our business over time.

Under the Budget Control Act of 2011, which went into effect for dates of service on or after April 1, 2013, Medicare payments, including payments to clinical laboratories, are subject to a 2% reduction due to implementation of the automatic expense reductions (sequester). Reductions made by the Congressional sequester are applied to total claims payment made. The sequester reductions do not result in a rebasing of the negotiated or established Medicare or Medicaid reimbursement rates.

State legislation on reimbursement applies to Medicaid reimbursement and Managed Medicaid reimbursement rates within that state. Some states have passed or proposed legislation that would revise reimbursement methodology for clinical laboratory payment rates under those Medicaid programs. In October 2011, CMS approved California's plan to reduce certain Medi Cal payments by 10% retroactive to June 1, 2011. In February 2012, Medi Cal began the recoupment process by sporadically adjusting payments on new claims. According to the California Department of Health Care Services, the cut applies to various healthcare providers and outpatient services including laboratory services with certain exceptions. State legislation requires the Department of Health Care Services to develop a new rate-setting methodology for clinical laboratories and laboratory services that is based on the average of the lowest prices other third-party payors are paying for similar services, and to implement an additional 10% reduction to payments for clinical laboratory or laboratory services retroactive to July 1, 2012 with the legislation mandating that these reductions continue until the new rate methodology has been approved by CMS. The Department of Health Care Services, or DHCS, has developed the new rate methodology, which involves the use of the range of rates that fell between zero and 80% of the calculated California Medicare rate and the calculation of a weighted average (based on units billed) of such rates. DHCS was targeting a July 1, 2015 effective date this new methodology, however, it has not yet been implemented.

Although recent changes to reimbursement methodology in states outside of California have not materially changed the payment rate for our tests, we cannot be certain that these or future changes will not affect payment rates in the future. We also cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which we may do business, or the effect any future legislation or regulation will have on us. The taxes imposed by new legislation, cost reduction measures and the expansion in government's role in the U.S. healthcare industry may result in decreased profits to us, lower reimbursements by payors for our products or reduced medical procedure volumes, all of which may adversely affect our business, financial condition and results of operations. In addition, sales of our tests outside the United States make us subject to foreign regulatory requirements and cost reduction measures, which may also change over time.

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

Clinical laboratory tests like ours are regulated under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, as well as by applicable state laws. Diagnostic kits that are sold and distributed through interstate commerce are regulated as medical devices by the FDA. Most LDTs are not currently subject to FDA regulation, although reagents or software provided by third parties and used to perform LDTs may be subject to regulation. We believe that our Oncotype DX tests are not diagnostic kits and also believe that they are LDTs. As a result, we believe our tests should not be subject to regulation at this time under established FDA policies. The container we provide for collection and transport of tumor samples from a pathology laboratory to our clinical reference laboratory may be a medical device subject to FDA regulation but is currently exempt from pre market review by the FDA.

At various times since 2006, the FDA has issued guidance documents or announced draft guidance regarding initiatives that may require varying levels of FDA oversight of our tests. In October 2014, the FDA issued draft guidance that sets forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. The FDA has indicated that it does not intend to implement its proposed framework until the draft guidance documents are finalized. It is unclear at this time if or when the draft guidance will be finalized, and even then, the new regulatory requirements are proposed to be phased-in consistent with the schedule set forth in the guidance. If this draft guidance is

Table of Contents

finalized as presently written, it includes an oversight framework that would require pre-market review for high and moderate risk LDTs.

Legislative proposals addressing oversight of genetic testing and LDTs have been introduced in previous Congresses and we expect that new legislative proposals will be introduced from time to time in the future. We cannot provide any assurance that FDA regulation, including pre-market review, will not be required in the future for our tests, whether through finalization of guidance issued by the FDA, new enforcement policies adopted by the FDA or new legislation enacted by Congress. It is possible that legislation will be enacted into law or guidance could be issued by the FDA which may result in increased regulatory burdens for us to continue to offer our tests or to develop and introduce new tests.

If pre-market review is required, our business could be negatively impacted until such review is completed and clearance or approval is obtained, and the FDA could require that we stop selling our tests pending pre market clearance or approval. If our tests are allowed to remain on the market but there is uncertainty about the regulatory status of our tests, if they are labeled investigational by the FDA, or if labeling claims the FDA allows us to make are more limited than the claims we currently make, orders or reimbursement may decline. The regulatory approval process may involve, among other things, successfully completing additional clinical trials and submitting a pre market clearance notice or filing a pre market approval application with the FDA. If pre market review is required by the FDA, there can be no assurance that our tests will be cleared or approved on a timely basis, if at all, nor can there be assurance that the labeling claims cleared or approved by the FDA will be consistent with our current claims or adequate to support continued adoption of and reimbursement for our tests. Ongoing compliance with FDA regulations would increase the cost of conducting our business, and subject us to inspection by and the regulatory requirements of the FDA, for example registration and listing and medical device reporting, and penalties in the event we fail 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.

We cannot predict the ultimate timing or form of final FDA guidance or regulation of LDTs and the potential impact on our existing tests, our tests in development or the materials used to perform our tests. While we qualify all materials used in our tests according to CLIA regulations, we cannot be certain that the FDA will not enact rules or guidance documents which could impact our ability to purchase certain materials necessary for the performance of our tests, such as products labeled for research use only. Should any of the reagents obtained by us from suppliers and used in conducting our tests be affected by future regulatory actions, our business could be adversely affected by those actions, including increasing the cost of testing or delaying, limiting or prohibiting the purchase of reagents necessary to perform testing.

If we were required to conduct additional clinical trials prior to continuing to sell our breast, colon and prostate cancer tests or launching any other tests we may develop, those trials could result in delays or failure to obtain necessary regulatory approvals, which could harm our business.

If the FDA decides to regulate our tests, it may require additional pre-market clinical testing before clearing or approving such tests for commercial sales. Such pre-market clinical testing could delay the commencement or completion of clinical testing, significantly increase our test development costs, delay commercialization of any future tests, and interrupt sales of our current tests. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to delay or denial of regulatory clearance or approval. The commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the clinical trial.

We may find it necessary to engage contract research organizations to perform data collection and analysis and other aspects of our clinical trials, which might increase the cost and complexity of our trials. We may also depend on clinical investigators, medical institutions and contract research organizations to perform the trials. 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



Table of Contents

our control. We may not be able to enter into replacement arrangements without undue delays or considerable expenditures. If there are delays in testing or approvals as a result of the failure to perform by third parties, our research and development costs would increase, and we may not be able to obtain regulatory clearance or approval for our tests. In addition, we may not be able to establish or maintain relationships with these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market our tests, or to achieve sustained profitability.

If third-party payors, including managed care organizations and Medicare, do not provide reimbursement, breach, rescind or modify their contracts or reimbursement policies or delay payments for our Oncotype DX tests, or we are unable to successfully renegotiate reimbursement contracts, our commercial success could be compromised.

Physicians and patients may not order our Oncotype DX tests unless third-party payors, such as managed care organizations as well as government payors such as Medicare and Medicaid and governmental payors outside of the United States, pay a substantial portion of the test price. Reimbursement by a 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 tests developed using our Oncotype 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 Oncotype DX breast cancer test, the test has received negative assessments in the past and our tests may receive negative assessments in the future. For example, in November 2010, the Medical Advisory Panel of the Blue Cross and Blue Shield Association's Technology Evaluation Center, a technology assessment group, published its conclusion that the existing clinical data in support of our Oncotype DX breast cancer test did not meet the panel's technology criteria for clinical effectiveness and appropriateness for usage in patients with N+ disease.

Since each payor makes its own decision as to whether to establish a policy to reimburse our test, seeking these approvals is a time-consuming and costly process. To date, we have positive coverage determinations for our Oncotype DX breast cancer test for N<sup>+</sup>, ER+ patients from most third party payors in the United States through contracts, agreements or policy decisions. We cannot be certain that coverage for this test will be provided in the future by additional third party payors or that existing contracts, agreements or policy decisions or reimbursement levels, including tests processed as out of network, will remain in place or be fulfilled within existing terms and provisions. From time to time payors change processes that may affect timely payment. These changes may result in uneven cash flow or impact the timing of revenue recognized with these payors.

We have obtained limited reimbursement from private third-party payors in the United States for our Oncotype DX colon cancer test and for our Oncotype DX breast cancer test for N+ and DCIS patients. Until further clinical data is presented, our N+ and DCIS indication for our breast cancer test and our colon cancer test may be considered investigational by payors and therefore may not be covered under their reimbursement policies.

We believe it may take several years to achieve reimbursement with a majority of third-party payors for these tests. In addition, the launch of our test for prostate cancer in May 2013 requires that we expend substantial time and resources in order to drive adoption of and reimbursement for this test.

Table of Contents

We have obtained Medicare reimbursement coverage for our prostate cancer test for low and very-low risk patients effective October 13, 2015. However, we may not be able to obtain Medicare reimbursement coverage for our prostate cancer test for intermediate risk patients or obtain other third-party payor reimbursement for patients with colon or prostate cancer or with N+ and DCIS breast cancer patients that is similar to the coverage we have obtained for our invasive breast cancer test for N-, ER- patients. If we fail to establish broad adoption of and reimbursement for these tests and any future tests we may develop, our reputation could be harmed and our future prospects and our business could suffer.

If we are unable to obtain or maintain reimbursement from private payors, such as the Blue Cross/Blue Shield family, and public payors, such as Medicare and Medicaid programs, for our existing tests or new tests or test enhancements we may develop in the future, our ability to generate revenues could be limited. We have in the past, and will likely in the future, experience delays and temporary interruptions in the receipt of payments from third-party payors due to modifications in existing contracts or arrangements, contract implementation matters, documentation requirements and other issues, which could cause our revenues to fluctuate from period to period.

If we are unable to obtain or maintain adequate reimbursement for our tests outside of the United States, our ability to expand internationally will be compromised.

The majority of our international Oncotype DX breast and colon cancer test revenues come from direct payor reimbursement, payments from our distributors, patient self pay, and clinical collaborations in various countries. In many countries outside of the United States, various coverage, pricing and reimbursement approvals are required. We expect that it will take several years to establish broad coverage and reimbursement for our tests with payors in countries outside of the United States, and our efforts may not be successful. Once established, reimbursement levels outside of the United States may vary considerably from the domestic reimbursement amounts we receive. In addition, because we rely on distributors to obtain reimbursement for our tests, to the extent we do not have direct reimbursement arrangements with payors, we may not be able to retain reimbursement coverage in certain countries with a particular payor if our agreement with a distributor is terminated or expires or a distributor fails to pay us for other reasons. Distributors of our tests may also be negatively affected by the financial instability of, and austerity measures implemented by, several countries in the European Union and elsewhere.

The prices at which our tests are reimbursed may be reduced by Medicare and private and other payors, and any such changes could have a negative impact on our revenues.

Even if we are being reimbursed for our tests, Medicare, Medicaid and private and other payors may withdraw their coverage policies, cancel their contracts with us at any time, review and adjust the rate of reimbursement, require co-payments from patients or stop paying for our tests, which would reduce our revenues. In addition, insurers, including managed care organizations as well as government payors such as Medicare and Medicaid, have increased their efforts to control the cost, utilization and delivery of healthcare services. These measures have resulted in reduced payment rates for and decreased utilization of clinical laboratory services. Noridian Healthcare Solutions and

Palmetto GBA (the Medicare Administrative Contractors, or MACs, that process Medicare claims and set Medicare coverage and payment policies, respectively, for most tests billed by our laboratory) and other MACs review coverage and reimbursement rates annually.

The recently enacted Protecting Access to Medicare Act of 2014, or PAMA, includes a substantial new payment system for clinical laboratory tests under the Clinical Laboratory Fee Schedule, or CLFS. Under PAMA, Medicare payment rates for tests will be equal to the volume-weighted median of the private payor payment rates for the test. The payment rates calculated under PAMA are expected to apply to our tests starting January 1, 2017, and will be reviewed annually for “advanced diagnostic laboratory tests” (and every three years for other tests), based on private payor payment rates and volumes for their tests. Laboratories that fail to report or erroneously report the required payment information may be subject to substantial civil money penalties. Although CMS has not yet issued regulations to implement PAMA, we believe our Oncotype DX tests each would be considered an advanced diagnostic laboratory test. While we do not believe the new payment rate system under PAMA will have a negative effect on the current payment rates of our Medicare-covered tests beginning in 2017, regulations implementing PAMA have not yet been promulgated. As a result, there can be no assurance that adequate payment rates will continue to be assigned to our tests.

Table of Contents

We have received a specific Current Procedural Terminology, or CPT, code for our Oncotype DX breast cancer test effective January 1, 2015. Medicare has established a national limitation amount for this code under the gapfill process that maintains the contractor amount currently in effect through 2016. New rates under PAMA are then expected to be adopted effective January 1, 2016.

On September 25, 2015, CMS published preliminary determinations for 2016 for payment for new and revised codes under the CLFS, including a new, specific code for our Oncotype DX colon test. In this preliminary determination, CMS has proposed a reduction in payment of 79% from the rate currently in effect. The final determinations should be published in November or December 2015. We cannot be sure that the reductions proposed in the preliminary determination will not be maintained in the final determination.

Additionally, on a five year rotational basis, Medicare requests bids for its regional MAC services. In September 2013, the claims processing function for our jurisdiction transitioned from Palmetto GBA to Noridian Healthcare Solutions, although coverage and payment rate determinations for our tests remain with Palmetto GBA at this time through the MolDx Program. The change in the MAC processing the Medicare claims for our tests delayed reimbursement for a brief period of time. Future changes in the MAC may affect our ability to obtain Medicare coverage and reimbursement for products for which we have coverage, for which we do not yet have coverage or any products we may launch in the future or delay payments, including payments for our Oncotype DX prostate cancer test.

We recently obtained Medicare coverage for our Oncotype DX prostate cancer test. Under the terms of the coverage determination, reimbursement is limited to tests ordered by physicians who agree to participate in a Certification and Training Registry and to provide certain information about Medicare beneficiaries who receive our test.

Because of Medicare billing rules or changes in Medicare billing rules and processes, we may not receive reimbursement for all tests provided to Medicare patients or may experience delays of receiving payments.

Under current Medicare billing rules, payment for our Oncotype DX tests performed on Medicare beneficiaries who were hospital patients at the time the tumor tissue samples were obtained and whose tests were ordered less than 14 days from discharge must be bundled into the payment that the hospital receives for the inpatient services provided. Accordingly, we are required to bill individual hospitals for tests ordered for Medicare beneficiaries during these time frames. Because we generally do not have written agreements in place with these hospitals to pay for these tests, we may not be paid or may have to pursue payment from the hospital on a case by case basis. We cannot ensure that hospitals will pay us for Oncotype DX tests performed on patients falling under these rules.

Although we believe patients coming under these rules represent less than 1% of our total claims, these billing rules may lead to confusion regarding whether Medicare provides adequate reimbursement for our tests, and could discourage providers from ordering our tests for Medicare patients. In addition, compared to our breast cancer tests, a greater proportion of eligible patients for our colon and prostate tests are covered by Medicare. We cannot assure you that Medicare will continue these billing rules in their current form or if Medicare will seek to expand the scope of its payment bundling rules in the future. In addition, changes in Medicare billing rules and processes could result in delays in receiving payments and any such delays could affect our results of operations.

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

Reimbursement on behalf of patients covered by Medicare accounted for 20% of our product revenues for the three and nine months ended September 30, 2015 and 2014. Accounts receivable on behalf of patients directly covered by Medicare represented 15% and 27% of our net accounts receivable at September 30, 2015 and December 31, 2014, respectively. While there were no other third-party payors representing 10% or more of our product revenues for these periods, there have been in the past, and may be in the future, other payors accounting for 10% or more of our product revenues. Because the majority of stage II and stage III colon cancer patients and prostate cancer patients in the United States are age 65 and over, and thus eligible for Medicare, we may become more dependent on Medicare reimbursement

Table of Contents

in the future. It is possible that Medicare or other third-party payors that provide reimbursement for our tests may suspend, revoke or discontinue coverage at any time, may require co-payments from patients, or may reduce the reimbursement rates payable to us. Any such action could have a negative impact on our revenues.

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

For the near future, we expect to continue to derive a substantial majority of our revenues from sales of one test, our Oncotype DX test for invasive breast cancer. While we launched our test for colon cancer in January 2010, we do not expect to recognize increased revenues from this test until significant levels of adoption and reimbursement for this test have been established. We have similar expectations for revenue related to our DCIS breast cancer test, which was launched in December 2011, and our prostate cancer test, which was launched in May 2013. We are in various stages of research and development for other tests that we may offer as well as for enhancements to our existing tests, including those using our liquid biopsy platform. We may not be able to successfully commercialize tests for other cancers or diseases. If we are unable to increase sales of our test for invasive breast cancer, establish adoption of and reimbursement for our colon, or prostate cancer or DCIS tests, or successfully develop and commercialize other tests or enhancements, our revenues and our ability to achieve sustained profitability would be impaired.

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 regulations mandate 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 through our accreditation by the College of American Pathologists, or CAP. 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.

Although we are required to hold a certificate of accreditation or compliance under CLIA that allows us to perform high complexity testing, we are not required to hold a certificate of accreditation through CAP. We could alternatively maintain a certificate of accreditation from another accrediting organization or a certificate of compliance through inspection by surveyors acting on behalf of the CLIA program. If our accreditation under CAP were to terminate, either voluntarily or involuntarily, we would need to convert our certification under CLIA to a certificate of compliance (or to a certificate of accreditation with another accreditation organization) in order to maintain our ability to perform clinical testing and to continue commercial operations. Whether we would be able to successfully maintain operations through either of these alternatives would depend upon the facts and circumstances surrounding termination of our CAP accreditation, such as whether any deficiencies were identified by CAP as the basis for termination and, if so, whether these were addressed to the satisfaction of the surveyors for the CLIA program (or

another accrediting organization).

We are also required to maintain a license to conduct testing in California. California laws establish standards for day to day operation of our clinical reference laboratory, including the training and skills required of personnel and quality control. In addition, our clinical reference laboratory is required to be licensed on a product specific basis by New York State. New York law also mandates proficiency testing for laboratories licensed under New York state law, regardless of whether or not such laboratories are located in New York. Moreover, several other states require that we hold licenses to test specimens from patients in those states. Other states may have similar requirements or may adopt similar requirements in the future. Finally, we may be subject to regulation in foreign jurisdictions as we seek to expand international distribution of our tests, which may require review of our tests in order to offer our services or may have other limitations such as prohibitions on the export of tissue necessary for us to perform our tests that may limit our ability to distribute outside of the United States.

If we were to lose our CLIA accreditation or California license, whether as a result of a revocation, suspension or limitation, we would no longer be able to sell our tests, which would limit our revenues and harm our business. If we



Table of Contents

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 in the United States by both the federal government and the states in which we conduct our business, as well as in other jurisdictions outside of the United States, including:

- Medicare billing and payment regulations applicable to clinical laboratories;
- the Federal Anti-kickback Law and state anti-kickback prohibitions;
- the Federal physician self-referral prohibition, commonly known as the Stark Law, and the state equivalents;
- the Federal Health Insurance Portability and Accountability Act of 1996;
- the Medicare civil money penalty and exclusion requirements;
- the Federal False Claims Act civil and criminal penalties and state equivalents; and
- the Foreign Corrupt Practices Act, the United Kingdom Anti-bribery Act and the European Data Protection Directive, all of which apply to our international activities.

We have adopted policies and procedures designed to comply with these laws. 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 and our expansion outside of the United States may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these or other 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 or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including civil and criminal penalties, damages and fines, we could be required to refund payments received by us, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

New test development involves a lengthy and complex process, and we may be unable to commercialize on a timely basis, or at all, any new tests we may develop.

We have multiple tests in development and devote considerable resources to research and development. There can be no assurance that our technologies will be capable of reliably predicting the recurrence of cancers other than breast, colon and prostate cancer with the sensitivity and specificity necessary to be clinically useful and commercially viable, or that our colon or prostate cancer tests will result in commercially successful products. In addition, before we can develop diagnostic tests for new cancers or other diseases and commercialize any new products, we will need to:

- conduct substantial research and development;
- conduct validation studies;
- expend significant funds;
- develop and scale our laboratory processes to accommodate different tests; and
  - develop and scale our infrastructure to be able to analyze increasingly large amounts of data.

Table of Contents

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

- failure of the product at the research or development stage;
- difficulty in accessing tissue and blood samples;
- challenges in timely patient enrollment in future clinical trials; or
- lack of clinical validation data to support the effectiveness of the product.

Few research and development projects result in commercial products, and success in early clinical trials often is not replicated in later studies. At any point, we may abandon development of a product candidate or we may be required to expend considerable resources repeating clinical trials, which would adversely impact the timing for generating potential revenues from those product candidates. In addition, as we develop products, we will have to make significant investments in product development, marketing and selling resources. If a clinical validation study fails to demonstrate the prospectively defined endpoints of the study, we 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. For example, in September 2013 we delayed our plan to initiate a validation study in 2013 utilizing results from our NSABP C 07 clinical trial. The decision to delay was based on analytical performance, during the pre validation phase, that did not meet our standards for a subset of the candidate predictive genes. In addition, competitors may develop and commercialize competing products faster than we are able to do so.

If we are unable to support demand for our tests, including successfully managing the evolution of our technology and manufacturing platforms, our business could suffer.

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

market demand or quality standards for our tests, our reputation could be harmed and our future prospects and our business could suffer.

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

If medical practitioners do not order our Oncotype DX tests or any future tests developed or offered by us, we will likely not be able to create or maintain demand for our products in sufficient volume for us to achieve sustained profitability. To generate demand, we will need to continue to make oncologists, urologists, surgeons and pathologists aware of the benefits of each type of test through published papers, presentations at scientific conferences and one on one education by our sales force. In addition, we will need to demonstrate our ability to obtain and maintain adequate reimbursement coverage from third party payors.

Prior to the inclusion of our Oncotype DX breast cancer test in clinical guidelines for treatment of N-, ER+ breast cancer, guidelines and practices regarding the treatment of breast cancer recommended that chemotherapy be considered in most cases, including many cases in which our test might indicate that, based on our clinical trial results, chemotherapy would be of little or no benefit. Accordingly, physicians may be reluctant to order a test that may suggest

Table of Contents

recommending against chemotherapy in treating breast cancer. Moreover, our test provides quantitative information not currently provided by pathologists and it is performed at our facility rather than by the pathologist in a local laboratory, so pathologists may be reluctant to support our test. These facts may make it difficult for us to convince medical practitioners to order our test for their patients, which could limit our ability to generate revenues and achieve sustained profitability.

Our Oncotype DX colon cancer test predicts recurrence but, unlike our test for invasive breast cancer, does not predict chemotherapy benefit. Our new Oncotype DX prostate cancer test provides physicians and patients with a new way to assess the aggressiveness of a patient's prostate cancer. We will need to educate physicians, patients and payors about the benefits and cost effectiveness of these tests and to establish reimbursement arrangements for these tests with payors. We have and expect to continue to hire additional commercial, sales, scientific, technical and other personnel to support this process. If our marketing and educational efforts do not result in sufficient physician or patient demand, we may not be able to obtain adequate reimbursement for these tests. If we fail to successfully establish adoption of and additional reimbursement beyond Medicare for our colon cancer test, our reputation could be harmed and our business could suffer. If we fail to successfully establish adoption of and reimbursement for our prostate cancer test, our reputation could be harmed and our business could suffer.

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

Some patients may decide not to use our Oncotype DX tests due to their price, all or part of which may be payable directly by the patient if the applicable payor denies reimbursement in full or in part. Even if medical practitioners recommend that their patients use our tests, patients may still decide not to use our tests, either because they do not want to be made aware of the likelihood of recurrence or they wish to pursue a particular course of therapy regardless of test results. Additionally, the current economic environment in the United States and abroad could continue to negatively impact patients, resulting in higher co-payments and insurance premiums or the loss of healthcare coverage, which may result in delayed medical checkups or an inability to pay for our tests. If only a small portion of the patient population decides to use our tests, we will experience limits on our revenues and our ability to achieve sustained profitability.

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

We license from third parties technology necessary to develop our products. For example, we license technology from Roche Molecular Systems, Inc. that we use to analyze genes in our clinical reference laboratory to conduct our tests. In return for the use of a third party's technology, we may agree to pay the licensor royalties based on sales of our products. Royalties are a component of cost of product revenues and impact the margins on our tests. We may need to license other technologies to commercialize future products. We may also need to negotiate licenses to patents and patent applications after launching any of our commercial 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, if the patents or patent applications are unavailable for license 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, or in countries in which we do not have intellectual property protection. Such companies could send test results into the United States and therefore reduce sales of our tests.

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

In recent years, there have been numerous advances in technologies relating to the diagnosis and treatment of cancer. For example, technologies in addition to ours now permit measurement of gene expression in fixed paraffin embedded tissue specimens or blood or urine. New chemotherapeutic or biologic strategies are being developed that may increase survival time and reduce toxic side effects. There have also been advances in methods used to analyze very large amounts of genomic information, specifically next generation sequencing, or NGS. These advances require us to continuously develop our technology, develop new products and enhance existing products to keep pace with evolving standards of care. Our tests could become obsolete unless we continually innovate and expand our products to demonstrate recurrence and treatment benefit in patients treated with new therapies. New treatment therapies typically have only a few years of clinical data associated with them, which limits our ability to perform clinical studies and

Table of Contents

correlate sets of genes to a new treatment's effectiveness. If we are unable to demonstrate the applicability of our tests to new treatments, sales of our test could decline, which would harm our revenues.

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

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

Our pending patent applications may not result in issued patents, and we cannot assure you that our issued patents or any patents that might ultimately be issued by the U.S. Patent and Trademark Office, or USPTO, will protect our technology. In addition, we do not file patent applications in every country nor is patent protection available in every country. We may face competition internationally in jurisdictions where we do not have intellectual property protection. 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.

If patent regulations or standards are modified, such changes could have a negative impact on our business.

From time to time, the U.S. Supreme Court, other federal courts, the U.S. Congress or the USPTO may change the standards of patentability and validity 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.

There have been several cases involving "gene patents" and diagnostic claims that have been considered by the U.S. Supreme Court. In March 2012, the Supreme Court in *Mayo Collaborative v. Prometheus Laboratories*, or

Prometheus, found a patented diagnostic method claim unpatentable because the relationship between a metabolite concentration and optimized dosage was a patent ineligible “law of nature.” In June 2013, the Supreme Court ruled in *ACLU v. Myriad Genetics, or Myriad*, that an isolated genomic DNA sequence is not patent eligible while cDNA is eligible. Both the Prometheus and Myriad decisions affect the legal concept of subject matter eligibility by seemingly narrowing the scope of the statute defining patentable inventions.

In December 2014, the USPTO published revised guidelines for patent examiners to apply when examining process claims for patent eligibility in view of several recent Supreme Court decisions, including *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, *Association for Molecular Pathology v. Myriad Genetics, Inc.*, and *Alice Corporation Pty. Ltd. V. CLS Bank International, et al.* The guidance indicates that claims directed to a law of nature, a natural phenomenon, or an abstract idea that do not meet the eligibility requirements should be rejected as non statutory, patent ineligible subject matter. We cannot assure you that our patent portfolio will not be negatively impacted by the decisions described above, rulings in other cases or changes in guidance or procedures issued by the USPTO.

Additional substantive changes to patent law, whether new or associated with the American Invents Act, may affect our ability to obtain, enforce or defend our patents. Accordingly, it is not clear what, if any, impact the new law will ultimately have on the cost of prosecuting our patent applications, our ability to obtain patents based on our discoveries and our ability to enforce or defend our issued patents, all of which could have a material adverse effect on our business.



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 in the past, and may in the future, receive notices of claims of infringement and misappropriation or misuse of other parties' proprietary rights and may from time to time receive additional notices. Some of these claims may lead to litigation. We cannot assure you that we will prevail in such actions, or that other actions alleging misappropriation or misuse by us of third party trade secrets, alleging infringement by us of third party patents and trademarks or challenging the validity of our patents, will not be asserted or prosecuted against us.

We may also initiate claims to defend our intellectual property or to seek relief on allegations that we use, sell, or offer to sell technology that incorporates third party intellectual property. Intellectual property litigation, regardless of outcome, is expensive and time consuming, could divert management's attention from our business and have a material negative effect on our business, operating results or financial condition. If there is a successful claim of infringement against us, we may be required to pay substantial damages (including treble damages if that infringement were found to be willful) to the party claiming infringement, develop non infringing technology, stop selling our tests or using technology that contains the allegedly infringing intellectual property or enter into royalty or license agreements that may not be available on acceptable or commercially practical terms, if at all. Our failure to develop non infringing technologies or license the proprietary rights on a timely basis could harm our business. In addition, revising our tests to include the non infringing technologies would require us to re validate our tests, which would be costly and time consuming. Also, we may be unaware of pending third-party patent applications that relate to our tests. Parties making infringement claims on future issued patents may be able to obtain an injunction that could prevent us from selling our tests or using technology that contains the allegedly infringing intellectual property, which could harm our business.

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

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

Our principal competition for our breast, colon and prostate cancer tests 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.

We also face competition from companies that offer products or have conducted research to profile genes, gene expression or protein expression in breast, colon or prostate cancer, including public companies such as GE Healthcare, a business unit of General Electric Company, Hologic, Inc., Myriad Genetics, Inc., NanoString Technologies, Inc., Novartis AG, Qiagen N.V. and Response Genetics, Inc., and many private companies. We also face competition from commercial laboratories with strong distribution networks for diagnostic tests, such as Laboratory Corporation of America Holdings and Quest Diagnostics Incorporated. We may also face competition from Illumina, Inc. and Thermo Fisher Scientific Inc., both of which have announced their intention to enter the clinical diagnostics market. Other potential competitors include companies that develop diagnostic tests such as Roche Diagnostics, a division of Roche Holding, Ltd, Siemens AG and Veridex LLC, a Johnson & Johnson company, as well as other companies and academic and research institutions.

In our newly established prostate cancer market, we face comparatively greater competition than in our breast cancer market, including competition from products which were on the market prior to our product launch and which are supported by clinical studies and published data. This existing direct and indirect competition for tests and procedures may make it difficult to gain market share, impact our ability to obtain reimbursement or result in a substantial increase in resources necessary for us to successfully commercialize our Oncotype DX prostate cancer test.

Table of Contents

Others may invent and commercialize technology platforms such as next generation sequencing approaches that will compete with our test. Projects related to cancer genomics have received government funding, both in the United States and internationally. 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 that these products may compete with ours. In addition, competitors may develop their own versions of our tests in countries where we did not apply for patents, where our patents have not been issued or where our intellectual property rights are not recognized and compete with us in those countries, including encouraging the use of their test by physicians or patients in other countries.

We have changed the list price of our tests in the past and we expect to change prices for our tests in the future. Any increase or decrease in pricing could impact reimbursement of and demand for our tests. Many of our present and potential competitors have widespread brand recognition and substantially greater financial and technical resources and development, production and marketing capabilities than we do. Others may develop lower priced tests that could be viewed by physicians and payors as functionally equivalent to our tests, or offer tests at prices designed to promote market penetration, which could force us to lower the list prices of our tests and impact our operating margins and our ability to achieve sustained profitability. Some competitors have developed tests cleared for marketing by the FDA. There may be a marketing differentiation or perception that an FDA cleared test is more desirable than Oncotype DX tests, and that may discourage adoption of and reimbursement for our tests. If we are unable to compete successfully against current or future competitors, we may be unable to increase market acceptance for and sales of our tests, which could prevent us from increasing or sustaining our revenues or achieving sustained profitability and could cause the market price of our common stock to decline.

Our research and development efforts will be hindered if we are not able to contract with third parties for access to tissue and blood samples or complete timely enrollment in future clinical trials.

Under standard clinical practice, tumor biopsies removed from patients are typically chemically preserved and embedded in paraffin wax and stored. Our clinical development relies on our ability to secure access to these tumor biopsy samples, as well as information pertaining to their associated clinical outcomes. Generally, the agreements under which we gain access to archival samples are nonexclusive. Other companies 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. In addition, our liquid biopsy-based tests in development require that we be able to access blood samples. If we are not able to negotiate access to clinical samples with hospitals, clinical partners, pharmaceutical companies, or companies developing therapeutics on a timely basis, or at all, 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. Finally, we may not be able to conduct or complete clinical trials on a timely basis if we are not able to enroll sufficient numbers of patients in such trials, and our failure to do so could have an adverse effect on our research and development and product commercialization efforts.

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. 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.

Table of Contents

Organizations may also have insufficient administrative and related infrastructure to enable collaborations with many companies at once, which can prolong the time it takes to develop, negotiate and implement 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 tests such as ours, and our inability to control when, if ever, results are published may delay or limit our ability to derive sufficient revenues from any product that may result from a collaboration.

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

The loss of key members of our senior management team or our inability to attract and 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, continue our international expansion and transition to a company with multiple commercialized products. If we were to lose one or more of these key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategies.

Our research and development programs and commercial laboratory operations depend on our ability to attract and retain highly skilled scientists and technicians, including 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. In addition, it is expected that there will be a shortage of clinical laboratory scientists in coming years, which would make it more difficult to hire sufficient numbers of qualified personnel. 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 urology and close relationships with medical oncologists, urologists, 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 tests. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that could adversely affect our ability to support our research and development and sales programs. All of our employees are at will, which means that either we or the employee may terminate their employment at any time.

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

We do not have redundant clinical reference laboratory facilities outside of Redwood City, California. Redwood City is situated near active 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 Oncotype DX tests could be performed following validation

Table of Contents

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

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

Our business strategy incorporates international expansion, including increasing the size of and maintaining direct sales and physician outreach and education capabilities outside of the United States and expanding our relationships with international payors and distributors. Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, privacy laws and reliance on associated safe harbors, regulatory requirements and other governmental approvals, permits and licenses;
- competition from local and regional product offerings;
- failure by us or our distributors to obtain regulatory approvals for the use of our tests in various countries;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient 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;

- lack of intellectual property protection in certain markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our tests and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism, and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and
- regulatory and compliance risks that relate to maintaining accurate information and control over the activities of our sales force and distributors that may fall within the purview of the FCPA, 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 sales of our Oncotype DX tests outside of the U.S. could limit or prevent us from selling our test in foreign markets and impact our revenue.



Table of Contents

As of September 30, 2015, we have entered into exclusive distribution agreements for the sale of our tests with distributors covering more than 90 countries. We may enter into other similar arrangements to distribute our tests in other countries in the future. We intend to continue 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 tests. Distributors may not commit the necessary resources to market and sell our tests to the level of our expectations. If current or future distributors do not perform adequately, or we are unable to enter into arrangements with distributors to market our tests in particular geographic areas, we may not realize long term international revenue growth. In addition, our revenue from distributors could be negatively impacted as a result of changes in business cycles, business or economic conditions, changes in foreign currency exchange rates that make our tests more expensive in our distributors' local currencies or other factors that could affect their ability to pay us for tests on a timely basis or at all. 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, form joint ventures or make investments in other companies or technologies 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, or make investments in other companies. We have recently experienced and may in the future experience losses related to the recognition of our portion of the net losses of equity method investees, and we may in the future experience impairment losses related to our investments in companies if we determine that the value of an investment is impaired. Losses related to our investments in other companies could have a material negative effect on our results of operations. We have no experience with respect to acquiring other companies and limited experience with respect to the formation of strategic alliances and joint ventures. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions by us also could result in significant write offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. Integration of an acquired company also may require management resources that otherwise would be available for ongoing development of our existing business. We may not identify or complete these transactions in a timely manner, on a cost effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance, joint venture or investment.

To finance any acquisitions or investments, we may choose to issue shares of our common stock as consideration, which would dilute the ownership of our stockholders. Periods of upheaval in the capital markets and world economy have in the past, and may in the future, cause volatility in the market price of our common stock. If the price of our common stock is low or volatile, we may not be able to acquire other companies for stock. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

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

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, similar types of investments have in the past and may in the future experience losses in value or liquidity issues which differ from historical patterns. In addition, in February 2015, a privately-held company in which we had invested completed its initial public offering and our investment is therefore recorded in short-term marketable securities at September 30, 2015. The fair value of this security was 23% of total short-term marketable securities as of September 30, 2015 and as a newly issued public security, it may be subject to volatility in its market value. For example, the price of this security fluctuated between \$6.58 per share and \$22.35 per share since the initial public offering in February 2015 through October 2015. Should a portion of our marketable securities lose value or have their liquidity impaired, it could negatively affect our financial results and our ability to fund our operations, and we may need to seek additional financing sooner than we might otherwise. Such financing, if available, may not be available on commercially reasonable terms.

Table of Contents

If it became necessary and we were unable to raise additional capital on acceptable terms in the future, it 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 Oncotype DX tests and enhancements to those tests;
- fund commercialization of any future tests we may develop;
- increase our selling and marketing efforts to drive market adoption and address competitive developments;
- further expand our clinical laboratory operations;
- expand our technologies into other areas of cancer or other diseases;
- expand our research and development activities;
- acquire, license or invest in technologies, including liquid biopsy;
- acquire or invest in complementary businesses or assets; and
- finance capital expenditures and general and administrative expenses.

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

- the rate of progress in establishing and maintaining reimbursement arrangements with domestic and international third-party payors;
- costs associated with expanding our commercial and laboratory operations, including our selling and marketing efforts;

Edgar Filing: GENOMIC HEALTH INC - Form 10-Q/A

- the rate of progress and cost of research and development activities associated with expansion of our Oncotype DX breast, colon and prostate cancer tests;
- the rate of progress and cost of selling and marketing activities associated with establishing adoption of and reimbursement for our Oncotype DX tests;
- costs related to future product launches;
- the rate of progress and cost of research and development activities associated with products in research and development focused on cancers other than breast, colon and prostate cancer;
- the rate of progress and cost of research and development activities associated with next generation sequencing;
- cost associated with acquiring, licensing or investing in technologies, including next generation sequencing and liquid biopsy;
- costs associated with acquiring or investing in complementary businesses or assets;
- costs related to acquiring or achieving access to tissue samples and technologies;

Table of Contents

- costs associated with 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;
- costs and delays in product development as a result of any changes in regulatory oversight applicable to our products or operations;
- the impact of changes in Federal, state and international taxation; and
- the economic and other terms and timing of any collaborations, licensing or other arrangements into which we may enter or investments or acquisitions we may seek to effect.

If we raise funds by issuing equity securities, dilution to our stockholders could result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings could impose significant restrictions on our operations. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or products, or grant licenses on terms that are not favorable to us. Accordingly, additional equity or debt financing might not be available on reasonable terms, if at all. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs or selling and marketing initiatives. In addition, we may have to work with a partner on one or more of our product or market development programs, which could lower the economic value of those programs to us.

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

We depend on information technology, or IT, and telecommunications systems for significant aspects of our operations. In addition, our third party billing and collections provider is dependent upon telecommunications and data systems provided by outside vendors and information it receives from us on a regular basis. These IT and telecommunications systems support a variety of functions, including test processing, sample tracking, quality control, customer service and support, billing and reimbursement, research and development activities, and our general and administrative activities. Failures or significant downtime of our IT or telecommunications systems or those used by our third party service providers could prevent us from processing tests, providing test results to physicians, billing

payors, processing reimbursement appeals, handling patient or physician inquiries, conducting research and development activities, and managing the administrative aspects of our business. Any disruption or loss of IT or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business and our product revenues.

We are currently in the process of transitioning to a new enterprise resource planning system, which we anticipate will become effective by end of 2015. The transition could result in delays in access to, or errors in, critical business and financial information. Any such errors or delays could harm our ability to operate certain aspects of our business or to file our period reports in a timely manner.

Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we and our third party billing and collections provider collect and store sensitive data, including legally protected health information, credit card information, personally identifiable information about our employees, customers and patients, intellectual property, and our proprietary business information and that of our customers, payors and collaboration partners. We manage and maintain our applications and data utilizing a combination of on site systems, managed data center systems and cloud based data center systems. These applications and data encompass a wide variety of business critical information including research and development information,

Table of Contents

commercial information and business and financial information. We face four primary risks relative to protecting this critical information, including loss of access risk, inappropriate disclosure risk and inappropriate modification risk combined with the risk of our being able to identify and audit our controls over the first three risks.

The secure processing, storage, maintenance and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure, and that of our third party billing and collections provider, may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as the Health Insurance Portability and Accountability Act of 1996, and regulatory penalties. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to process tests, provide test results, bill payors or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, collect, process and prepare company financial information, provide information about our tests and other patient and physician education and outreach efforts through our website, manage the administrative aspects of our business and damage our reputation, any of which could adversely affect our business.

In addition, the interpretation and application of consumer, health related and data protection laws in the U.S., Europe and elsewhere are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government imposed fines or orders requiring that we change our practices, which could adversely affect our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business.

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 replacement suppliers or immediately transition to alternative suppliers.

We rely on certain sole suppliers to supply and service some of the laboratory equipment on which we perform our tests. We believe that there are relatively few equipment manufacturers that are currently capable of supplying and servicing the equipment necessary for our tests. Although we have identified alternative suppliers, transition to a new supplier will be time consuming and expensive, and there can be no assurance that we will be able to secure alternative equipment and bring that equipment on line without experiencing interruptions in testing. If we should encounter delays or difficulties in securing the quality and quantity of equipment we require for our tests, we may need to reconfigure our test processes, which could result in an interruption in sales. If any of these events occur, our business and operating results could be harmed.

We also rely on several sole suppliers for certain laboratory reagents and 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, if the materials do not meet our quality specifications, or if we cannot obtain acceptable substitute materials, an interruption in test processing could occur. Any such interruption may significantly affect future product revenues.

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

Future growth will impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. In addition, rapid and significant growth may place strain on our administrative and operational infrastructure, including customer service and our clinical reference laboratory. Our ability to manage our operations and growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. We plan to implement new enterprise software affecting a broad range of business processes and functional areas including order fulfillment, sample processing, customer service, supply chain management, and others. The time and resources required to implement these new systems is uncertain, and failure to complete this in a timely and efficient manner could adversely affect our operations. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy.



Table of Contents

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 Oncotype DX breast cancer test for patients who do not have the same specific clinical attributes indicated on the report form as those for which the test provides clinical experience information from validation studies. It is our practice to offer medical consultation to physicians ordering our test for such patients, including patients with ER<sup>+</sup> breast cancers. A product liability or professional liability claim could result in substantial damages and be costly and time consuming for us to defend. Although we maintain product and professional liability insurance, we cannot assure you that our insurance would fully protect us from the financial impact of defending against product liability or professional liability claims or any judgments, fines or settlement costs arising out of any such 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 hazardous materials in a manner that causes injury, we could be liable for damages.

Our activities currently require the use of hazardous chemicals. 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.

We must implement additional and expensive business 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, accounting, and business operating systems, procedures and controls as we

grow our business and organization and to satisfy existing reporting requirements. If we fail to maintain or implement adequate controls, if we are unable to complete the required Section 404 assessment as to the adequacy of our internal control over financial reporting in future Form 10 K filings, or if our independent registered public accounting firm is unable to provide us with an unqualified report as to the effectiveness of our internal control over financial reporting in future Form 10 K filings, our ability to obtain additional financing could be impaired. In addition, investors could lose confidence in the reliability of our internal control over financial reporting and in the accuracy of our periodic reports filed under the Exchange Act. A lack of investor confidence in the reliability and accuracy of our public reporting could cause our stock price to decline.

We are subject to increasingly complex taxation rules and practices, which may affect how we conduct our business and our results of operations.

As our business grows, we are required to comply with increasingly complex taxation rules and practices. We are subject to tax in multiple U.S. tax jurisdictions and in foreign tax jurisdictions as we expand internationally. The development of our tax strategies requires additional expertise and may impact how we conduct our business. Our future effective tax rates could be unfavorably affected by changes in, or interpretations of, tax rules and regulations in the jurisdictions in which we do business, by lapses of the availability of the U.S. research and development tax credit or by changes in the valuation of our deferred tax assets and liabilities. Furthermore, we provide for certain tax liabilities that

Table of Contents

involve significant judgment. We are subject to the examination of our tax returns by federal, state and foreign tax authorities, which could focus on our intercompany transfer pricing methodology as well as other matters. If our tax strategies are ineffective or we are not in compliance with domestic and international tax laws, our financial position, operating results and cash flows could be adversely affected.

We face risks associated with currency exchange rate fluctuations, which could adversely affect our operating results.

We receive a portion of our revenues and pay a portion of our expenses in currencies other than the U.S. dollar, such as the Euro, the Swiss franc, the British pound and the Canadian dollar. As a result, we are at risk from exchange rate fluctuations between such foreign currencies and the U.S. dollar, which could affect our results of operations. For the three and nine months ended September 30, 2015, approximately 10% of our total product revenues came from foreign denominated currencies. If the U.S. dollar strengthens against foreign currencies, the translation of these foreign currency denominated transactions will result in decreased revenues, operating expenses and net income. We may not be able to offset adverse foreign currency impact with increased revenues. We have not to date utilized hedging strategies to mitigate foreign currency risk and even if we were to implement hedging strategies to mitigate foreign currency risk, these strategies might not eliminate our exposure to foreign exchange rate fluctuations and would involve costs and risks of their own, such as ongoing management time and expertise, external costs to implement the strategies and potential accounting implications.

## ITEM 6. EXHIBITS

Exhibit Number	Description
31.1	Rule 13a-14(a) Certification of Chief Executive Officer.
31.2	Rule 13a-14(a) Certification of Chief Financial Officer.
32.1#	Statement of Chief Executive Officer under Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. §1350).
32.2#	Statement of Chief Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. §1350).
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase.
101.DEF	XBRL Taxonomy Extension Definition Linkbase.
101.LAB	XBRL Taxonomy Extension Label Linkbase.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase.

---

#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: November 9, 2015    By: /s/ Kimberly J. Popovits  
Kimberly J. Popovits  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: November 9, 2015    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
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).
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase.
101.DEF	XBRL Taxonomy Extension Definition Linkbase.
101.LAB	XBRL Taxonomy Extension Label Linkbase.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase.

---

#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.