GENOMIC HEALTH INC
Form 10-Q
November 04, 2016
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2016

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)

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

301 Penobscot Drive

Redwood City, California 94063

(Address of principal executive offices, including Zip Code)

(650) 556-9300

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES 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 33,479,260 as of October 31, 2016.

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PART 1: FINANCIAL INFORMATION

Item 1. Financial Statements

GENOMIC HEALTH, INC.

Condensed Consolidated Balance Sheets

(In thousands)

(Unaudited)

	September 30, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 33,999	$ 32,533
Short-term marketable securities	64,602	62,410
Accounts receivable (net of allowance for doubtful accounts; 2016—$4,260, 2015—$3,988)	33,682	37,164
Prepaid expenses and other current assets	12,066	10,843
Total current assets	144,349	142,950
Property and equipment, net	39,465	39,746
Other assets	8,137	1,921
Total assets	$ 191,951	$ 184,617
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,411	$ 8,585
Accrued compensation and employee benefits	24,675	22,239
Accrued license fees	—	2,287
Accrued expenses and other current liabilities	13,599	8,922
Deferred revenues	28	431
Other current liabilities	231	208
Total current liabilities	43,944	42,672
Other liabilities	3,606	2,410
Commitments and contingencies		

Stockholders' equity:		
Common stock	3	3
Additional paid-in capital	415,144	395,059
Accumulated other comprehensive income	2,804	2,752
Accumulated deficit	(243,440)	(228,169)
Treasury stock, at cost	(30,110)	(30,110)
Total stockholders' equity	144,401	139,535
Total liabilities and stockholders' equity	$ 191,951	$ 184,617

See accompanying notes.

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GENOMIC HEALTH, INC.

Condensed Consolidated Statements of Operations

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenues:				
Product revenues	$ 82,136	$ 73,554	$ 244,916	$ 212,325
Contract revenues	122	—	210	—
Total revenues	82,258	73,554	245,126	212,325
Operating expenses:				
Cost of product revenues	13,062	13,718	44,083	39,513
Research and development	15,109	13,480	46,397	47,193
Selling and marketing	38,838	35,369	116,327	107,964
General and administrative	18,268	16,425	55,243	48,594
Total operating expenses	85,277	78,992	262,050	243,264
Loss from operations	(3,019)	(5,438)	(16,924)	(30,939)
Interest income	117	54	282	163
Gain on sale of equity securities	—	—	2,009	—
Other income (expense), net	(111)	(158)	(174)	(207)
Loss before income taxes	(3,013)	(5,542)	(14,807)	(30,983)
Income tax expense (benefit)	(193)	6,301	464	(410)
Net loss	$ (2,820)	$ (11,843)	$ (15,271)	$ (30,573)
Basic and diluted net loss per share	$ (0.08)	$ (0.36)	$ (0.46)	$ (0.95)
Shares used in computing basic and diluted net loss per share	33,391	32,498	33,141	32,294

See accompanying notes.

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GENOMIC HEALTH, INC.

Condensed Consolidated Statements of Comprehensive Income (Loss)

(In thousands)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Net loss	$ (2,820)	$ (11,843)	$ (15,271)	$ (30,573)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale marketable securities, net of tax expense (benefit) of $(349) for each of the three and nine months ended September 30, 2016 and $6,206 and $(765) for the three and nine months ended September 30, 2015, respectively	2,037	(10,696)	839	1,347
Reclassification adjustment for net gain on sale of equity securities included in net loss	—	—	(787)	—
Comprehensive loss	$ (783)	$ (22,539)	$ (15,219)	$ (29,226)

See accompanying notes.

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GENOMIC HEALTH, INC.

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2016	2015
Operating activities		
Net loss	$ (15,271)	$ (30,573)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	6,654	5,076
Employee stock-based compensation	14,102	12,055
Write-off of previously capitalized software costs	2,600	635
Impairment of assets held for sale	56	—
Gain on disposal of property and equipment	(158)	(61)
Outside director restricted stock awarded in lieu of fees	150	150
Gain on sale of equity securities	(2,009)	—
Deferred tax benefit from unrealized gain on available-for-sale marketable securities	(349)	(765)
Changes in assets and liabilities:		
Accounts receivable	3,482	1,162
Prepaid expenses and other assets	(1,456)	(383)
Accounts payable	(1,970)	(1,816)
Accrued compensation and employee benefits	2,436	3,096
Accrued expenses and other liabilities	2,777	1,863
Deferred revenues	(403)	(84)
Net cash provided by (used in) operating activities	10,641	(9,645)
Investing activities		
Purchases of property and equipment	(8,788)	(16,056)
Proceeds from sale of property and equipment	8	42
Purchases of marketable securities	(56,504)	(54,605)
Maturities of marketable securities	51,257	74,505
Proceeds from sales of marketable securities	5,117	—
Other investments	(6,100)	—
Net cash (used in) provided by investing activities	(15,010)	3,886
Financing activities		
Net proceeds from issuance of common stock under stock plans	9,105	7,766
Withholding taxes related to restricted stock units net share settlement	(3,270)	(3,723)
Net cash provided by financing activities	5,835	4,043
Net increase (decrease) in cash and cash equivalents	1,466	(1,716)
Cash and cash equivalents at the beginning of period	32,533	29,726

Cash and cash equivalents at the end of period	$ 33,999	$ 28,010
Non-cash investing and financing activities		
Accrued purchase of property and equipment	$ 3,802	$ 4,128
Change in fair value of equity investment	$ 942	$ 2,083

See accompanying notes.

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GENOMIC HEALTH, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2016

(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 ("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. In June 2016, the Company announced the commercial launch of Oncotype SEQ Liquid Select, its first Oncotype SEQ product, for the management and monitoring of multiple cancer types.

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, 2016: 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, 2016, condensed consolidated statements of operations and comprehensive income (loss) for the three and nine months ended September 30, 2016 and 2015, and condensed consolidated statements of cash flows for the nine months ended September 30, 2016 and 2015 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, 2015 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.

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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, 2015.

Revenue Recognition

The Company derives its revenues from product sales and contract research arrangements. 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 ordering 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 outside of the United States. 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 refunds were $397,000 and $609,000 at September 30, 2016 and December 31, 2015, respectively, and are included in accrued expenses and other current liabilities.

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

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

Allowance for Doubtful Accounts

The Company accrues an allowance for doubtful accounts against its accounts receivable 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, 2016 and December 31, 2015 was $4.3 million and $4.0 million, respectively. Write-offs for doubtful accounts of $1.5 million and $5.7 million were recorded against the allowance during the three and nine months ended September 30, 2016 and write-offs of $1.7 million and $4.0 million were recorded against the allowance during the three and nine months ended September 30, 2015, respectively. Bad debt expense was $1.6 million and $6.1 million for the three and nine months ended September 30, 2016, respectively, and $2.1 million and $4.7 million for the three and nine months ended September 30, 2015, respectively.

Marketable Securities

The Company invests in marketable securities, primarily money market funds, obligations of U.S. Government agencies and government sponsored entities, corporate bonds, commercial paper and equity securities. The Company considers all investments with a maturity date of less than one year as of the balance sheet date to be short term investments. Those investments with a maturity date greater than one year as of the balance sheet date are considered to be long term investments.

During the nine months ended September 30, 2016, the Company sold a portion of its shares of the common stock of Invitae Corporation for net proceeds of $5.1 million based on a cost of $6.28 per share, resulting in a realized gain of $2.0 million. There were no shares sold during the three months ended September 30, 2016. The fair value of the remaining investment was $15.0 million at September 30, 2016. This investment, which is accounted for under the cost method, was valued at $10.7 million at September 30, 2016. 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. During the nine months ended September 30, 2016, $787,000 of unrealized gain, net of tax of $448,000, related to the shares sold was reclassified out of accumulated other comprehensive income into earnings. There was no unrealized gain reclassified out of accumulated other comprehensive income into earnings during the three months ended September 30, 2016. These securities are subject to the resale limitations of Rule 144 under the Securities Act of 1933.

As of September 30, 2016 and December 31, 2015, respectively, all investments in marketable securities were classified as available for sale. These securities are carried at estimated fair value with unrealized gains and losses included in stockholders’ equity.

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Realized gains and losses and declines in value, if any, judged to be other than temporary on available for sale securities are reported in other income or expense. When securities are sold, any associated unrealized gain or loss initially recorded as a separate component of stockholders' equity is reclassified out of accumulated other comprehensive income on a specific identification basis and recorded in earnings for the period. The cost of securities sold is determined using specific identification.

Investments in Privately Held Companies

The Company determines whether its investments in privately held companies are debt or equity based on their characteristics, in accordance with the applicable accounting guidance for such investments. The Company also evaluates the investee to determine if the entity is a variable interest entity ("VIE") and, if so, whether the Company is the primary beneficiary of the VIE, in order to determine whether consolidation of the VIE is required in accordance with accounting guidance for consolidations. If consolidation is not required and the Company owns less than 50.1% of the voting interest of the entity, the investment is evaluated to determine if the equity method of accounting should be applied. The equity method applies to investments in common stock or in-substance common stock where the Company exercises significant influence over the investee, typically represented by ownership of 20% or more of the voting interests of an entity. If the equity method does not apply, investments in privately held companies determined to be equity securities are accounted for using the cost method. Investments in privately held companies determined to be debt securities are accounted for as available-for-sale or held-to-maturity securities, in accordance with the applicable accounting guidance for such investments.

In July 2016, the Company invested $6.1 million in subordinated convertible promissory notes of a private company. The subordinated convertible promissory notes represent a variable interest in the investee. The Company has concluded it is not the primary beneficiary and thus has not consolidated the investee pursuant to the requirements of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 810. However, the Company will continue to assess its investment and future commitments to the investee and to the extent its relationship with the investee changes, may be required to consolidate the investee in future periods. The Company determined that the investment was an available-for-sale debt security. As of September 30, 2016, the Company estimated the fair value of the subordinated convertible promissory notes to be approximately $5.8 million, which is recorded in other assets.

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Recently Issued Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update (“ASU”) No. 2014-09, “Revenue from Contracts with Customers,” to provide guidance on revenue recognition. This ASU 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. In March and April 2016, the FASB issued final amendments to clarify the implementation guidance for principal versus agent considerations, identifying performance obligations and the accounting for licenses of intellectual property. The Company is continuing to evaluate its method of adoption and the impact this ASU will have on its consolidated financial statements and related disclosures.

In January 2016, the FASB issued ASU No. 2016-01,"Recognition and Measurement of Financial Assets and Financial Liabilities." This ASU changes accounting for equity investments, financial liabilities under the fair value option and the presentation and disclosure requirements for financial instruments. In addition, it clarified guidance related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. The guidance will become effective for the Company beginning in the first quarter of 2018. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of this ASU will have on its consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-2, “Leases.” This ASU is aimed at making leasing activities more transparent and comparable, and requires substantially all leases be recognized by lessees on their balance sheet as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. This ASU is effective for the Company’s interim and annual reporting periods during the year ending December 31, 2019, and all annual and interim reporting periods thereafter. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of this ASU will have on its consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016-09, “Improvements to Employee Share-Based Payment Accounting,” which simplifies several aspects of the accounting for share-based payments, including immediate recognition of all excess tax benefits and deficiencies in the income statement, changing the threshold to qualify for equity classification up to the employees' maximum statutory tax rates, allowing an entity-wide accounting policy election to either estimate the number of awards that are expected to vest or account for forfeitures as they occur, and clarifying the classification on the statement of cash flows for the excess tax benefit and employee taxes paid when an employer withholds shares for tax-withholding purposes. The standard is effective for interim and annual reporting periods

beginning after December 15, 2016, although early adoption is permitted. The Company is currently assessing how the adoption of this standard will impact its consolidated financial statements and related disclosures.

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 602,000 and 616,000 shares of the Company's common stock were outstanding during the three and nine months ended September 30, 2016, respectively, and 189,000 and 135,000 RSUs were outstanding during the three and nine months ended September 30, 2016, respectively, but were not included in the computation of diluted net

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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.

Note 3. Fair Value Measurements

Fair Value Hierarchy

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 and Recorded at Fair Value on a Recurring Basis

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, 2016 or December 31, 2015. The following tables set forth the Company's financial instruments that were measured at fair value on a recurring basis at September 30, 2016 and December 31, 2015 by level within the fair value hierarchy:

	Actively Quoted Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	Balance at September 30, 2016
	(In thousands)			
As of September 30, 2016:				
Assets				
Money market deposits	$ 10,809	$ —	$ —	$ 10,809
Commercial paper	—	34,717	—	34,717
Corporate debt securities	—	14,883	—	14,883
Corporate equity securities	—	15,002	—	15,002
Total	$ 10,809	$ 64,602	$ —	$ 75,411

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	Actively Quoted Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	Balance at December 31, 2015
	(In thousands)			
As of December 31, 2015:				
Assets				
Money market deposits	$ 13,928	$ —	$ —	$ 13,928
Commercial paper	—	29,224	—	29,224
Corporate debt securities	—	22,359	—	22,359
Corporate equity securities	—	18,126	—	18,126
Total	$ 13,928	$ 69,709	$ —	$ 83,637

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.

In July 2016, the Company invested $6.1 million in subordinated convertible promissory notes of a private company. As of September 30, 2016, the Company estimated the fair value of the subordinated convertible promissory notes to be approximately $5.8 million, which is not included in the table above and recorded in other assets. The subordinated convertible promissory notes are classified as Level 3 as they are valued using unobservable inputs that are primarily based on the Company's estimate of the fair value of the underlying preferred stock into which the notes are convertible.

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, 2016			
	Cost or Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Total Estimated Fair Value
	(In thousands)			

Commercial paper	$ 34,615	$ 102	$ —	$ 34,717
Corporate debt securities	14,885	3	(5)	14,883
Corporate equity securities	10,749	4,253	—	15,002
Total	$ 60,249	$ 4,358	$ (5)	$ 64,602

	December 31, 2015			
	Cost or Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Total Estimated Fair Value
	(In thousands)			
Commercial paper	$ 23,684	$ 41	$ —	$ 23,725
Corporate debt securities	20,569	—	(10)	20,559
Corporate equity securities	13,857	4,269	—	18,126
Total	$ 58,110	$ 4,310	$ (10)	$ 62,410

The Company realized gains of $0 and $2.0 million on available-for-sale marketable securities for the three and nine months ended September 30, 2016, respectively. The Company had no realized gains or losses on available-for-sale marketable securities for the three and nine months ended September 30, 2015, respectively.

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All of the Company's available-for-sale marketable securities had contractual maturities of one year or less as of September 30, 2016 and December 31, 2015.

Assets Measured and Recorded at Fair Value on a Nonrecurring Basis

The Company reviews the fair value of long-lived assets, which include property and equipment, intangible assets and investments in privately held companies, for impairment whenever events or changes in business circumstances indicate that the carrying amounts of the assets may not be fully recoverable. During the three and nine months ended September 30, 2016, the Company wrote off $2.6 million of previously capitalized software development costs related to a project for enhanced report delivery due to delay and scope change. The impairment charge related the write off is included in the selling and marketing expenses.

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 $3.9 million for the three and nine months ended September 30, 2016, respectively, and $1.4 million and $10.8 million for the three and nine months ended September 30, 2015, respectively, relating to services provided in connection with these agreements. In addition to these expenses, some of the agreements contain provisions for royalties from inventions resulting from the collaborations. 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. 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 have annual minimum or maximum amounts. The Company recognized costs recorded under these agreements totaling $95,000 and $5.2 million for the three and nine months ended September 30, 2016, respectively, and $2.3 million and $6.9 million for the three and nine months ended September 30, 2015, respectively, which were included in cost of product revenues. The decrease in costs for these agreements for the three and nine months ended September 30, 2016 compared to the same periods in 2015, was primarily due to the satisfaction of certain royalty payment obligations. On October 28, 2016, the Company provided notice of termination of a license agreement with Roche Molecular Systems, Inc. ("Roche"), whereby the Company non-exclusively licensed from Roche a number of U.S. patents claiming nucleic acid amplification processes known as PCR, homogeneous polymerase chain reaction, and RT PCR. The Company is entitled to terminate this license agreement for any reason upon 30 days' notice, and the effective date of the termination will be November 25, 2016. The Company was required to provide royalty payments to Roche consisting

of a specified percentage of the Company's net product revenues until the date of expiration of the last to expire of the relevant patents specified in the license agreement.

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.

In June 2016, the Company entered into a collaboration agreement with Epic Sciences, Inc. ("Epic"), under which the Company has been granted exclusive distribution rights to commercialize Epic's AR-V7 liquid biopsy test in the United States. The Company has primary responsibility, in accordance with applicable laws and regulations, for marketing and

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promoting the test, order fulfillment, billing and collections of receivables, customer support, and providing order management systems for the test. Epic is responsible for performing analysis for all tests, performing studies including analytic and clinical validation studies, and seeking Medicare coverage and a Medicare payment rate from the Centers for Medicare and Medicaid Services ("CMS") for the test. Future revenues generated from the test will be shared by the Company and Epic in accordance with the terms of the agreement. Additional terms of the agreement include the Company's obligation to pay Epic $4.0 million upon achievement of certain milestones. Also, the Company has agreed, subject to certain conditions, to invest up to an aggregate amount of $7.5 million in subordinated convertible promissory notes of Epic that will convert into preferred stock of Epic upon the satisfaction of certain conditions and, upon achievement of one of the milestones, to invest an additional $2.5 million in Epic preferred stock. The agreement has a term of 10 years, unless terminated earlier under certain circumstances. During the three and nine months ended September 30, 2016, the Company invested $6.1 million in subordinated convertible promissory notes of Epic. The subordinated convertible promissory notes have been recognized at fair value, which the Company believes is approximately $5.8 million while the difference of $305,000 has been deferred and will be recognized as additional cost of future expected purchases of Epic tests, which the Company believes will be at a discount to fair value.

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, 2016, a final payment of $504,000 is due in 2017.

Note 5. Commitments and Contingencies

Lease Obligations

The Company has entered into non-cancellable operating leases for laboratory and office facilities. Rental expense under operating lease agreements was $1.6 million and $4.1 million for the three and nine months ended September 30, 2016, respectively, and $993,000 and $2.9 million for the three and nine months ended September 30, 2015, respectively.

Future non cancelable commitments under these operating leases at September 30, 2016 were as follows:

	Annual Payments (In thousands)
Years Ending December 31,	
2016 (remainder of year)	$ 1,273
2017	5,221

2018		5,961
2019		6,749
2020		7,078
2021 and thereafter		9,940
Total minimum payments	$	36,222

Contingencies

From time to time, the Company may be subject to various legal proceedings and claims arising in the ordinary course of business. The Company assesses contingencies to determine the degree of probability and range of possible loss for potential accrual in its consolidated financial statements. An estimated loss contingency is accrued in the consolidated financial statements if it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated.

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Note 6. Stock-Based Compensation

On September 8, 2005, the Board of Directors approved the 2005 Stock Incentive Plan (the "2005 Plan"), which was later approved by the Company's stockholders. Pursuant to the 2005 Plan, stock options, restricted shares, stock units, including RSUs, and stock appreciation rights may be granted to employees, consultants, and outside directors of the Company. Options granted may be either incentive stock options or nonstatutory stock options. The Company initially reserved 5,000,000 shares of common stock for issuance under the 2005 Plan, effective upon the closing of the Company's initial public offering on October 4, 2005. On June 8, 2009, the Company's stockholders approved an amendment to the 2005 Plan to increase the shares reserved for issuance under the 2005 Plan by 3,980,000 shares. The amended and restated plan also extends the term under which awards may be granted under the 2005 Plan until January 27, 2019. On June 11, 2015, the Company's stockholders approved an amendment to the amended and restated 2005 Plan to increase the shares reserved for issuance under the 2005 Plan by 1,500,000 shares. On June 9, 2016, the Company's stockholders approved an amendment to the amended and restated 2005 Plan to increase the shares reserved for issuance under the 2005 Plan by 1,500,000 shares.

Stock Options

A summary of the stock option activity under the 2005 Plan for the nine months ended September 30, 2016 is as follows:

	Outstanding Options	
	Number of Shares (In thousands)	Weighted-Average Exercise Price
Balance at December 31, 2015	3,630	$ 23.80
Options granted	716	$ 26.98
Options exercised	(344)	$ 18.58
Options forfeited	(24)	$ 29.42
Options expired	(42)	$ 28.70
Balance at September 30, 2016	3,936	$ 24.75
Exercisable at September 30, 2016	2,783	$ 23.19
Vested and expected to vest at September 30, 2016	3,840	$ 24.66

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Performance-Based Vesting Stock Options

In April 2016, the Company granted performance-based vesting stock options ("PV stock options") to purchase 75,531 shares of common stock with an exercise price of $31.12 per share. The number of shares potentially issuable under PV stock options are 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.

A summary of the PV stock option activity under the 2005 Plan for the nine months ended September 30, 2016 is as follows:

	Outstanding PV Stock Options	
	Number of Shares (In thousands)	Weighted-Average Exercise Price
Balance at December 31, 2015	—	$ —
PV stock options granted	76	$ 31.12
PV stock options exercised	—	$ —
PV stock options forfeited	—	$ —
PV stock options expired	—	$ —
Balance at September 30, 2016	76	$ 31.12
Exercisable at September 30, 2016	—	$ —
Vested and expected to vest at September 30, 2016	72	$ 31.12

Restricted Stock Units

A summary of the RSU activity under the 2005 Plan for the nine months ended September 30, 2016 is as follows:

	Number of Shares (In thousands)	Weighted-Average Grant Date Fair Value
Balance at December 31, 2015	682	$ 30.18
RSUs granted	586	$ 27.46

RSUs vested	(301)	$	30.10
RSUs cancelled	(73)	$	29.24
Balance at September 30, 2016	894	$	28.50

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Performance-Based Vesting Restricted Stock Units

In April 2016, the Company awarded 11,720 performance-based restricted stock units ("PVRSU") with a grant-date fair value of $329,000, or $28.09 per share. The amount potentially available under the PVRSU is subject to the attainment of a pre-established, objective performance goal over a specified period. In addition, the awards have a service vesting criteria following the achievement of performance criteria through February 2018.

A summary of the PVRSU activity under the 2005 Plan for the nine months ended September 30, 2016 is as follows:

	Number of Shares (In thousands)	Weighted-Average Grant Date Fair Value
Balance at December 31, 2015	6	$ 27.21
PVRSUs granted	12	$ 28.09
PVRSUs vested	(6)	$ 27.21
PVRSUs cancelled	—	$ —
Balance at September 30, 2016	12	$ 28.09

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 nine months ended September 30, 2016, the Company issued 5,245 shares of restricted stock to outside directors, with a grant date fair value of $150,000 and a weighted-average grant date fair value of $28.56 per share.

Employee Stock Purchase Plan

A total of 1,250,000 shares of common stock have been reserved for issuance under the Employee Stock Purchase Plan ("ESPP"), of which 436,624 shares were available for issuance as of September 30, 2016. Shares are issued twice yearly at the end of each offering period. During the nine months ended September 30, 2016, 119,272 shares of common stock were issued under the ESPP. As of September 30, 2016, there was $264,000 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

Share-based compensation expense recognized and included in the condensed consolidated statements of operations and comprehensive income (loss) was allocated as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
	(In thousands)		(In thousands)	
Cost of product revenues	$ 140	$ 129	$ 451	$ 401
Research and development	1,123	996	3,646	3,149
Selling and marketing	1,359	1,132	4,234	3,406
General and administrative	2,091	1,671	5,771	5,099
Total	$ 4,713	$ 3,928	$ 14,102	$ 12,055

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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, 2016, the majority of the Company's product revenues have been derived from sales of one product, the Oncotype DX breast cancer test.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
	(In thousands)		(In thousands)	
United States	$ 70,163	$ 63,051	$ 210,302	$ 181,459
Outside of the United States	12,095	10,503	34,824	30,866
Total revenues	$ 82,258	$ 73,554	$ 245,126	$ 212,325

Note 8. Income Taxes

The Company recognized an income tax benefit of $193,000 and income tax expense of $464,000 for the three and nine months ended September 30, 2016, respectively, which was computed using the "discrete" (or "cut-off") method. The income tax benefit and income tax expense for the three and nine months ended September 30, 2016, respectively, was primarily comprised of the intraperiod tax allocation of the deferred tax impact for available-for-sale marketable securities and foreign income tax expense. 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 or expense will change accordingly in subsequent periods.

For the three and nine months ended September 30, 2015, the Company recorded income tax expense of $6.3 million and an income tax benefit of $410,000, respectively, which was computed using the discrete (or "cut-off") method. The income tax expense and income tax benefit for the three and nine months ended September 30, 2015, respectively, was primarily comprised of the intraperiod tax allocation of the deferred tax impact for available-for-sale marketable securities, miscellaneous state income tax and foreign tax expense on earnings of the Company's foreign subsidiaries.

Based on all available objective evidence, the Company believes that it is still more likely than not that its net deferred tax assets will not be fully realized. Accordingly, the Company maintains a valuation allowance against all of its net deferred tax assets as of both September 30, 2016 and December 31, 2015. 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 $3.1 million and $2.8 million of unrecognized tax benefits at September 30, 2016 and December 31, 2015, respectively. 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 2001 through 2016 in U.S. federal and state jurisdictions, and for the years 2010 through 2016 in foreign jurisdictions.

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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 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; 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; 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 dependence on collaborative relationships to develop tests and the success of those relationships; our beliefs with respect to our collaboration with Epic Sciences; 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 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 regarding our future research and development, general and administrative and sales and marketing expenses 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; 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 and that we have all rights necessary to commercialize our tests; 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 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

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third parties; our ability to obtain capital when needed; the economic environment; and our history of operating losses. These forward-looking statements speak only as of the date hereof. We expressly disclaim any obligation or undertaking to update any forward-looking statements contained herein to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based.

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

Genomic Health, the Genomic Health logo, Oncotype, Oncotype DX, Recurrence Score, DCIS Score, Oncotype SEQ, Oncotype IQ, Oncotype TRACK and Genomic Intelligence Platform 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. In June 2016, we launched Oncotype SEQ Liquid Select, our first Oncotype SEQ product, for the management and monitoring of multiple cancer types. As of October 31, 2016, the list price of our Oncotype DX breast cancer tests in the United States was $4,620, the list price of our Oncotype DX colon cancer test was $4,420 and the list price of our Oncotype DX prostate cancer test was $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, 2016, more than 29,990 and 88,560 Oncotype DX test reports were delivered for use in treatment planning, compared to more than 27,820 and 79,340 test reports delivered for the same periods in 2015. All of our tests are conducted at our clinical reference laboratory in Redwood City, California.

Our clinical reference laboratory processing capacity is currently approximately 140,000 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.

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.

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We have continued to expand our business, both in the United States and internationally. We currently plan to continue to use substantially 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 counties, 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, on what conditions, for which other competing products, and 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, Hungary, Ireland, Israel, Saudi Arabia, Spain, Switzerland and the United Kingdom.

In September 2013, we announced that the National Institute for Health and Care Excellence, or 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 certain patients. 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 have entered into contracts with a majority of the more than 100 NHS England trusts, which is necessary to receive payment from a trust and recognize revenue on our test. We are receiving payments from those 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 multi-gene breast cancer test with the highest 1A level of evidence. The AGO guidelines also reconfirmed Oncotype DX as the only multi-gene expression test validated to provide predictive information on the likelihood of 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 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 N–, ER+ invasive disease. However, this increased demand is not necessarily indicative of future growth rates, and

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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 invasive breast cancer test for ER+ patients with 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.

We have established limited reimbursement coverage for the use of our Oncotype DX test in DCIS for some private third party payors. In many instances our test is covered under existing breast cancer coverage policies with the addition of the indicated diagnosis code for DCIS. We intend to continue to devote resources to gaining expanded reimbursement for our test in this patient population. We believe it may take several years to achieve reimbursement with a majority of third party payors for the use of our test for DCIS patients. However, we cannot predict whether, or under what circumstances, payors will reimburse for this test.

We have established coverage for our Oncotype DX breast cancer test for invasive breast cancer in 28 state Medicaid programs for N− disease. In addition, the Veterans Administration and the Department of Defense hospitals have processes in place that provide coverage for our Oncotype DX test for invasive breast cancer.

Oncotype DX Colon Cancer Test

We expect to continue to pursue global adoption of and reimbursement for our Oncotype DX colon cancer test. We believe the key factors that will drive adoption of this test include results from 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.

We are working with public and private payors and health plans to secure coverage for our Oncotype DX colon cancer test based upon our published and presented results in clinical validation studies and the completed and ongoing studies designed to demonstrate the treatment decision impact of the test in clinical practice. In September 2011, the local carrier with jurisdiction for claims submitted by us for Medicare patients established coverage for our colon cancer test for patients with stage II colon cancer. Additionally, the Veterans Administration, Department of Defense hospitals and a few additional private payors provide coverage and reimbursement. We are beginning to speak with state Medicaid providers regarding coverage and reimbursement for our Oncotype DX colon cancer test. We intend to pursue reimbursement while seeking to obtain formal coverage policies with a substantial number of payors and expect that this test will continue to be reviewed on a case by case basis until policy decisions have been established. We may need to hire additional commercial, scientific, technical and other personnel to support this process. We

believe it may take several years to achieve reimbursement with a majority of third party payors for our colon cancer test. However, we cannot predict whether, or under what circumstances, payors will reimburse for this test.

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Oncotype DX Prostate Cancer Test

We expect to continue to focus substantial resources on pursuing global adoption of and reimbursement for our Oncotype DX prostate cancer test. We believe the key factors that will drive adoption of this test include published data from our extensive clinical study program, including two validation studies from independent collaborations with the University of California, San Francisco and the Center for Prostate Disease Research, or CPDR. In both validation studies Oncotype DX GPS was confirmed as a strong independent predictor of adverse pathology. In the CPDR study the test was validated as an independent predictor of biochemical recurrence in men diagnosed with clinically low-risk prostate cancer. Additionally, we believe the ongoing studies we sponsor, conduct or collaborate on, as well as clinical presentations at major symposia and our ongoing commercial efforts, will support the use of and reimbursement for our test when determining initial treatment decisions for men diagnosed with clinically low and very-low risk prostate cancer.

In August 2015, Palmetto issued its final local coverage determination, or LCD, approving nationwide coverage of our prostate cancer test for qualified male Medicare patients with low and very low risk disease, as defined by the National Comprehensive Cancer Network guidelines, throughout the United States. The LCD includes specific requirements for certification and training of physicians who order the test and requirements for collection and reporting of specific data elements related to the use of our test and patient outcomes. Effective October 2015, Palmetto initiated reimbursement of the Oncotype DX prostate cancer test for qualified Medicare patients with very-low and low risk disease. Other than Medicare coverage, we have obtained limited reimbursement coverage from third party payors for our Oncotype DX prostate cancer test. As a new test, our prostate cancer test may be considered investigational by payors and therefore may not be covered under their reimbursement policies. Consequently, we intend to pursue case by case reimbursement and expect that this test will continue to be reviewed on this basis until policy decisions have been made by third-party payors. We plan to work with public and private payors and health plans to secure coverage for our Oncotype DX prostate cancer test based upon clinical evidence demonstrating the utility of the test. We believe it may take several years to achieve reimbursement with a majority of third party payors for our prostate cancer test. However, we cannot predict whether, or under what circumstances, payors will reimburse for this test. We plan to hire additional commercial, scientific, technical and other personnel to support this process.

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Oncotype SEQ

In June 2016, we announced the commercial launch of Oncotype SEQ Liquid Select, our first Oncotype SEQ product, for the management and monitoring of multiple cancer types. The initial phase of the targeted launch for Oncotype SEQ Liquid Select is focused on select clinics for the treatment of stage IV lung cancer patients. Oncotype SEQ tests are non-invasive liquid biopsy mutation panels that use next-generation sequencing to identify and select actionable genomic alterations to quantify the presence and burden of cancer, as well as help predict the sensitivity or resistance to specific drugs for patients with certain late-stage cancers, such as late stage lung, breast, colon, melanoma, ovarian or gastrointestinal cancer. As a targeted blood-based panel, Oncotype SEQ Liquid Select is designed to meet the needs of community oncologists by delivering actionable clinical information to more than 350,000 cancer patients who recur or present with late-stage disease each year in the United States, with potentially lower cost to both patients and payors.

Analytical validation results for Oncotype SEQ were presented at the European Society for Medical Oncology congress in Copenhagen, Denmark in October 2016, which demonstrated that Oncotype SEQ is highly sensitive, specific and reproducible. The validation study established the per-sample specificity of Oncotype SEQ to be greater than 99 percent. Sensitivity was also very high in that 95 percent of the time, the test was able to detect cell free DNA from the tumor at the low frequencies (0.19%-0.56%) commonly found in the plasma of patients with metastatic cancer. Study results also demonstrated that Oncotype SEQ was highly reproducible by detecting more than 95 percent of all observed variants in each run, underscoring the accuracy of the test results.

As new clinical evidence continues to be introduced, we intend to accordingly introduce new versions of the Oncotype SEQ test, which could include additional genes or updated interpretations of genes already included in such tests.

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 tests. These development efforts may lead to a 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 patient monitoring.

Potential new products may address a variety of specific clinical needs by leveraging one or multiple technological capabilities including our next-generation sequencing, or NGS, capabilities. Additionally, we believe potential new products can be implemented in the form of non invasive tests performed on blood or urine, similar to our Oncotype SEQ product.

We have started the research and development phases on our first Oncotype TRACK products for non-invasive tumor monitoring. The positive results from our first two feasibility studies were presented in December 2014, demonstrating our ability to detect the presence of bladder cancer in urine and breast cancer in blood. Tests such as Oncotype TRACK could leverage a variety of technologies such as digital PCR or NGS, to cover an increasing range of indications and cancer types.

Commercial Collaborations

In June 2016, we entered into a collaboration agreement with Epic Sciences, Inc., or Epic, under which we have been granted exclusive distribution rights to commercialize Epic's AR-V7 liquid biopsy test in the United States. The AR-V7 test will be performed by Epic Sciences in its centralized, CLIA-certified laboratory in San Diego, California. The blood-based test detects the V7 variant of the androgen receptor, or AR, protein in the nucleus of circulating

tumor cells, and provides information to help guide treatment selection in patients with metastatic castration-resistant prostate cancer. We believe that this collaboration is complementary to our product development efforts for Oncotype SEQ and allows us to leverage our commercial channel in a way that we believe may generate growth across our business in the United States. We may also pursue additional collaboration opportunities that are intended to complement our expanding product portfolio.

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Technology

Next Generation Technologies

When the presence of tumor-derived DNA in blood or urine is high and persists or increases over time, the cancer is likely growing and a new course of treatment may be appropriate. We plan on monitoring this tumor-derived DNA through a variety of technologies to expand our focus beyond early stage treatment decision support toward patients with later stage disease to help guide therapeutic choices, monitor progression and response to therapeutics, and monitor disease recurrence. Although the first product we launched uses cell-free circulating tumor DNA in blood, we may pursue additional research and development opportunities using other analytes such as circulating tumor cells, RNA, and proteins. Additionally, while we are aggressively expanding our use of NGS for future clinical development in tandem with our existing RT-PCR approach, we might also use a number of other technologies across our various development programs and to implement our products. We have begun to further advance our research and development pipeline with NGS to develop non invasive liquid biopsy tests that can be performed on blood or urine, such as our Oncotype SEQ liquid biopsy mutation panel. The positive results from our first two feasibility studies were presented in December 2014, demonstrating our ability to detect the presence of bladder cancer in urine and breast cancer in blood. We continue to work on developing non-invasive tests for real-time patient monitoring. While early stage cancer continues to represent a significant opportunity with near term revenue potential, we now have the opportunity to expand our business further along the patient's cancer journey.

Next Generation Sequencing

We have selected NGS to be our primary technology for future biomarker discovery and have begun using NGS for future clinical development and product implementation 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 of formalin-fixed, paraffin-embedded, or FPE, tissue, tissue nucleic acids, and created bioinformatics programs and infrastructure for data storage and analysis. We have also explored the combination and superimposition of certain whole transcriptome derived RNA information (standardized expression; univariate biomarker direction of association) on genomic information to reveal the genomic landscapes of cancers. Employing NGS methods, we have also demonstrated feasibility for fusion transcript and mutation detection in RNA from FPE tissue samples and copy number aberration and structural variation mutations in DNA from FPE tissue samples.

Advanced Information Technology

We have developed computer programs to automate our RT PCR and NGS assay processes. We have also developed and optimized laboratory information management systems to track our gene specific reagents, instruments, assay processes and the data generated. Similarly, we have automated data analysis, storage and process quality control. We use statistical methods to optimize and monitor assay performance and to analyze data from our development studies. We are investigating methods to further automate our workflow. In addition, we have begun investing in informatics infrastructure that incorporates a high performance computer cluster, both locally and cloud based, to analyze and store large NGS genomic data sets.

We are also working with a number of different technologies, such as digital PCR to expand our capabilities, and developing methods to enable genomic testing using a variety of biological materials such as blood and urine.

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

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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, 2016. 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 Reimbursement and Regulatory Environment

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 invasive breast cancer test since 2006 and for our Oncotype DX colon cancer test since 2011. In October 2015, we obtained Medicare coverage for our Oncotype DX prostate cancer test for patients with very-low and low risk prostate cancer. 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.

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.

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; this tax has been suspended for 2016 and 2017, but is scheduled for re-imposition in 2018. 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 or as to the effect of any FDA regulation on our product revenues, cost of product revenues and operating expenses.

We received a specific CPT code for our Oncotype DX invasive 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 calculated using the methodology under the Protecting Access to Medicare Act of 2014, or PAMA, are expected to be adopted in 2017.

We have also received a specific CPT code for our Oncotype DX colon cancer test, effective January 1, 2016. For 2016, Medicare claims are paid at the rate established by the local MACs under the gapfill process. Our local MAC will continue to set the payment rate for claims submitted by us through 2016. New rates required under PAMA are expected to be adopted in 2017.

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In addition, PAMA includes a substantial new payment system for certain clinical laboratory tests that is anticipated to be effective starting in 2018. Under PAMA, laboratories that receive the majority of their Medicare revenues from payments made under the Clinical Laboratory Fee Schedule, or CLFS, or the Physician Fee Schedule will be required to report their private payor payment rates and volumes annually for their advanced diagnostic laboratory tests. The Centers for Medicare and Medicaid Services, or 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.

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 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 (MAC) 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

The preparation of our condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts in the financial statements and related disclosures. On an ongoing basis, management evaluates its significant accounting policies and estimates. We base our estimates on historical experience and on various market-specific and other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ significantly from these estimates. Estimates are assessed each period and updated to reflect current information. A summary of our critical accounting policies is presented in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2015. There have been no material changes to our critical accounting policies during the quarter ended September 30, 2016.

Results of Operations

Three and Nine Months Ended September 30, 2016 and 2015

We recognized a net loss of $2.8 million and $15.3 million for the three and nine months ended September 30, 2016 compared to a net loss of $11.8 million and $30.6 million for the three and nine months ended September 30, 2015. On a basic and diluted per share basis, net loss per share was $0.08 and $0.46 for the three and nine months ended September 30, 2016 compared to net loss per share of $0.36 and $0.95 for the three and nine months ended September 30, 2015. 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, 2016, the substantial majority 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

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results to the ordering 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,	
	2016	2015	2016	2015
	(In thousands)		(In thousands)	
Product revenues	$ 82,136	$ 73,554	$ 244,916	$ 212,325
Contract revenues	122	—	210	—
Total revenues	$ 82,258	$ 73,554	$ 245,126	$ 212,325
Period over period dollar increase in product revenues	$ 8,582		$ 32,591	
Period over period percentage increase in product revenues	12 %		15 %	

The period over period increase in product revenues resulted, in part, from increased adoption. Test volume increased by 8% and 12% for the three and nine months ended September 30, 2016 compared to the three and nine months ended September 30, 2015, respectively. Of the growth in test volume, approximately 7% and 11%, respectively, was from breast cancer tests delivered worldwide. The revenue increase exceeded the increase in test volume primarily due to a 26% and 28% increase in cash revenue for the three and nine months ended September 30, 2016 compared to the three and nine months ended September 30, 2015.

International product revenues were $12.1 million, or 15%, and $34.8 million, or 14%, of product revenues for the three and nine months ended September 30, 2016, respectively, compared to $10.5 million, or 14%, and $30.9 million, or 15%, or product revenues, for the three and nine months ended September 30, 2015, respectively.

Approximately $57.5 million, or 70%, and $173.4 million, or 71%, of product revenues for the three and nine months ended September 30, 2016 were recorded on an accrual basis and recognized at the time the test results were delivered, compared to $54.1million, or 74%, and $156.5 million, or 74%, of product revenues for the three and nine months ended September 30, 2015. 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, 2016 were $17.3 million, or 21%, and $52.3 million, or 21%, of product revenues, respectively, compared to $15.1 million, or 20%, and $43.2 million, or 20%, of product revenues for the three and nine months ended September 30, 2015, respectively. There were no other third-party payors comprising product revenues of 10% or more for those periods.

Cost of Product Revenues

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2016	2015	2016	2015
	(In thousands)		(In thousands)	
Tissue sample processing costs	$ 12,827	$ 11,246	$ 38,468	$ 32,261
Stock-based compensation	140	129	451	401
Total tissue sample processing costs	12,967	11,375	38,919	32,662
License fees	95	2,343	5,164	6,851
Total cost of product revenues	$ 13,062	$ 13,718	$ 44,083	$ 39,513
Period over period dollar increase in tissue sample processing costs	$ 1,581		$ 6,207	
Period over period percentage increase in tissue sample processing costs	14 %		19 %	

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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. Historically, 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 were recorded as license fees in cost of product revenues at the time product revenues are recognized or in accordance with other contractual obligations. For the three and nine months ended September 30, 2016, the decrease in license fees is primarily due to the satisfaction of certain royalty payment obligations for the license of PCR patents under a license agreement with Roche Molecular Systems, Inc. In previous periods, license fees were generally calculated as a percentage of product revenues, however, the percentage change in license fees does not correlate exactly to the percentage change 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. Historically, License fees have represented a significant component of our cost of product.

Tissue sample processing costs increased $1.6 million, or 14%, for the three months ended September 30, 2016 compared to the three months ended September 30, 2015. Tissue sample processing costs increased $6.2 million, or 19%, for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015. These increases were driven primarily by the increase in test volume of 8% and 12%, respectively, for the three and nine months ended September 30, 2016 compared to the same periods in 2015, as well as an increase in information technology cost allocation associated with the implementation of new systems. We expect the cost of product revenues to increase in future periods to the extent we process more tests.

Research and Development Expenses

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2016	2015	2016	2015
	(In thousands)		(In thousands)	
Personnel-related expenses	$ 7,637	$ 7,598	$ 25,518	$ 22,744
Stock-based compensation	1,123	996	3,646	3,149
Collaboration expenses	1,016	411	2,891	8,138
Reagents and laboratory supplies	622	981	1,571	2,071
Allocated information technology, facilities and other costs	3,231	1,953	7,588	6,136
Other costs	1,480	1,541	5,183	4,955
Total research and development expenses	$ 15,109	$ 13,480	$ 46,397	$ 47,193
Period over period dollar increase (decrease)	$ 1,629		$ (796)	
Period over period percentage increase (decrease)	12 %		(2) %	

Research and development expenses represent costs incurred to develop our technology, our proprietary liquid platform and continuous process improvement, and carry out clinical studies, primarily related to our ongoing work in breast, colon and prostate cancer. Research and development expenses include personnel related expenses, reagents and supplies used in research and development laboratory work, collaboration expenses, infrastructure expenses, including allocated overhead and facility occupancy costs, contract services and other outside costs.

The $1.6 million or 12%, increase in research and development expenses for the three months ended September 30, 2016 compared to the three months ended September 30, 2015 was primarily due to a $1.3 million increase in allocated information technology, facilities and other costs and a $605,000 increase in collaboration expense partially offset by a $359,000 decrease in reagents and laboratory supplies.

The $796,000, or 2%, decrease in research and development expenses for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015 was primarily due to the $5.3 million decrease in collaboration expenses partially offset by a $2.8 million increase in personnel-related expenses. The $8.1 million of collaboration

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expenses 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. Exclusive of this one-time expense, research and development expenses for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015 increased by $4.7 million, or 11%, primarily due to a $2.8 million increase in personnel-related expenses, a $1.5 million increase in allocated information technology, facilities and other costs and a $497,000 increase in stock-based compensation expense partially offset by a $500,000 decrease in reagents and laboratory supplies. The increase in personnel-related expenses was primarily attributable to a $1.4 million increase in salaries, benefits and related expenses due to increased headcount and higher benefits costs and a $1.1 million increase in bonuses.

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.

Selling and Marketing Expenses

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2016	2015	2016	2015
	(In thousands)		(In thousands)	
Personnel-related expenses	$ 19,303	$ 18,965	$ 60,280	$ 58,214
Stock-based compensation	1,359	1,132	4,234	3,406
Promotional and marketing materials	3,864	4,005	11,981	13,397
Travel, meetings and seminars	3,512	3,770	12,127	12,111
Collaboration expenses	347	964	980	2,634
Allocated information technology, facilities and other costs	6,783	5,462	20,992	14,506
Other costs	3,670	1,071	5,733	3,696
Total selling and marketing expenses	$ 38,838	$ 35,369	$ 116,327	$ 107,964
Period over period dollar increase	$ 3,469		$ 8,363	
Period over period percentage increase	10 %		8 %	

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 $3.5 million, or 10%, increase in selling and marketing expenses for the three months ended September 30, 2016 compared to the three months ended September 30, 2015 was primarily due to a $2.6 million increase in other costs from the write off of previously capitalized software development costs and a $1.3 million increase in allocated information technology, facilities and other costs primarily associated with the implementation of new systems partially offset by a $617,000 decrease in collaboration expense.

The $8.4 million or 8%, increase in selling and marketing expenses for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015 was primarily due to a $6.5 million increase in allocated information technology, facilities and other costs primarily associated with the implementation of new systems, a $2.1 million increase in personnel-related expenses, a $2.0 million increase in other costs from the write off of previously capitalized software development costs and an $828,000 increase in stock-based compensation partially offset by a $1.6 million decrease in collaboration expenses and a $1.4 million decrease in promotional and marketing materials. The $2.1 million increase in personnel-related expenses was primarily attributable to a $3.4 million increase in salaries, benefits and related expenses due primarily to increased headcount, including new hires related to our international growth, expansion of our prostate business, annual salary increases and higher benefits costs and a $332,000 increase in bonuses partially offset by a $1.7 million decrease in contract labor and consulting expenses.

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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.

General and Administrative Expenses

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2016	2015	2016	2015
	(In thousands)		(In thousands)	
Personnel-related expenses	$ 14,440	$ 11,015	$ 42,418	$ 33,257
Stock-based compensation	2,091	1,671	5,771	5,099
Occupancy and equipment expenses	7,525	6,511	21,771	16,942
Billing and collection fees	2,524	2,448	8,554	7,745
Bad debt expense	1,597	2,056	6,096	4,727
Professional fees and other expenses	2,954	2,413	7,895	7,520
Information technology, facilities and other cost allocations	(12,863)	(9,689)	(37,262)	(26,696)
Total general and administrative expenses	$ 18,268	$ 16,425	$ 55,243	$ 48,594
Period over period dollar increase	$ 1,843		$ 6,649	
Period over period percentage increase	11 %		14 %	

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 $1.8 million, or 11%, increase in general and administrative expenses for the three months ended September 30, 2016 compared to the three months ended September 30, 2015 was primarily due to a $3.4 million increase in personnel expenses, and a $1.0 million increase in occupancy and equipment expenses resulting from increased software license expenses and depreciation expense related to our new enterprise resource planning system partially offset by a $3.2 million increase in information technology, facilities and other costs allocated to other functional areas. Of the $3.4 million increase in personnel-related expenses, $2.5 million was attributable to an increase in salaries and benefits expenses due to increased headcount and $736,000 was attributable to an increase in bonuses.

The $6.6 million, or 14%, increase in general and administrative expenses for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015 was primarily due to a $9.2 million increase in personnel expenses, a $4.8 million increase in occupancy and equipment expenses driven by increased software license expenses and increased depreciation expense related to our new enterprise resource planning system, a $1.4 million increase in bad debt expense and an $809,000 increase in billing and collection fees partially offset by a $10.6 million increase in information technology, facilities and other costs allocated to other functional areas. Of the $9.2 million increase in personnel-related expenses, $6.6 million was attributable to increase in salaries and benefits expenses due to increased headcount and higher benefits costs, $1.3 million was attributable to higher contract labor and consulting expenses to support growth of our business and $1.3 million was attributable to an increase in bonuses.

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 $117,000 and $282,000 for the three and nine months ended September 30, 2016, respectively, compared to $54,000 and $163,000 for the three and nine months ended September 30, 2015, respectively. We expect our interest income will remain nominal if the current low interest rate environment continues.

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Gain on sale of equity securities

For the three and nine months ended September 30, 2016, we realized gain on sale of equity securities of $0 and $2.0 million, respectively, in connection with the sale of a portion of our common stock of Invitae Corporation, or Invitae. There were no sales of equity securities during the three months and nine months ended September 30, 2015.

Other Income (Expense), Net

Other expense, net was $111,000 and $174,000 for the three and nine months ended September 30, 2016, respectively, compared to other expense, net of $158,000 and $207,000 for the three and nine months ended September 30, 2015, respectively. Other expense, net for the three and nine months ended September 30, 2016 was primarily related to $118,000 and $201,000 of net foreign currency loses, respectively, resulting from valuation adjustments to our international accounts 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 an income tax benefit of $193,000 and income tax expense of $464,000 for the three and nine months ended September 30, 2016, respectively, which was computed using the “discrete” (or “cut-off”) method. The income tax benefit and income tax expense for the three and nine months ended September 30, 2016, respectively, was primarily comprised of the intraperiod tax allocation of the deferred tax impact for available-for-sale marketable securities and foreign income tax expense. 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.

For the three and nine months ended September 30, 2015, we recorded an income tax expense of $6.3 million and an income tax benefit of $410,000, respectively, which was computed using the discrete (or “cut-off”) method. The income tax expense and income tax benefit for the three and nine months ended September 30, 2015, respectively, was primarily comprised of the intraperiod tax allocation of the deferred tax impact for available-for-sale marketable securities, miscellaneous state income tax and foreign tax expense on earnings of our foreign subsidiaries.

Based on all available objective evidence, management believes that it is still more likely than not that our net deferred tax assets will not be fully realized. Accordingly, we maintain a valuation allowance against all of our net

deferred tax assets as of both September 30, 2016 and December 31, 2015. 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, 2016, we had an accumulated deficit of $243.4 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.

	September 30, 2016	December 31, 2015
	(in thousands)	
Cash, cash equivalents and short-term marketable securities	$ 98,601	$ 94,943
Working capital	100,405	100,278

Sources (Uses) 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, 2016, we had cash, cash equivalents and short-term marketable securities of

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$98.6 million compared to $94.9 million at December 31, 2015. The $3.7 million increase was attributable to increased cash collections from increased sales of our tests and sale of equity securities offset by investments in the growth of our business, including research and development, global expansion, and activities related to reimbursement coverage of our tests. Of the total cash, cash equivalents and marketable securities, $15.0 million relates to our investment in Invitae. As a publicly traded security, the market price of Invitae's common stock may be subject to volatility. For example, the price of Invitae's common stock over the 52-weeks ended October 31, 2016 has fluctuated between $5.66 per share and $11.85 per share. In accordance with our investment policy, available cash is invested in short-term and long-term, 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, 2016 and December 31, 2015, $33.7 million, or 18%, and $37.2 million, or 20%, respectively, of our total assets consisted of accounts receivable. The $3.5 million decrease in accounts receivable from December 31, 2015 to September 30, 2016 was primarily attributable to increased cash collections. 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 September 30, 2016 and December 31, 2015, our weighted average DSOs were 73 days and 75 days, respectively. The timing of our billing and cash collections may also cause fluctuations in our monthly DSOs and accounts receivable.

The following tables summarize accounts receivable by payor mix at September 30, 2016 and December 31, 2015:

	September 30, 2016							
	Total	% of Total	Current	31 - 60 Days	61 - 90 Days	91 - 120 Days	121 to 180 Days	Over 180 Days
	(In thousands)							
Managed care and other	$ 31,457	83 %	$ 12,055	$ 4,830	$ 3,165	$ 2,277	$ 2,892	$ 6,238
Medicare	6,485	17	4,429	249	203	282	389	933
Total	37,942	100 %	$ 16,484	$ 5,079	$ 3,368	$ 2,559	$ 3,281	$ 7,171
Allowance for doubtful accounts	(4,260)							
Net accounts receivable	$ 33,682							

	December 31, 2015							
	Total	% of Total	Current	31 - 60 Days	61 - 90 Days	91 - 120 Days	121 to 180 Days	Over 180 Days
	(In thousands)							
Managed care and other	$ 35,488	86 %	$ 8,284	$ 9,768	$ 3,412	$ 3,356	$ 4,319	$ 6,349
Medicare	5,664	14	1,936	2,626	177	81	116	728
Total	41,152	100 %	$ 10,220	$ 12,394	$ 3,589	$ 3,437	$ 4,435	$ 7,077
Allowance for doubtful accounts	(3,988)							
Net accounts receivable	$ 37,164							

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Cash Flows

The following table summarizes our cash flow activities:

	2016	2015
	(In thousands)	
For the nine months ended September 30,		
Cash provided by (used in):		
Operating activities	$ 10,641	$ (9,645)
Investing activities	(15,010)	3,886
Financing activities	5,835	4,043
Capital expenditures (included in investing activities above)	$ (8,788)	$ (16,056)

Cash Provided by (Used in) Operating Activities

Cash provided by operating activities was $10.6 million for the nine months ended September 30, 2016 and consisted primarily of net loss of $15.3 million, adjusted for non-cash items of $23.0 million, gain on sale of equity securities of $2.0 million and $4.9 million related to changes in operating assets and liabilities.

Cash used in operating activities was $9.6 million for the nine months ended September 30, 2015 and consisted primarily of net loss of $30.6 million, adjusted for non-cash items of $17.2 million and $3.8 million related to changes in operating assets and liabilities.

Cash (Used in) Provided by Investing Activities

Cash used in investing activities for the nine months ended September 30, 2016 was $15.0 million, consisting of $8.9 million in capital expenditures related to the expansion of our business, $6.1 million in other investments related to our collaboration agreement with Epic and $5.2 million in net purchase of marketable securities offset by $5.1 million in sales of marketable securities.

Cash provided by investing activities for the nine months ended September 30, 2015 was $3.9 million, consisting of $19.9 million in net maturities of marketable securities offset by $16.0 million in capital expenditures related to the expansion of our business.

Cash Provided by Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2016 was $5.8 million, consisting primarily of $9.1 million of proceeds from the issuance of our common stock upon the exercise of stock options offset by $3.3 million of cash paid for tax withholdings related to net share settlements of RSUs.

Cash provided by financing activities for the nine months ended September 30, 2015 was $4.0 million, consisting primarily of $7.7 million of proceeds from the issuance of our common stock upon the exercise of stock options offset by $3.7 million of cash paid for tax withholdings 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, 2015.

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

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efforts, our efforts to expand adoption of and reimbursement for our tests and our international expansion efforts. We expect to spend approximately $14 million over the next 12 months for planned laboratory equipment, information technology and facilities expansion. 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.

We may also use cash to acquire or invest in complementary businesses, technologies, services or products. For example, under our collaboration agreement with Epic, we have agreed, subject to certain conditions, to invest an additional $1.4 million in subordinated convertible promissory notes of Epic that will convert into Epic preferred stock upon the satisfaction of certain conditions. In addition, we have agreed to pay to Epic up to $4.0 million upon achievement of specified milestones and, upon achievement of one of the milestones, to invest an additional $2.5 million in Epic preferred stock. To date we have invested $6.1 million in Epic's subordinated convertible promissory notes.

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;
- 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 next generation sequencing, or 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;
- expenditures in connection with strategic relationships and license agreements, including our agreement with Epic;
- 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;

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- 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.

Off-Balance Sheet Arrangements

As of September 30, 2016, we had no material off-balance sheet arrangements.

Recently Issued Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2014-09, “Revenue from Contracts with Customers” to provide guidance on revenue recognition. This ASU 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. In March and April 2016, the FASB issued final amendments to clarify the implementation guidance for principal versus agent considerations, identifying performance obligations and the accounting for licenses of

intellectual property. We are continuing to evaluate our method of adoption and the impact this ASU will have on our consolidated financial statements and related disclosures.

In January 2016, the FASB issued ASU No. 2016-01,"Recognition and Measurement of Financial Assets and Financial Liabilities." This ASU changes accounting for equity investments, financial liabilities under the fair value option and the presentation and disclosure requirements for financial instruments. In addition, it clarified guidance related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. The guidance will become effective for us beginning in the first quarter of 2018. Early

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adoption is permitted. We are currently evaluating the impact that the adoption of this ASU will have on our consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-2, “Leases.” This ASU is aimed at making leasing activities more transparent and comparable, and requires substantially all leases be recognized by lessees on their balance sheet as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. This ASU is effective for our interim and annual reporting periods during the year ending December 31, 2019, and all annual and interim reporting periods thereafter. Early adoption is permitted. We are currently evaluating the impact that the adoption of this ASU will have on our consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016-09, “Improvements to Employee Share-Based Payment Accounting,” which simplifies several aspects of the accounting for share-based payments, including immediate recognition of all excess tax benefits and deficiencies in the income statement, changing the threshold to qualify for equity classification up to the employees' maximum statutory tax rates, allowing an entity-wide accounting policy election to either estimate the number of awards that are expected to vest or account for forfeitures as they occur, and clarifying the classification on the statement of cash flows for the excess tax benefit and employee taxes paid when an employer withholds shares for tax-withholding purposes. The standard is effective for interim and annual reporting periods beginning after December 15, 2016, although early adoption is permitted. We are currently assessing how the adoption of this standard will impact 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, 2016, we had cash, cash equivalents and short-term marketable securities of $98.6 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, 2016, 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 weak economic conditions in foreign markets will affect our financial results. We recognized net foreign currency losses of $118,000 and $201,000 for the three and nine months ended September 30, 2016, respectively, compared to net foreign exchange transaction losses of $197,000 and $259,000 for the three and nine months ended September 30, 2015, 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

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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 conditions.

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

(b) Changes in internal control over financial reporting. There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that occurred during the third quarter of 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1A. RISK FACTORS.

Risks Relating to our Business and Business Strategy

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 through September 30, 2016, we had an accumulated deficit of $243.4 million. We expect to continue to invest in our product pipeline, including our current Oncotype DX tests and future Oncotype SEQ and TRACK products, and in our global commercial infrastructure, our laboratory operations and next generation sequencing, or NGS, and other technology. For the three and nine months ended September 30, 2016, our research and development expenses were $15.1 million and $46.4 million, respectively, and our selling and marketing expenses were $38.8 million and $116.3 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 and prostate cancer tests, drive adoption of and reimbursement for our Oncotype DX colon and prostate cancer tests and develop and commercialize new tests, including our Oncotype SEQ liquid biopsy mutation panel. As a result, we will need to generate significant growth in revenues in order to achieve sustained profitability. Our failure to achieve increased revenue or sustained profitability in the future could cause the market price of our common stock to decline.

If third-party payors, including managed care organizations and Medicare, do not provide reimbursement, 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, and that they are medically necessary, 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.

Our Oncotype DX breast cancer test has received certain negative assessments in the past relating to technology criteria for clinical effectiveness and appropriateness for use in patients with N+ disease, and our tests may receive similar negative assessments in the future. Since each payor makes its own decision as to whether to establish a policy to reimburse our test, seeking these approvals is a time-consuming and costly process. To date, we have positive coverage determinations for our Oncotype DX breast cancer test for N , 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 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

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invasive breast cancer test for N-, ER- patients. We believe that it may take several years to achieve reimbursement with a majority of third-party payors for our tests. If we fail to establish broad adoption of and reimbursement for all of our tests and any future tests we may develop, our reputation could be harmed and our future prospects and our business could suffer.

Under the terms of the coverage determination for our Oncotype DX prostate cancer test, coverage for the test is limited to tests ordered by physicians who agree to participate in a Certification and Training Registry, or CTR, and to provide certain information about Medicare beneficiaries who receive our test. If physicians do not timely submit necessary information as part of participating in the CTR, the timeframe in which we are reimbursed and recognize revenue for those tests may be accordingly delayed and negatively affect our results of operations.

Changes in payment rates may result in delays receiving payments and a related increase in accounts receivable balances as payors update their billing systems to reflect the changes. 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 to Noridian Healthcare Solutions, although coverage and payment rate determinations for our tests remain with Palmetto at this time through the MolDx Program. Future changes in the MAC may affect our ability to obtain Medicare coverage and reimbursement for products for which we have coverage, for products for which we do not yet have coverage or for any products we may launch in the future or delay payments.

If we are unable to obtain or maintain reimbursement from both private and public payors 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.

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 breast cancer test. While we launched our test for colon cancer in January 2010, we do not expect to recognize significant revenues from this test until increased 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 and obtained Medicare reimbursement coverage in October 2015 for patients with very low- and low-risk disease. 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 our Oncotype SEQ liquid biopsy mutation panel. We may not be able to successfully commercialize tests for other cancers or diseases. If we are unable to increase sales of our Oncotype DX breast cancer test, establish adoption of and reimbursement for our colon or prostate cancer or DCIS tests, or successfully develop and commercialize new products such as our Oncotype SEQ liquid biopsy mutation panel or enhancements to currently commercialized tests, our revenues and our ability to achieve sustained profitability would be impaired.

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.

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The 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, 2018, 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. We believe our Oncotype DX tests each could be considered an advanced diagnostic laboratory test. We may or may not, however, seek designation as an advanced diagnostic laboratory test for any of our established tests. There can be no assurance that under PAMA adequate Medicare payment rates will continue to be assigned to our tests.

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. Even if public or private reimbursement is obtained, it may cover competing tests, the reimbursement may be conditioned upon local performance of the tests or other requirements we may have difficulty satisfying. 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. We may also be negatively affected by the financial instability of, and austerity measures implemented by, several countries in the European Union and elsewhere.

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 21% of our product revenue for the three and nine months ended September 30, 2016 and 20% of our product revenue for the three and nine months ended September 30, 2015, respectively. Accounts receivable on behalf of patients directly covered by Medicare represented 17% and 14% of our total accounts receivable at September 30, 2016 and December 31, 2015, 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 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.

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 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.

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Although we believe patients coming under these rules represent less than 1% of our total claims for our breast cancer test, 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.

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 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.

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 and collaborations 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, collaborations and joint ventures. To the extent we enter into strategic alliances, collaborations or joint ventures, we may not have final decision making authority on the technical aspects of the products subject to such an arrangement, and we may be dependent on the ability of our collaborators to perform their obligations under our

agreements with them or otherwise support any products under such arrangements. Any failure of our collaborators to so perform their obligations could negatively impact the development of our product candidates, lead to our loss of potential product revenues and otherwise diminish our expected benefits from the arrangement. 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

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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.

International expansion of our business exposes us to business, regulatory, political, operational, financial, compliance 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:

- difficulties in complying with multiple, conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, privacy laws, regulatory requirements and other governmental approvals, permits and licenses;
- significant competition from local and regional product offerings;
- difficulties in complying with unclear product regulations in various jurisdictions;
- 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.

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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, 2016, approximately 10% of our product revenues came from foreign denominated currencies. If the U.S. dollar strengthens against foreign currencies, as it had during 2015, the translation of these foreign currency denominated transactions will result in decreased revenues and operating expenses and increased net losses. 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.

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, 2016. The fair value of this security was 23% of total short-term marketable securities as of September 30, 2016 and as a publicly-traded security, it may be subject to volatility in its market value. For example, the price of Invitae’s common stock over the 52-weeks ended October 31, 2016 has fluctuated between $5.66 per share and $11.85 per share. Should 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.

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, expand and fund the commercialization of our products, increase our selling and marketing efforts, further expand our clinical laboratory operations, technologies and research and development activities, invest in complementary businesses or assets or finance capital expenditures and general and administrative expenses.

Our present and future funding requirements will depend on many factors, including establishing and maintaining reimbursement arrangements with third-party payors, costs associated with expanding our commercial and laboratory operations, spending on research and development activities, costs associated with acquiring, licensing or investing in new technologies or complementary businesses, costs associated with protecting our intellectual property rights, costs associated with international expansion, and the costs and potential delays involved with regulatory clearances and approvals.

We cannot assure you that we would be able to obtain additional funds on acceptable terms, or at all. If we raise funds by issuing equity securities, dilution to our stockholders could result. Any equity or debt securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock and could impose

significant restrictions on our operations. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or products, or grant licenses on terms that are not favorable to us. If 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. Any or all of these factors could harm our business, operating results and financial condition.

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We may be unable to manage our future growth and operational expansion 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. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy.

We have recently implemented a new enterprise resource planning system to streamline a broad range of business processes and functional areas including order fulfillment, sample processing, customer service, supply chain management, and others. The implementation and transition of these new systems has, in some cases, resulted in delays in access to, or could result in errors in, critical business and financial information. The time and resources required to complete the implementation of these new systems is uncertain, and failure to complete this implementation in a timely and efficient manner could adversely affect our operations. Unexpected errors or delays could also harm our ability to operate certain aspects of our business or to file our periodic reports in a timely manner.

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.

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, 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

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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. For example, in October 2015, the European Court of Justice invalidated the U.S./E.U. Safe Harbor Framework regarding the overseas transfer of E.U. residents' personal data, under which we held certification. Companies, such as us, who relied upon the invalid Safe Harbor Framework were exposed to additional scrutiny from the E.U. data protection authorities without the protection of the Safe Harbor Framework. The newly agreed-upon U.S-E.U. Privacy Shield, or the Privacy Shield, has been open to registrants as of August 1, 2016. On September 28, 2016, we submitted an application to the Department of Commerce for self-certification of compliance with the Privac Shield, which we believe will mitigate customer concerns about overseas data transfers. However there continue to be concerns about whether the Privacy Shield will face additional challenges (similar to those that invalidated the Safe Harbor Framework), and it is not guaranteed that companies who have self-certified under the Privacy Shield will be free of additional ongoing scrutiny by E.U. data protection authorities. It is possible that each of these privacy 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.

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 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 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 incur increased costs as a result of operating as a public company, and must continually implement additional and expensive business systems, procedures and controls to satisfy public company reporting requirements.

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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, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC, NASDAQ or other regulatory authorities which could require additional financial and management resources.

Risks Related to Governmental Regulation

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 through December 31, 2015, each medical device manufacturer was required to 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. The medical device tax has been suspended for 2016 and 2017, but is scheduled to return beginning in 2018. 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 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 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, or DHCS, the cut applies to various healthcare providers and outpatient services including laboratory services with certain exceptions. Moreover, state legislation required DHCS 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, effective July 1, 2012

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through June 30, 2015, to payments for clinical laboratory and laboratory services. DHCS has developed and CMS has approved 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. Effective July 1, 2015, this new methodology was implemented by DHCS.

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 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 this Congress, 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

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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 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.

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, facilities administration, quality systems, inspections, and proficiency testing. 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. Inspectors may also make random inspections of our clinical reference laboratory.

Although we are required to hold a certificate of accreditation or compliance under CLIA 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

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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 our clinical tests 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 the termination of our CAP accreditation, such as whether any deficiencies were identified by CAP as the basis for termination and, if so, whether these deficiencies were addressed to the satisfaction of the surveyors for the CLIA program (or another accrediting organization).

We are also required to maintain a California clinical laboratory 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 test 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, such as Pennsylvania, Maryland and Rhode Island, require that we hold licenses to test specimens from patients in those states or states such as Florida, receive specimens from clinical laboratories 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 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.

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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 or by changes in the valuation of our deferred tax assets and liabilities. Furthermore, we provide for certain tax liabilities that 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.

Risks Relating to Product Development, Commercialization and Sales of our Products

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 Oncotype DX tests 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. We also cannot be certain that the Oncotype SEQ liquid biopsy mutation panel we plan to launch will attain widespread use among its intended target of community oncologists. 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.

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. 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. In addition, competitors may develop and commercialize competing products faster than we are able to do so.

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If we are unable to support demand for our tests, including successfully managing the evolution of our technology and business systems, 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 Oncotype SEQ liquid biopsy mutation panel, 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 or patients 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 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.

We will need to continue to educate physicians, patients and payors about the benefits and cost effectiveness of our 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 our tests. If we fail to successfully establish adoption of and additional reimbursement beyond Medicare for our colon and prostate cancer tests, our reputation could be harmed and our business could suffer.

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 for the breast and colon cancer tests and likelihood of adverse

pathology for the prostate cancer test 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.

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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.

As of September 30, 2016, 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, reimbursement rates, 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.

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. 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.

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. 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 correlate sets of genes to a new treatment's effectiveness. Additionally, as new products are developed, evolving industry standards and metrics may slow the widespread adoption of any new products we may introduce. If we are unable to demonstrate the applicability of our tests to new treatments or to keep pace with new industry standards, sales of our test could decline, which would harm our revenues.

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

We compete in a rapidly evolving and highly competitive industry, and there are a number of private and public companies that offer products or have conducted research to profile genes and gene expression in breast, colon and prostate cancer, including companies such as Agendia Inc., BioTheranostics, Clarient International Ltd. (a NeoGenomics Technologies company), GenomeDx Biosciences Inc., Hologic Inc., Myriad Genetics Inc., NanoString

Technologies Inc., Novartis AG and Qiagen N.V. As we expand our research, development and commercialization efforts into the liquid biopsy and pan-cancer clinical diagnostics market, we face competition from companies such as Foundation Medicine, Grail, MDxHealth, Natera Inc. and Trovagene Inc. A number of other companies have announced their intention to enter the liquid biopsy market, and we currently believe that the barrier for entry into this business is low compared to profiling genes and gene expression in cancers, primarily due to wider adoption of NGS technologies.

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Historically, our principal competition for our Oncotype DX tests has also come from existing diagnostic methods used by pathologists, oncologists, and urologists, and traditional diagnostic methods can be difficult to change or supplement. 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. 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 continue to commercialize our Oncotype DX prostate cancer test.

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 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 tests cleared through CLIA such as our Oncotype DX tests, and that may discourage adoption of and reimbursement for our tests. Further, companies may bring to market liquid biopsy tests that cover significantly more genes than the liquid biopsy tests we may bring to market, and there could exist a perception or marketing differentiation that a higher number of genes tested via liquid biopsy is more desirable, which could discourage adoption of and reimbursement for those 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 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 archived 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. 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.

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

We rely on and expect to continue to rely on clinical collaborators to perform a substantial portion of our clinical trial functions. If any of our collaborators were to breach or terminate its agreement with us or otherwise fail to conduct 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. 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.

The loss of key members of our senior management team or our inability to attract and retain highly skilled scientists, software engineers, 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, commercial laboratory operations and information technology infrastructure depend on our ability to attract and retain highly skilled scientists, technicians and engineers, including licensed laboratory technicians, chemists, biostatisticians and software engineers. We may not be able to attract or retain qualified scientists, technicians and software engineers in the future due to the competition for qualified personnel among life science and technology businesses, particularly in the San Francisco Bay Area. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. In addition, our success depends on our ability to attract and retain salespeople with extensive experience in oncology and urology and close relationships with medical oncologists, urologists, surgeons, pathologists and other hospital personnel. All of our employees in the United States are at will, which means that either we or the employee may terminate their employment at any time. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, our business and operating results could be harmed.

We rely on a limited number of suppliers or, in many 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 many 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 would be time consuming and expensive, and there can be no assurance that we would 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.

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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.

Risks Related to Our Intellectual Property

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.

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 of patents within the genomic diagnostic space, 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 America 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

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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.

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 or affect our ability to commercialize our tests. 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. 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.

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. 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.

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.

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SIGNATURES

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

GENOMIC HEALTH, INC.

Date: November 4, 2016 By: /s/ Kimberly J. Popovits
Kimberly J. Popovits
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 4, 2016 By: /s/ G. Bradley Cole
G. Bradley Cole
Chief Operating Officer and Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

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GENOMIC HEALTH, INC.

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