GENOMIC HEALTH INC
Form 10-Q
August 04, 2017
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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 June 30, 2017

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, smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth 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
	Emerging growth company

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

The number of outstanding shares of the registrant's Common Stock, $0.0001 par value, was 34,645,568 as of July 31, 2017.

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PART 1: FINANCIAL INFORMATION

Item 1. Financial Statements

GENOMIC HEALTH, INC.

Condensed Consolidated Balance Sheets

(In thousands)

(Unaudited)

	June 30, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 42,200	$ 40,404
Short-term marketable securities	67,599	56,585
Accounts receivable (net of allowance for doubtful accounts; 2017—$3,106, 2016—$4,508)	32,427	35,179
Prepaid expenses and other current assets	12,278	13,796
Total current assets	154,504	145,964
Property and equipment, net	48,908	45,688
Other assets	9,518	9,462
Total assets	$ 212,930	$ 201,114
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,322	$ 2,864
Accrued compensation and employee benefits	21,355	27,900
Accrued expenses and other current liabilities	12,185	10,180
Other current liabilities	222	231
Total current liabilities	39,084	41,175
Other liabilities	3,899	3,834
Commitments and contingencies		
Stockholders' equity:		
Common stock	3	3
Additional paid-in capital	445,713	427,102

Accumulated other comprehensive (loss) income	(26)	1,198
Accumulated deficit	(245,633)	(242,088)
Treasury stock, at cost	(30,110)	(30,110)
Total stockholders' equity	169,947	156,105
Total liabilities and stockholders' equity	$ 212,930	$ 201,114

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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Revenues:				
Product revenues	$ 85,487	$ 81,886	$ 169,467	$ 162,780
Contract revenues	—	88	—	88
Total revenues	85,487	81,974	169,467	162,868
Operating expenses:				
Cost of product revenues	13,798	15,598	27,471	31,752
Research and development	15,781	14,948	30,655	30,557
Selling and marketing	40,656	37,989	82,163	77,489
General and administrative	18,395	18,537	35,146	36,975
Total operating expenses	88,630	87,072	175,435	176,773
Loss from operations	(3,143)	(5,098)	(5,968)	(13,905)
Interest income	206	87	364	165
Gain on sale of equity securities	—	676	2,807	2,009
Other income (expense), net	357	(150)	452	(63)
Loss before income taxes	(2,580)	(4,485)	(2,345)	(11,794)
Income tax expense	159	1,615	1,200	657
Net loss	$ (2,739)	$ (6,100)	$ (3,545)	$ (12,451)
Basic and diluted net loss per share	$ (0.08)	$ (0.18)	$ (0.10)	$ (0.38)
Shares used in computing basic and diluted net loss per share	34,428	33,130	34,219	33,015

See accompanying notes.

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GENOMIC HEALTH, INC.

Condensed Consolidated Statements of Comprehensive Income (Loss)

(In thousands)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Net loss	$ (2,739)	$ (6,100)	$ (3,545)	$ (12,451)
Other comprehensive Loss:				
Unrealized loss, net, on available-for-sale marketable securities, net of tax expense of $0 for both the three and six months ended June 30, 2017 and $1,257 and $0 for the three and six months ended June 30, 2016, respectively	(4)	(3,589)	(97)	(1,198)
Reclassification adjustment for net gain on sale of equity securities included in net loss	—	(345)	(1,127)	(787)
Comprehensive loss	$ (2,743)	$ (10,034)	$ (4,769)	$ (14,436)

See accompanying notes.

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GENOMIC HEALTH, INC.

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Six Months Ended June 30,	
	2017	2016
Operating activities		
Net loss	$ (3,545)	$ (12,451)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	5,434	4,365
Employee stock-based compensation	10,302	9,389
Impairment of assets held for sale and long-lived assets	—	56
Gain on disposal of property and equipment	35	—
Outside director restricted stock awarded in lieu of fees	100	100
Gain on sale of equity securities	(2,807)	(2,009)
Deferred tax benefit from unrealized gain on available-for-sale marketable securities, net	820	348
Changes in assets and liabilities:		
Accounts receivable	2,752	3,553
Prepaid expenses and other assets	1,384	(1,186)
Accounts payable	2,161	(2,368)
Accrued compensation and employee benefits	(6,545)	(1,725)
Accrued expenses and other liabilities	1,795	3,970
Deferred revenues	—	(197)
Net cash provided by operating activities	11,886	1,845
Investing activities		
Purchases of property and equipment	(8,057)	(6,879)
Proceeds from sale of property and equipment	10	—
Purchases of marketable securities	(50,338)	(35,932)
Maturities of marketable securities	29,932	40,007
Proceeds from sales of marketable securities	10,155	5,117
Net cash (used in) provided by investing activities	(18,298)	2,313
Financing activities		
Net proceeds from issuance of common stock under stock plans	12,522	7,072
Withholding taxes related to restricted stock units net share settlement	(4,314)	(3,103)
Net cash provided by financing activities	8,208	3,969
Net increase in cash and cash equivalents	1,796	8,127
Cash and cash equivalents at the beginning of period	40,404	32,533
Cash and cash equivalents at the end of period	$ 42,200	$ 40,660

Non-cash investing and financing activities		
Accrued purchases of property and equipment	$ 2,005	$ 605
Change in fair value of equity investment	$ —	$ (1,404)

See accompanying notes.

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GENOMIC HEALTH, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2017

(Unaudited)

Note 1. Organization and Summary of Significant Accounting Policies

The Company

Genomic Health, Inc. (the "Company") is a global healthcare company that provides actionable genomic information to personalize cancer treatment decisions. 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 was incorporated in Delaware in August 2000. The Company's first product, the Oncotype DX 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. The tests for invasive breast and colon cancers result in a quantitative score referred to as a Recurrence Score. 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, which provides a Genomic Prostate Score, or GPS, to predict disease aggressiveness in men with low risk prostate cancer 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 introduced Oncotype SEQ Liquid Select, the first of several planned non-invasive liquid biopsy tests that the Company plans to deliver, along with its Oncotype DX tests, as part of its Oncotype IQ Genomic Intelligence Platform.

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 June 30, 2017: 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 nine 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 June 30, 2017, condensed consolidated statements of operations and comprehensive income (loss) for the three and six months ended June 30, 2017 and 2016, and condensed consolidated statements of cash flows for the six months ended June 30, 2017 and 2016 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, 2016 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, 2016.

There have been no material changes in the Company's significant accounting policies, other than the adoption of Accounting Standards Update ("ASU") 2016-09 described below, as compared to the significant accounting policies described in the Company's Annual Report on Form 10-K for the year ended December 31, 2016.

Certain reclassifications have been made to prior period amounts to conform to the current period presentation. For the three and six months ended June 30, 2016, a reclassification of certain expenses from research and development to cost of product revenue was made in the condensed consolidated statements of operations to conform to the current period presentation.

Revenue Recognition

The Company derives its revenues from product sales and, to a lesser extent from contracts with biopharmaceutical and pharmaceutical companies. The majority of the Company's historical product revenues have been derived from the sale of the Oncotype DX breast cancer test. The Company generally bills third-party payors upon generation and delivery of a patient report to the physician. As such, the Company takes assignment of benefits and the risk of collection with the third-party payor. The Company generally bills the patient directly for amounts owed after multiple requests for payment have been denied or only partially paid by the insurance carrier. The Company pursues case-by-case reimbursement where medical policies are not in place or payment history has not been established.

The Company's product revenues for tests performed are recognized when the following revenue recognition criteria are met: (1) persuasive evidence that an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. Criterion (1) is satisfied when the Company has an arrangement to pay or a contract with the payor in place addressing reimbursement for the Oncotype 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 revenue 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 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 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

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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 $216,000 and $487,000 at June 30, 2017 and December 31, 2016, respectively, and are included in accrued expenses and other current liabilities.

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 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 June 30, 2017 and December 31, 2016 was $3.1 million and $4.5 million, respectively. Write-offs for doubtful accounts of $1.7 million and $3.0 million were recorded against the allowance during the three and six months ended June 30, 2017, respectively, and write-offs of $1.8 million and $4.2 million were recorded against the allowance during the three and six months ended June 30, 2016, respectively. Bad debt expense was $1.2 million and $1.6 million for the three and six months ended June 30, 2017, respectively, and $2.2 million and $4.5 million for the three and six months ended June 30, 2016, 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 six months ended June 30, 2017, the Company sold its remaining shares of the common stock of Invitae Corporation for net proceeds of $10.2 million based on a cost of $6.28 per share, resulting in a realized gain of $2.8 million. During the six months ended June 30, 2016, the Company sold a portion of its shares of the common stock of Invitae Corporation for net proceeds of $5.1 million at the cost of $6.28 per share, resulting in a realized gain of $2.0 million. This investment, which was accounted for under the cost method, was valued at $10.7 million at June 30, 2016. Unrealized gains or losses resulting from changes in the fair value of this investment were recorded in other comprehensive income until the securities are sold. During the six months ended June 30, 2017 and 2016, $1.1 million

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and $787,000, respectively, of unrealized gain, net of tax of $821,000 and $448,000, respectively, related to the shares sold was reclassified out of accumulated other comprehensive income into earnings.

As of June 30, 2017 and December 31, 2016, respectively, all investments in marketable securities were classified as available-for-sale securities. These securities are carried at estimated fair value with unrealized gains and losses included in stockholders' equity.

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.

During the six months ended June 30, 2017 and the year ended December 2016, the Company invested $1.4 million and $6.1 million, respectively, in the subordinated convertible promissory notes of a private company (see Note 4). On March 8, 2017, all of the Company's investment in subordinated convertible promissory notes was converted into preferred stock of the private company representing approximately 9% of the private entity's voting interests, at which time the Company estimated the fair value of the subordinated convertible promissory notes to be approximately $7.1 million. The preferred stock represents 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. The Company determined that the investment is an equity investment for which the Company does not have the ability to exercise significant influence. 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 equity

investments are accounted for using the cost method of accounting and recorded in other assets on the Company's condensed consolidated balance sheets.

Recently Issued Accounting Pronouncements

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). Topic 606 supersedes the revenue recognition requirements in Accounting Standards Codification Topic 605, Revenue Recognition, and requires entities to recognize revenue when they transfer control of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. In addition, Topic 606 requires more detailed disclosures to enable users of financial statements to understand the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. Topic 606 will be effective for the Company in the first quarter of 2018, with the option to adopt it in the first quarter of 2017. The Company intends to adopt Topic 606 effective January 1, 2018. Topic 606 permits the use of either a retrospective or modified retrospective application. The Company intends to use the modified retrospective approach. The Company also plans to elect the practical expedient of applying the new guidance only to contracts that are not completed as of the date

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of initial application. Upon adoption, the Company will recognize the cumulative effect of adopting this guidance as an adjustment to its opening accumulated deficit balance. Prior periods will not be retrospectively adjusted. The Company is in the process of completing its assessment of the impact Topic 606 will have on its consolidated financial statements and related disclosures. The Company's implementation of this standard includes a project management framework that includes a dedicated lead project manager and an implementation team responsible for assessing the impact that Topic 606 will have on the Company's accounting, financial statement presentation and disclosure for contracts with customers. The assessment phase of this project has included the analysis of the Company's current portfolio of customer contracts, including a review of historical accounting policies and practices to identify potential differences in applying Topic 606. The Company is also performing a comprehensive review of its current processes and systems to determine and implement changes required to support the adoption of Topic 606. The assessment has resulted in the identification of potential accounting changes to the timing of revenue recognition from certain payors who are not currently accrual payors to be accelerated. During the second quarter of 2017, the implementation team continued to identify changes to business processes, systems and controls to support recognition, presentation and disclosure under the new standard. An implementation plan for the second half of 2017 has been developed and includes tasks around documentation, design of new processes and controls as well as testing of the controls.

In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments-Overall (Subtopic 825-10): 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 (Topic 842). Topic 842 generally requires entities to recognize operating and financing lease liabilities and corresponding right-of-use assets on the balance sheet. Topic 842 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. Entities are required to use a modified retrospective approach for leases that exist or are entered into after the beginning of the earliest comparative period in the financial statements, and there are certain optional practical expedients that an entity may elect to apply. Full retrospective application is prohibited and early adoption by public entities is permitted. The Company is currently evaluating the impact that the adoption of Topic 842 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 adopted this ASU in the first

quarter of 2017 and elected to continue to estimate forfeitures expected to occur to determine the amount of compensation cost to be recognized in each period. As a result, in the first quarter of 2017, the Company recorded an $11.6 million cumulative-effect adjustment decrease in accumulated deficit and an offsetting increase in deferred tax assets for previously unrecognized excess tax benefits that existed as of December 31, 2016. However, as all of the Company's deferred tax assets, net of deferred tax liabilities, are subject to a valuation allowance and the realization of these assets is not more likely than not to be achieved, the Company recorded an $11.6 million valuation allowance against these deferred tax assets with an offsetting increase in accumulated deficit. The presentation requirement for cash flows related to employee taxes paid for

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withheld shares will not impact the statements of cash flows since such cash flows have historically been presented as a financing activity. The adoption was on a prospective basis and therefore had no impact on prior periods.

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.

The following potentially dilutive common shares were excluded from the computation of diluted net loss per share for the periods presented because they would have been anti-dilutive:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(In thousands)		(In thousands)	
Options and RSUs excluded from the computation	788	677	774	737

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 June 30, 2017 or December 31, 2016. The following tables set forth the Company's

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financial instruments that were measured at fair value on a recurring basis at June 30, 2017 and December 31, 2016 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 June 30, 2017
	(In thousands)			
As of June 30, 2017:				
Assets				
Money market deposits	$ 10,830	$ —	$ —	$ 10,830
Commercial paper	—	37,774	—	37,774
Corporate debt securities	—	29,825	—	29,825
Total	$ 10,830	$ 67,599	$ —	$ 78,429

	Actively Quoted Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	Balance at December 31, 2016
	(In thousands)			
As of December 31, 2016:				
Assets				
Money market deposits	$ 13,198	$ —	$ —	$ 13,198
Commercial paper	—	32,421	—	32,421
Corporate debt securities	—	14,869	—	14,869
Corporate equity securities	—	9,295	—	9,295
Total	$ 13,198	$ 56,585	$ —	$ 69,783

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.

During the year ended December 31, 2016, the Company invested $6.1 million in subordinated convertible promissory notes of a private company. As of December 31, 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 were 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. In March 2017, the subordinated convertible promissory notes were converted into preferred stock of the privately held company. The Company accounted for such preferred stock using the cost method of accounting and accordingly recorded such preferred stock in other assets on its condensed consolidated balance sheets. There was no change in the fair value of such preferred stock during the three months ended June 30, 2017.

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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:

	June 30, 2017			
	Cost or Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Total Estimated Fair Value
	(In thousands)			
Commercial paper	$ 37,782	$ 1	$ (8)	$ 37,775
Corporate debt securities	29,842	—	(18)	29,824
Total	$ 67,624	$ 1	$ (26)	$ 67,599

	December 31, 2016			
	Cost or Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Total Estimated Fair Value
	(In thousands)			
Commercial paper	$ 32,350	$ 71	$ —	$ 32,421
Corporate debt securities	14,868	3	(2)	14,869
Corporate equity securities	7,348	1,947	—	9,295
Total	$ 54,566	$ 2,021	$ (2)	$ 56,585

The Company realized gains of $0 and $2.8 million on available-for-sale marketable securities for the three and six months ended June 30, 2017, respectively, and $676,000 and $2.0 million for the three and six months ended June 30, 2016, respectively.

All of the Company's available-for-sale marketable securities had contractual maturities of one year or less as of June 30, 2017 and December 31, 2016.

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. There were no impairments recorded during both of the three and six months ended June 30, 2017 and $0 and $56,000 in three and six months ended June 30, 2016, respectively.

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 $912,000 and $1.8 million for the three and six months ended June 30, 2017, respectively, and $1.6 million and $2.5 million for the three and six months ended June 30, 2016, 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 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 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 $94,000 and $190,000 for the three and six months ended June 30, 2017, respectively, and $2.5 million and $5.1 million for the three and six months ended June 30, 2016, respectively, which were included in cost of product revenues. The decrease in costs for these agreements for the three and six months ended June 30, 2017 compared to the same periods in 2016, was primarily

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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 polymerase chain reaction ("PCR"), homogeneous polymerase chain reaction, and reverse transcription polymerase chain reaction ("RT-PCR"). The effective date of the termination was November 27, 2016. The Company believes it has satisfied all obligations to make royalty payments to Roche.

In June 2016, the Company entered into a collaboration agreement with Epic Sciences, Inc. ("Epic Sciences"), under which the Company was granted exclusive rights to commercialize in the United States a test developed by Epic Sciences, which test we refer to as Oncotype DX AR-V7 Nucleus Detect. The Company has primary responsibility, in accordance with applicable laws and regulations, for marketing and promoting the test, order fulfillment, billing and collections of receivables, customer support, and providing order management systems for Oncotype DX AR-V7 Nucleus Detect. Epic Sciences is responsible for performing test analysis, performing studies, including analytic and clinical validation studies, and seeking Medicare coverage from the Centers for Medicare and Medicaid Services ("CMS") for the test at a certain minimum rate. The collaboration agreement has a term of 10 years, unless terminated earlier under certain circumstances. As of June 30, 2017, the Company had invested $7.5 million in subordinated convertible promissory notes of Epic Sciences that converted into shares of Epic Sciences' preferred stock in March 2017. The subordinated convertible promissory notes had been recognized at fair value, which the Company believed was approximately $7.1 million while the difference of $375,000 has been deferred and will be recognized as additional cost of future expected purchases of Oncotype DX AR-V7 Nucleus Detect tests, which the Company believes will be at a discount to fair value as of June 30, 2017. Upon achievement of an additional milestone, the Company has agreed to invest an additional $2.5 million in Epic Sciences' preferred stock. Future revenues generated from sales of Oncotype DX AR-V7 Nucleus Detect will be shared by the Company and Epic Sciences in accordance with the terms of the collaboration agreement. Additional terms of the agreement include the Company's obligation to pay Epic Sciences $4.0 million in cash upon achievement of certain additional milestones.

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 June 30, 2017, 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 $3.1 million for the three and six months ended June 30, 2017, respectively, and $1.3 million and $2.5 million for the three and six months ended June 30, 2016, respectively.

Future non cancelable commitments under these operating leases at June 30, 2017 were as follows:

	Annual Payments (In thousands)
Years Ending December 31,	
2017 (remainder of year)	$ 2,621
2018	5,965
2019	6,752
2020	7,082
2021	4,825
2022 and thereafter	5,117
Total minimum payments	$ 32,362

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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.

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. On June 15, 2017, 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 six months ended June 30, 2017 is as follows:

	Number of Shares (In thousands)	Weighted-Average Exercise Price
Balance at December 31, 2016	3,606	$ 25.07
Options granted	684	$ 27.84
Options exercised	(460)	$ 21.20

Options forfeited	(19)	$ 28.30
Options expired	(4)	$ 20.08
Balance at June 30, 2017	3,807	$ 26.02
Exercisable at June 30, 2017	2,502	$ 24.96
Vested and expected to vest at June 30, 2017	3,707	$ 25.98

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Restricted Stock Units

A summary of the RSU activity under the 2005 Plan for the six months ended June 30, 2017 is as follows:

	Number of Shares (In thousands)	Weighted-Average Grant Date Fair Value
Balance at December 31, 2016	871	$ 28.42
RSUs granted	538	$ 27.97
RSUs vested	(346)	$ 28.70
RSUs cancelled	(51)	$ 28.41
Balance at June 30, 2017	1,012	$ 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 six months ended June 30, 2017, the Company issued 3,285 shares of restricted stock to outside directors, with a grant date fair value of $100,000 and a weighted-average grant date fair value of $30.40 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"). On June 15, 2017, the Company's stockholders approved an amendment to the ESPP to increase the shares reserved for issuance under the ESPP by 1,250,000 shares. 1,472,734 shares were available for issuance as of June 30, 2017. Shares are issued twice yearly at the end of each offering period. During the six months ended June 30, 2017, 106,859 shares of common stock were issued under the ESPP. As of June 30, 2017, there was $595,000 of unrecognized compensation expense related to the ESPP, which is expected to be recognized over a period of five 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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(In thousands)		(In thousands)	
Cost of product revenues	$ 170	$ 152	$ 361	$ 312
Research and development	1,443	1,269	2,831	2,522
Selling and marketing	1,478	1,437	2,989	2,875
General and administrative	2,106	1,989	4,121	3,680
Total	$ 5,197	$ 4,847	$ 10,302	$ 9,389

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. The Company's Oncotype DX breast, colon and prostate cancer tests have similar economic and other characteristics, including the nature of the products and production processes, type of customers, distribution methods and regulatory environment. As of June 30, 2017, the majority of the Company's product revenues have been derived from sales of one product, the Oncotype DX breast cancer test.

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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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(In thousands)		(In thousands)	
United States	$ 72,409	$ 69,644	$ 142,998	$ 140,139
Outside of the United States	13,078	12,330	26,469	22,729
Total revenues	$ 85,487	$ 81,974	$ 169,467	$ 162,868

Note 8. Income Taxes

The Company recognized income tax expense of $159,000 and $1.2 million for the three and six months ended June 30, 2017 respectively, and income tax expense of $1.6 million and $657,000 for the three and six months ended June 30, 2016, respectively, which was computed using the “discrete” (or “cut-off”) method. The income tax expense for the three and six months ended June 30, 2017 and June 30, 2016 was primarily comprised of the intraperiod tax allocation of the deferred tax impact for available-for-sale marketable securities and foreign income tax expense.

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 June 30, 2017 and December 31, 2016. 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 $2.2 million and $2.1 million of unrecognized tax benefits at June 30, 2017 and December 31, 2016, 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 2017 in U.S. federal and state jurisdictions, and for the years 2011 through 2017 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 our expectation that, for the foreseeable future, a significant amount of our revenues will be derived from our Oncotype DX invasive breast cancer test; 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; 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 or collaborate on in the future; the factors we believe drive demand for our tests and our ability to sustain or increase such demand; our success in increasing patient and physician demand as a result of our direct sales approach and our salesforces' capacity to sell our tests; plans for, and the timeframe for the development or commercial launch of future tests, test enhancements or new technologies; 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; 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 next generation sequencing and non-invasive test technology, and their potential benefits; our belief that multi gene analysis provides superior analytical information; our beliefs regarding the benefits of genomic analysis in various patient populations; our expectations regarding our research and development, general and administrative and sales and marketing expenses and our anticipated uses of our 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 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 on our business; our belief that we have taken reasonable steps to protect our intellectual property; the impact of changing interest rates; our beliefs regarding 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; the success of our collaborations; 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 DX AR-V7 Nucleus Detect 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 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 July 2017, the Oncotype DX AR-V7 Nucleus Detect test for men with metastatic castration-resistant prostate cancer, or mCPRC, became commercially available as part of a clinical utility program. As of July 31, 2017, 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, the list price of our Oncotype DX prostate cancer test was $4,520 and the list price of our Oncotype SEQ Liquid Select test was $5,800. 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 six months ended June 30, 2017, more than 31,550 and 63,130 Oncotype test reports were delivered for use in treatment planning, compared to more than 29,060 and 58,570 test reports delivered for the same periods in 2016. All of our internally-developed tests are conducted at our clinical reference laboratory in Redwood City,

California. Our clinical reference laboratory processing capacity is currently approximately 150,000 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 and require both histology and pathology assessments. We believe that we currently have sufficient capacity to process current demand for our tests.

We have expanded our clinical laboratory facilities and processing capacity to accommodate future next generation sequencing, or NGS, testing and research and development. We expect our continued commercialization efforts of our tests will result in increased costs for laboratory testing, including staffing-related costs, incremental sales and marketing personnel to introduce our products to physicians and patients, costs for clinical utility studies and costs associated with obtaining reimbursement coverage.

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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. 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 low and very-low risk as defined by National Comprehensive Cancer Network, or NCCN, guidelines. 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, also referred to as Coverage with Data Development, or CDD. A draft local coverage determination, or LCD, has been issued for our prostate cancer test for qualified patients with favorable intermediate-risk prostate cancer and recommends Medicare coverage for use of the test in qualified patients, subject to a standard comment period, which ended in late July 2017, and finalization by Medicare. On December 16, 2015, Palmetto GBA, a Medicare Administrative Contractor that processes Medicare claims and sets Medicare coverage and payment policies for certain tests performed by our laboratory, informed us that they believe it was appropriate to establish a unique identifier code and independent coverage for the Oncotype DX DCIS test. We have obtained a unique identifier code for the Oncotype DX DCIS test, and we submitted to Palmetto additional validation and clinical utility data generated since its previous decision in May 2013, to cover the Oncotype DX DCIS test for all qualified Medicare patients with DCIS breast cancer. On January 19, 2017, Palmetto announced that it would cover the Oncotype DX DCIS test under a new LCD with CDD, for services furnished beginning March 6, 2017.

We have continued to expand our business, both in the United States and internationally. 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 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 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 established reimbursement with NHS England following NICE's recommendation for our breast cancer test, and in 2015 we began to receive payments from NHS England trusts with whom we have completed contractual arrangements.

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In 2014, the Gynecologic Oncology Working Group in Germany updated their guidelines to recommend Oncotype DX as the only breast cancer gene expression test to predict chemotherapy benefit in early-stage, hormone receptor-positive invasive breast cancer. We expect that it will take several years to establish broad coverage and reimbursement for our Oncotype DX breast, colon and prostate cancer tests with payors in countries outside of the United States and there can be no assurance that our efforts will be successful.

Oncotype DX Breast Cancer Test

We expect to continue to focus substantial resources on pursuing global adoption of and reimbursement for our Oncotype DX breast cancer test. We believe increased demand for our Oncotype DX breast cancer test resulted from our ongoing commercial efforts, expanded utility for new breast cancer patient groups, continued publication of peer-reviewed articles on studies we sponsored, conducted or collaborated on that support the use of and reimbursement for the test, clinical presentations at major symposia, and the inclusion of our breast cancer test in clinical practice guidelines for, node negative, or N−, estrogen receptor positive, ER+, invasive disease. However, this increased demand is not necessarily indicative of future growth rates, and we cannot provide assurance that this level of increased demand can be sustained or that publication of articles, future appearances or presentations at medical conferences, increased commercial efforts or expansion of utility to new breast cancer patient groups will have a similar impact on demand for our breast cancer test in the future. Sequential quarterly demand for our breast cancer test may also be impacted by other factors, including the economic environment and seasonal variations that have historically impacted physician office visits, any shift in commercial focus, 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 Administrator 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. 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 DCIS test 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 have also received a new LCD with CDD for our Oncotype DX DCIS test beginning March 6, 2017. We intend to continue to devote resources to expanding private reimbursement for our Oncotype DX DCIS 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 a majority of 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

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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 continuing 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 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 additional reimbursement with third-party payors for our colon cancer test. However, we cannot predict whether, or under what circumstances, payors will reimburse for this test.

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 publication of the clinical validation study conducted in collaboration with the University of California, San Francisco and other studies we sponsored, conducted or collaborated on that support the use of and reimbursement for the test, clinical presentations at major symposia and our ongoing commercial efforts.

In August 2015, Palmetto issued its final LCD, approving nationwide coverage of our prostate cancer test for qualified male Medicare patients with low and very-low risk disease, as defined by NCCN 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. In May 2017, a draft LCD with CDD was issued for our prostate cancer test for qualified patients with intermediate-risk prostate cancer. The draft LCD recommends Medicare coverage for use of the test in qualified patients with favorable intermediate-risk prostate cancer, subject to a standard comment period which ended in late July 2017.

Other than Medicare coverage, we have obtained limited reimbursement coverage from third-party payors for our Oncotype DX prostate cancer 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 individual 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 may continue to hire additional commercial, scientific, technical and other personnel to support this process.

Oncotype SEQ Liquid Select

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, such as Oncotype SEQ Liquid Select, are non-invasive liquid biopsy mutation panels that use NGS 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 Liquid Select were presented at the European Society for Medical Oncology congress in Copenhagen, Denmark in October 2016. The validation study results demonstrated that Oncotype SEQ Liquid Select is highly sensitive, specific and reproducible. The validation study established the per-sample specificity of the test to be greater than 99 percent. The test's sensitivity is also very high, detecting cell free DNA from

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tumors at the low frequencies commonly found in the plasma of patients with metastatic cancer in 95% of cases. Finally, study results demonstrated that Oncotype SEQ Liquid Select was highly reproducible in that it detected more than 95% of all observed variants in each run.

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

We intend to pursue reimbursement while seeking to obtain formal coverage policies with payors and expect that this test will 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 a sufficient level of reimbursement with third party payors for our Oncotype SEQ Liquid Select test. However, we cannot predict whether, if, or under what circumstances, payors will reimburse for this test.

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 NGS, digital PCR and circulating tumor cell, or CTC, capture. 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 Liquid Select product.

We have started the research and development phases on our first Oncotype TRACK products for non-invasive tumor monitoring, based upon positive results from our first two feasibility studies presented in December 2014. 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.

As new clinical evidence continues to be introduced, we intend to incorporate such evidence into additional iterations of these tests, which could include additional genes or updated interpretations of genes already included in such tests.

Commercial Collaborations

In June 2016, we entered into a collaboration agreement with Epic Sciences, Inc., or Epic Sciences, under which we have been granted exclusive distribution rights to commercialize Oncotype DX AR-V7 Nucleus Detect in the United States. Oncotype DX AR-V7 Nucleus Detect will be performed by Epic Sciences in its centralized laboratory in San Diego, California, which is accredited under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and certified by the College of American Pathologists, or CAP. This 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, or mCRPC. In January 2017, investigators from Memorial Sloan Kettering Cancer Center and Epic Sciences published findings in European Urology, that only nuclear localization of AR-V7 protein in CTCs from mCRPC patient blood samples is predictive of therapeutic benefit. Previous work by the same team, reported in JAMA Oncology, demonstrated that nuclear localized AR-V7 protein in CTCs was predictive of a 76% reduction of risk of death for mCRPC patients who received taxane chemotherapy versus Androgen Receptor Signaling inhibitors. We believe that this collaboration is complementary to our product development efforts for our Oncotype SEQ tests 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 have launched uses cell-free circulating tumor DNA in blood, we may pursue additional research and development opportunities using other analytes such as CTCs, RNA, and proteins. Additionally, while we are 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 utilized NGS to develop Oncotype SEQ Liquid Select, and plan to continue to further utilize NGS to develop additional non-invasive liquid biopsy tests that can be performed on blood or urine. Based on the positive results from two feasibility studies presented in December 2014, we are working to develop non-invasive tests for real-time patient monitoring. While early stage cancer continues to represent a significant opportunity with near term revenue potential, we believe we 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 utilize NGS for Oncotype SEQ Liquid Select. We will further utilize NGS for 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, fixed paraffin-embedded, or FPE, 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 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 and detection and capture methods for CTCs, to expand our capabilities, and we are 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 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.

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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 six months ended June 30, 2017. 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

The healthcare industry has undergone significant change driven by various efforts to reduce costs. The effect of the implementation of the Affordable Care Act, or ACA, or any future changes to 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 various proposals have been put forth, including by the FDA that, if finalized, would result in FDA regulation of 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.

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 ACA and subsequent proposals to repeal or replace the 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.

In addition, the Protecting Access to Medicare Act of 2014, or PAMA includes a substantial new payment system for certain clinical laboratory tests that is currently scheduled 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 every three years (or annually for “advanced diagnostic laboratory tests”), private payor payment rates and volumes for their 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.

We received a specific Current Procedural Terminology, or 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 2017. New rates calculated using the methodology under PAMA are currently expected to be adopted in 2018.

We received a specific CPT code for our Oncotype DX colon cancer test, effective January 1, 2016. For 2016, Medicare claims were paid at the rate established by the local MACs under the gapfill process. Medicare has established a national limitation amount for this code that maintains the contractor amount through 2017. New rates required under PAMA will be adopted in 2018.

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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, which is not subject to the same five-year rotation as for regional MAC services. 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, 2016. There have been no material changes to our critical accounting policies during the quarter ended June 30, 2017, other than the adoption of Accounting Standards Update ("ASU") 2016-09 described below.

Results of Operations

Three and Six Months Ended June 30, 2017 and 2016

We recognized a net loss of $2.7 million and $3.5 million for the three and six months ended June 30, 2017, respectively, compared to a net loss of $6.1 million and $12.5 million for the three and six months ended June 30, 2016, respectively. On a basic and diluted per share basis, net loss per share was $0.08 and $0.10 for the three and six months ended June 30, 2017, respectively, compared to net loss per share of $0.18 and $0.38 for the three and six months ended June 30, 2016, respectively. 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 June 30, 2017, 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 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 June 30,		For the Six Months Ended June 30,	
	2017	2016	2017	2016
	(In thousands)		(In thousands)	
Product revenues	$ 85,487	$ 81,886	$ 169,467	$ 162,780
Contract revenues	—	88	—	88
Total revenues	$ 85,487	$ 81,974	$ 169,467	$ 162,868
Period over period dollar increase in product revenues	$ 3,601		$ 6,687	
Period over period percentage increase in product revenues	4 %		4 %	

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The period over period increase in product revenues resulted, in part, from increased adoption. Test volume increased by 9% and 8% for the three and six months ended June 30, 2017 compared to the three and six months ended June 30, 2016. Of the growth in test volume, approximately 6% and 5%, respectively, was from breast cancer tests delivered worldwide.

International product revenues were $13.1 million, or 15% and $26.5 million or 16% of product revenues for the three and six months ended June 30, 2017, respectively, compared to $12.3 million, or 15% of product revenues and $22.7 million or 14% of product revenues, for the three and six months ended June 30, 2016, respectively.

Approximately $59.4 million, or 69%, and $120.1 million, or 71%, of product revenues for the three and six months ended June 30, 2017, respectively, were recognized on an accrual basis at the time the test results were delivered, compared to $56.6 million, or 69%, and $115.9 million, or 71%, of product revenues for the three and six months ended June 30, 2016, respectively. For all periods, the balance of product revenues was recognized upon cash collection as payments were received. The timing of recognition of revenues related to third-party payments may cause fluctuations in product revenues from period to period.

Product revenues related to Medicare patients for the three and six months ended June 30, 2017 were $18.4 million, or 22%, and $38.3 million, or 23%, of product revenues, respectively, compared to $17.7 million, or 22%, and $36.0 million, or 22%, of product revenues for the three and six months ended June 30, 2016, 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 June 30,		For the Six Months Ended June 30,	
	2017	2016	2017	2016
	(In thousands)		(In thousands)	
Tissue sample processing costs	$ 13,534	$ 12,901	$ 26,920	$ 26,339
Stock-based compensation	170	169	361	345
Total tissue sample processing costs	13,704	13,070	27,281	26,684
License fees	94	2,528	190	5,068
Total cost of product revenues	$ 13,798	$ 15,598	$ 27,471	$ 31,752
Period over period dollar increase in tissue sample processing costs	$ 633		$ 581	
Period over period percentage increase in tissue sample processing costs	5 %		2 %	

Cost of product revenues includes 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 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 six months ended June 30, 2017, 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. As a result of the termination of the Roche license agreement, we expect license fees expense to be consistent with the levels recognized during the three and six months ended June 30, 2017, which are significantly less than amounts recognized in the first half of 2016.

Tissue sample processing costs increased $633,000 for the three months ended June 30, 2017 compared to the three months ended June 30, 2016. Tissue sample processing costs increased $581,000 for the six months ended June 30, 2017

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compared to the six months ended June 30, 2016. These increases were driven primarily by the increase in test volumes of 9% and 8%, respectively, for the three and six months ended June 30, 2017, compared to the same periods in 2016, as well as an increase in personnel-related expenses due to increased headcount offset by a decrease of cost allocations from other functional areas. 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 June 30,		For the Six Months Ended June 30,	
	2017	2016	2017	2016
	(In thousands)		(In thousands)	
Personnel-related expenses	$ 9,157	$ 7,885	$ 18,332	$ 17,367
Stock-based compensation	1,443	1,252	2,831	2,489
Collaboration expenses	686	1,171	1,507	1,876
Reagents and laboratory supplies	1,218	310	1,995	949
Allocated information technology, facilities and other costs	1,636	2,295	3,112	4,231
Other costs	1,641	2,035	2,878	3,645
Total research and development expenses	$ 15,781	$ 14,948	$ 30,655	$ 30,557
Period over period dollar increase	$ 833		$ 98	
Period over period percentage increase	6 %		- %	

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 $833,000, or 6%, increase in research and development expenses for the three months ended June 30, 2017 compared to the three months ended June 30, 2016 was primarily due to a $1.3 million increase in personnel-related expenses, a $908,000 increase in reagents and laboratory supplies, and a $191,000 increase in stock-based compensation expense, partially offset by a $659,000 decrease in allocated information technology, facilities and other costs, a $485,000 decrease in collaboration expenses and a $394,000 decrease in other costs.

The $98,000 increase in research and development expenses for the six months ended June 30, 2017 compared to the six months ended June 30, 2016 was primarily due to a $1.0 million increase in personnel-related expenses, a $1.0 million increase in reagents and laboratory supplies and a $342,000 increase in stock-based compensation expense,

partially offset by a $1.1 million decrease in allocated information technology, facilities and other costs, a $767,000 decrease in other costs and a $369,000 decrease in collaboration expenses.

We expect our research and development expenses 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.

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Selling and Marketing Expenses

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2017	2016	2017	2016
	(In thousands)		(In thousands)	
Personnel-related expenses	$ 20,455	$ 19,603	$ 41,836	$ 40,977
Stock-based compensation	1,478	1,437	2,989	2,875
Promotional and marketing materials	3,991	4,452	8,121	8,117
Travel, meetings and seminars	3,911	3,917	8,458	8,615
Collaboration expenses	226	399	340	633
Allocated information technology, facilities and other costs	9,512	7,125	18,262	14,208
Other costs	1,083	1,056	2,157	2,064
Total selling and marketing expenses	$ 40,656	$ 37,989	$ 82,163	$ 77,489
Period over period dollar increase	$ 2,667		$ 4,674	
Period over period percentage increase	7 %		6 %	

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 $2.7 million, or 7%, increase in selling and marketing expenses for the three months ended June 30, 2017 compared to the three months ended June 30, 2016 was primarily due to a $2.4 million increase in allocated information technology, facilities and other costs primarily associated with the implementation of new systems and an $852,000 increase in a personnel-related expenses, partially offset by a $461,000 decrease in promotional and marketing materials.

The $4.7 million, or 6%, increase in selling and marketing expenses for the six months ended June 30, 2017 compared to the six months ended June 30, 2016 was primarily due to a $4.1 million increase in allocated information technology, facilities and other costs primarily associated with the implementation of new systems and an $859,000 increase in personnel-related expenses, partially offset by a $293,000 decrease in collaboration expenses.

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.

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General and Administrative Expenses

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2017	2016	2017	2016
	(In thousands)		(In thousands)	
Personnel-related expenses	$ 13,490	$ 13,779	$ 26,668	$ 27,978
Stock-based compensation	2,106	1,989	4,121	3,680
Occupancy and equipment expenses	8,583	7,192	16,334	14,246
Billing and collection fees	3,218	3,023	6,138	6,030
Bad debt expense	1,187	2,220	1,599	4,499
Professional fees and other expenses	3,117	2,459	5,744	4,941
Information technology, facilities and other cost allocations	(13,306)	(12,125)	(25,458)	(24,399)
Total general and administrative expenses	$ 18,395	$ 18,537	$ 35,146	$ 36,975
Period over period dollar decrease	$ (142)		$ (1,829)	
Period over period percentage decrease	(1) %		(5) %	

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 $142,000 or 1%, decrease in general and administrative expenses for the three months ended June 30, 2017 compared to the three months ended June 30, 2016 was primarily due to a $1.2 million increase in information technology, facilities and other costs allocated to other functional areas, a $1.0 million decrease in bad debt expense driven by improved cash collections and decreased bad debt reserves, partially offset by a $1.4 million increase in occupancy and equipment expenses driven by increased software license expenses and facility expansion and a $658,000 increase in professional fees and other expenses.

The $1.8 million, or 5%, decrease in general and administrative expenses for the six months ended June 30, 2017 compared to the six months ended June 30, 2016 was primarily due to a $2.9 million decrease in bad debt expense driven by improved cash collections and decreased bad debt reserves, a $1.3 million decrease in personnel-related expenses, and a $1.1 million increase in information technology, facilities and other costs allocated to other functional areas, partially offset by a $2.1 million increase in occupancy and equipment expenses driven by increased software license expenses and facility expansion, an $803,000 increase in professional fees and other expenses and a $441,000 increase in stock-based compensation. The $1.3 million decrease in personnel-related expenses was primarily due to a $2.3 million decrease in contract labor and consulting expenses partially offset by a $978,000 increase in salaries, benefits and bonus expenses due to increased headcount and higher benefits costs.

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 $206,000 and $364,000 for the three and six months ended June 30, 2017, respectively, compared to $87,000 and $165,000 for the three and six months ended June 30, 2016, respectively. We expect our interest income will remain nominal if the current low interest rate environment continues.

Gain on sale of equity securities

For the three and six months ended June 30, 2017, we realized gain on sale of equity securities of $0 and $2.8 million, respectively, in connection with the sale of our common stock of Invitae Corporation, or Invitae. For the three and six months ended June 30, 2016, we realized gain on sale of equity securities of $676,000 and $2.0 million,

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respectively, in connection with the sale of our common stock of Invitae. As of June 30, 2017, we had sold all of our remaining shares of common stock of Invitae.

Other Income (Expense), Net

Other income, net was $357,000 and $452,000 for the three and six months ended June 30, 2017, respectively, compared to other expense, net of $150,000 and $63,000 for the three and six months ended June 30, 2016, respectively. Other income, net for the three and six months ended June 30, 2017 was primarily related to $347,000 and $424,000 of net foreign currency gains, respectively. Other expense, net for the three and six months ended June 30, 2016 was primarily related to $157,000 and $83,000 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 recognized income tax expense of $159,000 and $1.2 million for the three and six months ended June 30, 2017, respectively, which was computed using the “discrete” (or “cut-off”) method. The income tax expense for the three and six months ended June 30, 2017 was primarily comprised of the intraperiod tax allocation of the deferred tax impact for available-for-sale marketable securities and foreign income tax expense.

We recognized an income tax expense of $1.6 million and $657,000 for the three and six months ended June 30, 2016, respectively, which was computed using the “discrete” (or “cut-off”) method. The income tax expense for the three and six months ended June 30, 2016 was primarily comprised of the intraperiod tax allocation of the deferred tax impact for available-for-sale marketable securities and foreign income tax expense.

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 June 30, 2017 and December 31, 2016. 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 June 30, 2017, we had an accumulated deficit of $245.6 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 expenses, selling and marketing expenses 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.

	June 30, 2017	December 31, 2016
	(in thousands)	
Cash, cash equivalents and short-term marketable securities	$ 109,799	$ 96,989
Working capital	115,420	104,789

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 June 30, 2017, we had cash, cash equivalents and short-term investments of $109.8 million compared to $97.0 million at December 31, 2016. The $12.8 million increase was attributable to an increase in cash generated from operations, sales of marketable securities, and net sales proceeds from the issuance of common stock under our 2005 Stock Incentive Plan, partially offset by investments in the growth of our business, including research and development, global expansion, and activities related to reimbursement coverage of our tests. In accordance with our investment policy, available cash is invested in short-term and long-term, low-risk, investment-grade debt instruments.

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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 June 30, 2017 and December 31, 2016, $32.4 million, or 15%, and $35.2 million, or 17%, respectively, of our total assets consisted of accounts receivable. The $2.8 million decrease in accounts receivable from December 31, 2016 to June 30, 2017 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 June 30, 2017 and December 31, 2016, our weighted average DSOs were 56 days and 71 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 June 30, 2017 and December 31, 2016:

	June 30, 2017							
	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	$ 29,939	84 %	$ 12,930	$ 4,527	$ 2,398	$ 2,173	$ 1,879	$ 6,032
Medicare	5,594	16	4,510	235	137	209	111	392
Total	35,533	100 %	$ 17,440	$ 4,762	$ 2,535	$ 2,382	$ 1,990	$ 6,424
Allowance for doubtful accounts	(3,106)							
Net accounts receivable	$ 32,427							

December 31, 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	$ 30,209	76 %	$ 12,061	$ 5,108	$ 2,298	$ 1,792	$ 2,608	$ 6,342
Medicare	9,478	24	6,043	997	119	281	511	1,527
Total	39,687	100 %	$ 18,104	$ 6,105	$ 2,417	$ 2,073	$ 3,119	$ 7,869
Allowance for doubtful accounts	(4,508)							
Net accounts receivable	$ 35,179							

Cash Flows

The following table summarizes our cash flow activities:

	2017	2016
	(In thousands)	
For the six months ended June 30,		
Cash provided by (used in):		
Operating activities	$ 11,886	$ 1,845
Investing activities	(18,298)	2,313
Financing activities	8,208	3,969
Capital expenditures (included in investing activities above)	$ (8,057)	$ (6,879)

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Cash Provided by Operating Activities

Cash provided by operating activities was $11.9 million for the six months ended June 31, 2017 and consisted primarily of net loss of $3.5 million adjusted for non-cash items of $16.7 million, gain on sale of equity securities of $2.8 million and $1.5 million related to changes in operating assets and liabilities.

Cash provided by operating activities was $1.8 million for the six months ended June 30, 2016 and consisted primarily of net loss of $12.5 million, adjusted for non-cash items of $14.3 million, gain on sale of equity securities of $2.0 million and $2.0 million related to changes in operating assets and liabilities.

Cash (Used in) Provided by Investing Activities

Cash used in investing activities for the six months ended June 30, 2017 was $18.3 million, consisting of $20.4 million net purchases of marketable securities and $8.1 million in capital expenditures related to the expansion of our business offset by $10.2 million of proceeds from sales of marketable securities.

Cash provided by investing activities for the six months ended June 30, 2016 was $2.3 million, consisting of $5.1 million of proceeds from sales of marketable securities and $4.1 million in net maturities of marketable securities offset by $6.9 million in capital expenditures related to the expansion of our business.

Cash Provided by Financing Activities

Cash provided by financing activities for the six months ended June 30, 2017 was $8.2 million, consisting primarily of $12.5 million of proceeds from the issuance of our common stock upon the exercise of stock options offset by $4.3 million of cash paid for tax withholdings related to net share settlements of RSUs.

Cash provided by financing activities for the six months ended June 30, 2016 was $4.0 million, consisting primarily of $7.1 million of proceeds from the issuance of our common stock upon the exercise of stock options offset by $3.1 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, 2016.

Operating Capital and Capital Expenditure Requirements

We currently anticipate that our cash, cash equivalents and short-term marketable securities, together with payments for our tests, will be sufficient to fund our operations and facilities expansion plans for at least the next 12 months, including the expansion of our research and development programs, our proprietary liquid platforms development efforts, our commercialization efforts related to Oncotype DX AR-V7 Nucleus Detect, our efforts to expand adoption of and reimbursement for our tests and our international expansion efforts. We expect to spend approximately $13 million over the next 12 months for planned laboratory equipment, information technology and facilities expansion. We may also use cash to acquire or invest in complementary businesses, technologies, services or products. We expect that our cash, cash equivalents and short term marketable securities will also be used to fund working capital and for other general corporate purposes, such as licensing technology rights, distribution arrangements for our tests both within and outside of the United States or expanding our direct sales capabilities worldwide.

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

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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 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 Sciences;
- costs related to future product launches;
- costs related to acquiring or achieving access to tissue samples and technologies;
- costs related to filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the effect of competing technological and market developments;
- costs related to international expansion;
- costs and delays in product development as a result of any changes in regulatory oversight applicable to our products or operations;
- the impact of changes in Federal, state and international taxation; and
- the economic and other terms and timing of any collaborations, licensing or other arrangements into which we may enter or investments or acquisitions we might seek to effect.

If we are not able to generate and maintain sustained product revenues to finance our cash requirements, we will need to finance future cash needs primarily through public or private equity offerings, debt financings, borrowings or strategic collaborations or licensing arrangements. If we raise funds by issuing equity securities, dilution to stockholders may result. Any equity securities issued may also provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock. The terms of debt securities or borrowings could impose significant restrictions on our operations. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or products, or grant licenses on terms that are not

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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 June 30, 2017, 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 (Topic 606). Topic 606 supersedes the revenue recognition requirements in Accounting Standards Codification Topic 605, Revenue Recognition, and requires entities to recognize revenue when they transfer control of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. In addition, Topic 606 requires more detailed disclosures to enable users of financial statements to understand the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. Topic 606 will be effective for us in the first quarter of 2018, with the option to adopt it in the first quarter of 2017. We intend to adopt Topic 606 effective January 1, 2018. Topic 606 permits the use of either a retrospective or modified retrospective application. We intend to use the modified retrospective approach. We also plan to elect the practical expedient of applying the new guidance only to contracts that are not completed as of the date of initial application. Upon adoption, we will recognize the cumulative effect of adopting this guidance as an adjustment to our opening accumulated deficit balance. Prior periods will not be retrospectively adjusted. We are in the process of completing our assessment of the impact Topic 606 will have on our consolidated financial statements and related disclosures. Our implementation of this standard includes a project management framework that includes a dedicated lead project manager and an implementation team responsible for assessing the impact that Topic 606 will have on our accounting, financial statement presentation and disclosure for contracts with customers. The assessment phase of this project has included the analysis of our current portfolio of customer contracts, including a review of historical accounting policies and practices to identify potential differences in applying Topic 606. We are also performing a comprehensive review of our current processes and systems to determine and implement changes required to support the adoption of Topic 606. The assessment has resulted in the identification of potential accounting changes to the timing of revenue recognition from certain payors who are not currently accrual payors to be accelerated. During the second quarter of 2017, the implementation team continued to identify changes to business processes, systems and controls to support recognition, presentation and disclosure under the new standard. An implementation plan for the second half of 2017 has been developed and includes tasks around documentation, design of new processes and controls as well as testing of the controls.

In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments-Overall (Subtopic 825-10): 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 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 (Topic 842). Topic 842 generally requires entities to recognize operating and financing lease liabilities and corresponding right-of-use assets on the balance sheet. Topic 842 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. Entities are required to use a modified retrospective approach for leases that exist or are entered into after the beginning of the earliest comparative period in the financial statements, and there are certain optional practical expedients that an entity may elect to apply. Full retrospective

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application is prohibited and early adoption by public entities is permitted. We are currently evaluating the impact that the adoption of Topic 842 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 adopted this ASU in the first quarter of 2017 and elected to continue to estimate forfeitures expected to occur to determine the amount of compensation cost to be recognized in each period. As the result, in the first quarter of 2017, we recorded an $11.6 million cumulative-effect adjustment decrease in accumulated deficit and an offsetting increase in deferred tax assets for previously unrecognized excess tax benefits that existed as of December 31, 2016. However, as all of our deferred tax assets, net of deferred tax liabilities, are subject to a valuation allowance and the realization of these assets is not more likely than not to be achieved, we recorded an $11.6 million valuation allowance against these deferred tax assets with an offsetting increase in accumulated deficit. The presentation requirement for cash flows related to employee taxes paid for withheld shares will not impact the statements of cash flows since such cash flows have historically been presented as a financing activity. The adoption was on a prospective basis and therefore had no impact on prior periods.

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 June 30, 2017, we had cash, cash equivalents and short-term marketable securities of $109.8 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 securities and are, due to their short-term nature, subject to minimal interest rate risk. To date, we have not experienced a loss of principal on any of our investments. Although we currently expect that our ability to access or liquidate these investments as needed to

support our business activities will continue, we cannot ensure that this will not change. We believe that, if market interest rates were to change immediately and uniformly by 10% from levels at June 30, 2017, 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 continue to 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 gains of $347,000 and $424,000 for the three and six months ended June 30, 2017 compared to net foreign exchange transaction losses of $157,000 and $83,000 for the three and six months ended June 30, 2016. 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 second quarter of 2017 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1A. RISK FACTORS.

Risks 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 August 2000 through June 30, 2017, we had an accumulated deficit of $245.6 million. We expect to continue to invest in our product pipeline, including our current Oncotype DX and Oncotype SEQ Liquid Select tests and future Oncotype SEQ and cancer burden monitoring products, and in our global commercial infrastructure, our laboratory operations, next generation sequencing, or NGS, and other technology. For the three and six months ended June 30, 2017, our research and development expenses were $15.8 million and $30.7 million, respectively, and our selling and marketing expenses were $40.7 million and $82.2 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 cancer and prostate cancer tests and develop and commercialize new tests, including Oncotype SEQ Liquid Select and Oncotype DX AR-V7 Nucleus Detect. 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.

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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 tests, or we are unable to successfully renegotiate reimbursement contracts, our commercial success could be compromised.

Physicians and patients may not order our 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 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+ breast cancer patients that is similar to the coverage we have obtained for our 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. There has been issued a draft local coverage determination, or LCD, for our prostate cancer test for qualified patients with intermediate-risk prostate cancer. The draft LCD recommends Medicare coverage for use of the test in qualified patients with favorable intermediate-risk prostate cancer, subject to a standard comment period which ended in late July 2017.

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.

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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 invasive 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 invasive 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. 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 Select product. 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 invasive breast cancer test, establish expanded adoption of and reimbursement for our prostate cancer or DCIS tests, or successfully develop and commercialize new products such as our Oncotype SEQ Liquid Select product 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.

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 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

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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 22% and 23% of our product revenues for the three and six months ended June 30, 2017, respectively, and 22% and 20% for the three and six months ended June 30, 2016, respectively. Accounts receivable on behalf of patients directly covered by Medicare represented 16% and 24% of our total accounts receivable at June 30, 2017 and December 31, 2016, 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 inpatients 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. In addition, for Medicare beneficiaries who were hospital outpatients at the time the tumor tissue samples were obtained, the hospital must bill for the test when it is ordered less than 14 days from the outpatient encounter even when the test is not bundled into the hospital payment for the encounter. In these circumstances, hospitals are required to furnish services such as our tests as “services furnished under arrangements between a provider and an outside vendor” and only the hospital may bill Medicare for such tests. Under these circumstances, for us to obtain payment for these services, we are required to bill individual hospitals for tests ordered for Medicare beneficiaries. Such hospitals have generally been unwilling to enter into written agreements with us to assume the financial responsibility for these tests ordered for Medicare beneficiaries and consequently we generally cancel such orders when received within the 14-day timeframe when written agreements from such hospitals are not in place.

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, that Medicare will not seek to expand the scope of its payment bundling rules in the future, or that other payers will not adopt similar billing rules. 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 Oncotype laboratory facilities become 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 for our Oncotype tests. Redwood City is situated near active earthquake fault lines. Our facilities 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 facilities 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

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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 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 outside of our Redwood City, California facilities, 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 that leverage our core technology and industry experience to expand our product offerings or distribution, or make investments in other companies. We have in the past and may in the future experience losses related to the recognition of our portion of the net losses of equity method investees, and we may in the future experience impairment losses related to our investments in companies if we determine that the value of an investment is impaired. Losses related to our investments in other companies could have a material negative effect on our results of operations. We have no experience with respect to acquiring other companies and limited experience with respect to the formation of strategic alliances and joint ventures. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions by us also could result in significant write offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. Integration of an acquired company also may require management resources that otherwise would be available for ongoing development of our existing business. We may not identify or complete these transactions in a timely manner, on a cost effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance, joint venture or investment. Additionally, although we are not currently a majority investor in any other company, we cannot guarantee that a company in whom we invest in the future will not be considered a variable interest entity, or VIE, under relevant accounting standards and guidance. If an entity in which we invest is determined to be a VIE, we may have to consolidate that entity's financial results with ours, and such consolidation could have a negative effect on our financial results.

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.

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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 or complying with local regulations concerning the analysis of tissue, 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 U.S. Foreign Corrupt Practices Act, or 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.

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 six months ended June 30, 2017, approximately 9% of our product revenues came from foreign denominated currencies. If the U.S. dollar strengthens against foreign currencies, as it had during 2016, 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

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costs and risks of their own, such as ongoing management time and expertise, external costs to implement the strategies and potential accounting implications.

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.

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.

The implementation and transition to 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 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

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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 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. We have self-certified with the Department of Commerce for compliance with the Privacy 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.

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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 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 materials and medical specimens. 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 or specimens. 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, as well as regulations relating to the safety and health of laboratory employees. 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.

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 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 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 various

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proposals have been put forth, including by the FDA that, if finalized, would result in FDA regulation of 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.

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. The current U.S. President and other U.S. lawmakers have made statements about potentially repealing and/or replacing the ACA and efforts are currently underway in the U.S. Congress to consider legislative actions to that end. We are monitoring the impact of the ACA and proposals to repeal, replace or refine the ACA 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 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.

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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 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 documents outlining its intent to require varying levels of FDA oversight of many LDTs, including 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. On January 13, 2017, the FDA published a “discussion paper” in which the FDA outlined a substantially revised “possible approach” to the oversight of LDTs. The discussion paper explicitly states that it is not a final version of the 2014 draft guidance and that it does not represent the FDA’s “formal position.” It is unclear at this time if or when the FDA will finalize its plans to end enforcement discretion for LDTs, and even then, whether the new regulatory requirements are expected to be phased-in over time. However, the FDA may decide to regulate certain LDTs on a case-by-case basis at any time.

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

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

We cannot predict the ultimate timing or form of final FDA guidance, legislation 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.

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If we were required to conduct additional clinical trials prior to continuing to sell our current 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 any of 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 other 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.

Our business could be harmed by the loss, suspension, or other restriction on a license, certification, or accreditation, or by the imposition of a fine or penalties, under CLIA, its implementing regulations, or other state, federal and foreign laws and regulations affecting licensure or certification, or by future changes in these laws or regulations.

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 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, Pennsylvania, Maryland and Rhode Island require that we hold licenses to test specimens from patients in those states and Florida requires that we hold a license when we receive specimens from clinical laboratories in that state. Other states may have

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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 numerous U.S. and foreign laws and governmental regulations, and any governmental enforcement action may materially affect our financial condition and business operations.

We are subject to 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 (as amended);
- 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.

The U.S. Attorney's Offices have increased their scrutiny over the healthcare industry in recent years. The U.S. Congress, Department of Justice, Office of Inspector General of the Department of Health and Human Services, and Department of Defense have all issued subpoenas and other requests for information to conduct investigations of, and commenced civil and criminal litigation against, healthcare companies, related to financial arrangements with health care providers, regulatory compliance, product promotional practices, and documentation, coding and billing practices. In addition, the Federal False Claims Act has led to whistleblowers filing numerous qui tam civil lawsuits against healthcare companies, in part, because a whistleblower can receive a portion of any amount obtained by the government through such a lawsuit.

Governmental enforcement action or qui tam civil litigation against us may result in material costs and occupy significant management resources, even if we ultimately prevail. In addition, governmental enforcement action may result in substantial fines, penalties or administrative remedies, including exclusion from government reimbursement programs and entry into corporate integrity agreements with governmental agencies, which would entail significant obligations and costs.

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.

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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.

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 tests in development and devote considerable resources to research and development. There can be no assurance that our Oncotype tests will be capable of reliably predicting the recurrence of cancers with the sensitivity and specificity necessary to be clinically useful and commercially viable. We also cannot be certain that the Oncotype SEQ Liquid Select product we have launched, or future Oncotype SEQ tests, will attain widespread use among the 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

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· 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.

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, 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 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 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

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

Our dependence on distributors for sales of our Oncotype tests outside of the U.S. could limit or prevent us from selling our test in foreign markets and impact our revenue.

As of June 30, 2017, 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, determine to unilaterally stop supplying technologies or products subject to a 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 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, Exact Sciences, Inc. GenomeDx Biosciences Inc., Hologic Inc., Myriad Genetics Inc. (and its Sividon Diagnostics subsidiary), NanoString Technologies Inc., NeoGenomics, Inc., Novartis AG, and Qiagen N.V. As we expand our research, development and

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commercialization efforts into the liquid biopsy and pan-cancer clinical diagnostics market, we face competition from companies such as Danaher Corporation (and its Cepheid, Inc. subsidiary), Foundation Medicine, Grail, Guardant Health, MDxHealth, Metamark, Inc., Natera Inc. and Novartis AG. 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. Historically, our principal competition for our Oncotype tests has also come from existing diagnostic methods used by pathologists and oncologists, 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 or approved for marketing by the FDA. There may be a marketing differentiation or perception that an FDA cleared or approved test is more desirable than Oncotype tests, which are LDTs, 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 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 successfully maintain or manage our current collaborations or enter into new collaborations, our product development could be delayed and our introduction of new products into the market could be adversely affected which could have an adverse effect on our financial results.

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.

We have limited experience in commercializing products through collaborations with third parties, which includes our commercial collaboration with Epic Sciences. This collaborative arrangement poses a number of risks, including, among others, whether we will be able to obtain adequate reimbursement for Oncotype DX AR-V7 Nucleus Detect with both public and private payors, whether our commercial channel will be successful in creating market demand for Oncotype DX AR-V7 Nucleus Detect, whether Epic Sciences is able to obtain and maintain appropriate state laboratory licensure, and whether our information technology and reporting systems are adequately and securely integrated with those of Epic Sciences. We are also subject to the same risks with regards to the performance and delivery of Oncotype DX AR-V7 Nucleus Detect tests, given that Epic Sciences is a centralized CLIA laboratory performing such tests.

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.

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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.

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.

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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 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. 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.

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ITEM 6. EXHIBITS

Exhibit Number	Description
10.1*	Form of Indemnification Agreement (incorporated by reference to exhibit 10.1 filed with the Company's Current Report on Form 8-K dated May 16, 2017).
10.2*	Genomic Health, Inc. Amended and Restated 2005 Stock Incentive Plan, as amended.
10.3*	Genomic Health, Inc. Employee Stock Purchase Plan, as amended.
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.

* Indicates management contract or compensatory plan or arrangement.

#In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release No. 34-47986, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10-Q and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act"). Such exhibits will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Exchange Act.

SIGNATURES

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

GENOMIC HEALTH, INC.

Date: August 4, 2017 By: /s/ Kimberly J. Popovits
Kimberly J. Popovits
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 4, 2017 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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