GENOMIC HEALTH INC
Form 10-Q
August 07, 2018
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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, 2018

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 35,855,233 as of July 31, 2018.

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PART 1: FINANCIAL INFORMATION

Item 1. Financial Statements

GENOMIC HEALTH, INC.

Condensed Consolidated Balance Sheets

(In thousands)

(Unaudited)

	June 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 53,847	$ 45,518
Short-term marketable securities	99,098	84,057
Accounts receivable (net of allowance for doubtful accounts; 2018—$2,184, 2017—$3,884)	48,982	31,161
Prepaid expenses and other current assets	13,449	13,524
Total current assets	215,376	174,260
Property and equipment, net	40,054	46,440
Other assets	13,586	10,917
Total assets	$ 269,016	$ 231,617
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,192	$ 156
Accrued compensation and employee benefits	21,750	24,953
Accrued expenses and other current liabilities	12,705	14,084
Other current liabilities	340	323
Total current liabilities	39,987	39,516
Other liabilities	3,826	3,810
Commitments and contingencies		
Stockholders' equity:		
Common stock	3	3
Additional paid-in capital	482,835	464,637
Accumulated other comprehensive loss	(65)	(294)
Accumulated deficit	(227,460)	(245,945)
Treasury stock, at cost	(30,110)	(30,110)
Total stockholders' equity	225,203	188,291
Total liabilities and stockholders' equity	$ 269,016	$ 231,617

See accompanying notes.

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GENOMIC HEALTH, INC.

Condensed Consolidated Statements of Operations

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Product revenues	$ 95,619	$ 85,487	$ 188,244	$ 169,467
Operating expenses:				
Cost of product revenues	14,383	13,798	33,116	27,471
Research and development	15,312	15,781	32,119	30,655
Selling and marketing	40,337	40,656	82,092	82,163
General and administrative	18,487	18,395	38,205	35,146
Total operating expenses	88,519	88,630	185,532	175,435
Income (loss) from operations	7,100	(3,143)	2,712	(5,968)
Interest income	400	206	817	364
Gain on sale of equity securities	—	—	—	2,807
Unrealized gain on equity securities	1,283	—	1,410	—
Other income (expense), net	(248)	357	61	452
Income (loss) before income taxes	8,535	(2,580)	5,000	(2,345)
Income tax expense	218	159	458	1,200
Net income (loss)	$ 8,317	$ (2,739)	$ 4,542	$ (3,545)
Basic net income (loss) per share	$ 0.23	$ (0.08)	$ 0.13	$ (0.10)
Diluted net income (loss) per share	$ 0.23	$ (0.08)	$ 0.12	$ (0.10)
Shares used in computing basic net income (loss) per share	35,544	34,428	35,372	34,219
Shares used in computing diluted net income (loss) per share.	36,716	34,428	36,360	34,219

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,	
	2018	2017	2018	2017
Net income (loss)	$ 8,317	$ (2,739)	$ 4,542	$ (3,545)
Other comprehensive loss:				
Unrealized gain (loss), net, on available-for-sale marketable securities, net of tax of $0 for the three and six months ended June 30, 2018 and 2017, respectively	83	(4)	49	(97)
Reclassification adjustment for net gain on sale of equity securities included in net loss	—	—	—	(1,127)
Comprehensive income (loss)	$ 8,400	$ (2,743)	$ 4,591	$ (4,769)

See accompanying notes.

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GENOMIC HEALTH, INC.

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Six Months Ended June 30,	
	2018	2017
Operating activities		
Net income (loss)	$ 4,542	$ (3,545)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	6,224	5,434
Employee stock-based compensation	10,341	10,302
Write-off of previously capitalized software costs	2,347	—
Impairment of long-lived assets	2,095	—
Loss 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)
Unrealized gain on revaluation of equity investment	(1,410)	—
Write-off of convertible promissory note	1,329	—
Deferred tax benefit from unrealized gain on available-for-sale marketable securities, net	—	820
Changes in assets and liabilities:		
Accounts receivable	(3,698)	2,752
Prepaid expenses and other assets	(76)	1,397
Accounts payable	4,749	2,161
Accrued compensation and employee benefits	(3,203)	(6,545)
Accrued expenses and other liabilities	(1,099)	1,795
Net cash provided by operating activities	22,241	11,899
Investing activities		
Purchases of property and equipment	(4,225)	(8,057)
Proceeds from sale of property and equipment	—	10
Purchases of marketable securities	(64,388)	(50,338)
Maturities of marketable securities	49,522	29,932
Proceeds from sales of marketable securities	—	10,155
Other investments	(2,500)	—
Net cash used in investing activities	(21,591)	(18,298)
Financing activities		
Proceeds from issuance of common stock under stock plans	12,548	12,522
Withholding taxes related to restricted stock units net share settlement	(4,791)	(4,314)
Net cash provided by financing activities	7,757	8,208
Net increase in cash, cash equivalents and restricted cash	8,407	1,809

Cash, cash equivalents and restricted cash at the beginning of period	45,708	40,585
Cash, cash equivalents and restricted cash at the end of period	$ 54,115	$ 42,394
Non-cash investing and financing activities		
Accrued purchases of property and equipment	$ 747	$ 2,005
Change in fair value of investment	$ 81	$ —

See accompanying notes.

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GENOMIC HEALTH, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2018

(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 cancer 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 disease 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 ("GPS") to predict disease aggressiveness in men with low risk prostate cancer and to improve treatment decisions for prostate cancer patients, in conjunction with the Gleason score, or tumor grading. In February 2018, the Oncotype DX AR-V7 Nucleus Detect test for men with metastatic castration-resistant prostate cancer ("mCRPC") became commercially available.

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, 2018: 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 eight 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, 2018, condensed consolidated statements of operations and comprehensive income (loss) for the three and six months ended June 30, 2018 and 2017, and condensed consolidated statements of cash flows for the six months ended June 30, 2018 and 2017 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, 2017 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, 2017.

During the first quarter of 2018, the Company adopted new accounting guidance related to revenue recognition, accounting for financial instruments and presentation of restricted cash in the statement of cash flows, each of which is described below. There have been no other significant changes in the Company's accounting policies during the three and six months ended June 30, 2018 as compared to the significant accounting policies described in its Annual Report on Form 10-K for the year ended December 31, 2017.

The Company recast prior period consolidated statement of cash flows to conform with the adoption of the new accounting guidance related to presentation of restricted cash in the statement of cash flows as described below.

Revenue Recognition

Revenues are recognized when control of the promised goods or services is transferred to customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods or services. To determine revenue recognition for the arrangements that the Company determines are within the scope of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 606, Revenue from Contracts with Customers, the Company performs the following five steps: (1) identify the contract(s) with a customer, (2) identify the performance obligations in the contract, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations in the contract and (5) recognize revenue when (or as) the entity satisfies a performance obligation. See Note 2 for further discussion on Revenues.

Concentration of Risk

The Company is subject to credit risk from its portfolio of cash equivalents and marketable securities. The Company invests in money market funds through a major U.S. bank and is exposed to credit risk in the event of default by the financial institution to the extent of amounts recorded on the consolidated balance sheets. The Company invests in short term, investment grade debt instruments and by policy limits the amount in any one type of investment, except for securities issued or guaranteed by the U.S. government. Under its investment policy, the Company limits amounts invested in such securities by credit rating, maturity, industry group, investment type and issuer, except for securities issued by the U.S. government. The Company is not exposed to any significant concentrations of credit risk from these financial instruments. The goals of the Company's investment policy, in order of priority, are as follows: safety and preservation of principal and diversification of risk; liquidity of investments sufficient to meet cash flow requirements; and a competitive after tax rate of return.

The Company is also subject to credit risk from its accounts receivable related to its product sales. The majority of the Company's accounts receivable arise from product sales in the United States. Reimbursement on behalf of patients covered by Medicare accounted for 24% and 25% of the Company's product revenues for the three and six months ended June 30, 2018 and 22% and 23% for the three and six months ended June 30, 2017. Accounts receivable on behalf of patients directly covered by Medicare represented 15% and 23% of the Company's total accounts receivable at June 30, 2018 and December 31, 2017, respectively. No other third party payor represented more than 10% of the Company's product revenues or accounts receivable balances for these periods.

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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.

Prior to January 1, 2018, if the equity method did not apply, investments in privately held companies determined to be equity securities were accounted for using the cost method. As discussed below, on January 1, 2018, the Company adopted Accounting Standards Update ("ASU") No. 2016-01, Financial Instruments-Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities, which changed the way it accounts for non-marketable securities. The Company adjusts the carrying value of its non-marketable equity securities for changes from observable transactions for identical or similar investments of the same issuer, less impairment. All gains and losses on non-marketable equity securities, realized and unrealized, are recognized in other income (expense), net.

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 years ended December 31, 2017 and 2016, the Company invested $1.4 million and $6.1 million, respectively, in the subordinated convertible promissory notes of Epic Sciences, Inc. ("Epic Sciences"). See Note 6, "Collaboration and Commercial Technology Licensing Agreements," for additional information regarding the terms of this investment. On March 8, 2017, all of the Company's investment in the subordinated convertible promissory notes were converted into preferred stock of Epic Sciences representing approximately 9% of Epic Sciences' voting interests, at which time the Company estimated the fair value of the subordinated convertible promissory notes to be approximately $7.1 million. In June 2018, the Company invested an additional $2.5 million in preferred stock of Epic Sciences as part of a new equity financing. As a result of this transaction, the Company's ownership interest in Epic Sciences was reduced to approximately 8%. 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 FASB ASC 810, Consolidation. The Company will continue to assess its investment and future commitments to the investee and to the extent its relationship with the investee changes, may be required to consolidate the investee in future periods. The Company determined that the investment is an equity investment for which the Company does not have the ability to exercise significant influence. Prior to the adoption of ASU 2016-01, the Company accounted for such preferred stock using the cost method of accounting and accordingly recorded such preferred stock in other assets. There were no identified events or changes in circumstances that had a significant adverse effect on the fair value of the preferred stock during the remainder of the year ended December 31, 2017. On January 1, 2018, the Company adopted ASU No. 2016-01 which changed the way it accounts for non-marketable

equity securities. The Company adjusts the carrying value of its non-marketable equity securities for changes from observable transactions for identical or similar investments of the same issuer, less impairment. All gains and losses on non-marketable equity securities, realized and unrealized, are recognized in other income (expense), net. As of June 30, 2018, the carrying value of the preferred stock of Epic Sciences was $10.8 million, of which $8.3 million was remeasured to fair value based on observable transactions during the three and six months ended June 30, 2018. The upward adjustment of $1.2 million was recorded as an unrealized gain on equity securities and included as an adjustment to the carrying value of other assets held as of June 30, 2018. The preferred stock of Epic Sciences is classified within Level 3 in the fair value hierarchy because the Company estimated the value during the three months ended June 30, 2018 utilizing an option pricing model that considered a recent observable transaction and other unobservable inputs including volatility and long-term plans of Epic Sciences.

During the year ended December 31, 2017, the Company invested $2.0 million in a convertible promissory note of Cleveland Diagnostics, Inc. (“Cleveland Diagnostics”). The investment in the convertible promissory note represented a

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variable interest in the investee. The Company had concluded it was not the primary beneficiary and thus had not consolidated the investee pursuant to the requirements of FASB ASC 810. The Company determined that it did not have the ability to exercise significant influence over the investee company. In June 2018, the Company made a business decision to terminate its milestone-based collaboration with Cleveland Diagnostics and wrote off the convertible promissory note. See Note 6, “Collaboration and Commercial Technology Licensing Agreements,” for additional information.

Derivative Financial Instruments

The Company hedges a portion of its foreign currency exposures related to outstanding monetary assets and liabilities using foreign currency forward contracts. The foreign currency forward contracts the Company uses to hedge the exposure are not designated as hedges, and as a result, changes in their fair value are recorded in other income (expense). As of June 30, 2018 and December 31, 2017, the Company had foreign currency contracts with notional amounts of $20.6 million and $16.1 million, respectively.

Impairment of Long Lived Assets

The Company reviews 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. For property and equipment and intangible assets, an impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. Impairment, if any, is assessed using undiscounted cash flows. For investments in non-marketable equity securities, evidence of impairment might include the absence of an ability to recover the carrying amount of the investment or the inability of the investee to sustain an earnings capacity which would justify the carrying amount of the investment. If the fair value of the investment is determined to be less than the carrying value, the asset is written down to its fair value. During the six months ended June 30, 2018, the Company wrote off $2.1 million and $2.3 million of previously capitalized equipment and software development costs, respectively, due to disposal activities. See Note 11, “Restructuring Costs” for additional information regarding the disposal activities. There was no impairment recorded during the three months ended June 30, 2018 and the three and six months ended June 30, 2017.

Recently Adopted 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 ASC 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. The Company

adopted Topic 606 as of January 1, 2018 using the modified retrospective transition method applied to those contracts which were not completed as of January 1, 2018. The Company recorded an increase to opening accounts receivable, net, and a reduction to opening accumulated deficit of $14.1 million as of January 1, 2018 due to the cumulative impact of adopting Topic 606, with the impact related to certain payors who were not accrual payors. See Note 2 for additional information.

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 Company adopted the ASU as of January 1, 2018 using the modified retrospective method for marketable equity securities and the prospective method for non-marketable equity securities. The Company recorded a reduction to accumulated deficit of $180,000 as of January 1, 2018 due to the cumulative impact of adopting the ASU, with the impact related to unrealized loss of Biocartis N.V. (“Biocartis”) common stock at December 31, 2017. The Company has elected to use the measurement alternative for its non-marketable equity securities, defined as cost adjusted for changes from observable transactions for identical or

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similar investments of the same issuer, less impairment. The adoption of ASU 2016-01 increases the volatility of other income (expense), net, as a result of the remeasurement of the Company's equity securities.

In November 2016, the FASB issued ASU Nos. 2016-15 and 2016-18 amending the presentation of restricted cash within the statement of cash flows. The guidance requires that restricted cash be included within cash and cash equivalents on the statement of cash flows. The ASU became effective retrospectively for reporting periods beginning after December 15, 2017. The Company adopted these standards effective January 1, 2018.

Recently Issued Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU No. 2016-02, 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. 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.

Note 2. Revenues

Adoption of ASC Topic 606, Revenue from Contracts with Customers

On January 1, 2018, the Company adopted Topic 606 using the modified retrospective method applied to those contracts which were not completed as of January 1, 2018. Results for reporting periods beginning after January 1, 2018 are presented under Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with the Company's historic accounting under Topic 605. See Note 1 of the Company's Annual Report on Form 10-K for the year ended December 31, 2017 for the Company's revenue recognition policy under Topic 605.

The Company recorded a one-time increase to opening accounts receivable, net, and a reduction to opening accumulated deficit of $14.1 million as of January 1, 2018 due to the cumulative impact of adopting Topic 606, with the impact related to certain payors who were not accrual payors.

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In accordance with the new revenue standard requirements, the disclosure of the impact of adoption on the Company's condensed consolidated balance sheet as of June 30, 2018 and statements of operations for the three and six months ended June 30, 2018 was as follows:

	As Reported	Balance Without Adoption of ASC 606	Adjustments
		(In thousands)	
Income statement			
Three Months Ended June 30, 2018			
Revenues:			
Product revenues	$ 95,619	$ 95,789	$ (170)
Operating expenses:			
General and administrative	18,487	18,990	(503)
Net income	8,317	7,984	333
Income statement			
Six Months Ended June 30, 2018			
Revenues:			
Product revenues	188,244	189,828	(1,584)
Operating expenses:			
General and administrative	38,205	39,732	(1,527)
Net income	4,542	4,599	(57)
Balance Sheet at June 30, 2018			
Assets:			
Accounts receivable, net	48,982	34,549	14,433
Equity:			
Accumulated deficit	(227,460)	(241,526)	14,066

Revenue Recognition

Revenues are recognized when control of the promised goods or services is transferred to customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods or services. The estimated uncollectible amounts that were historically classified as bad debt expense are now generally considered implicit price concessions that are a direct reduction to accounts receivable rather than allowance for doubtful accounts.

The majority of the Company's historical product revenues have been derived from the sale of its Oncotype DX breast cancer test. For product revenues, the Company estimates the transaction price which is the amount of consideration it expects to be entitled to receive in exchange for providing services based on its historical collection experience using a portfolio approach as a practical expedient to account for patient contracts as collective groups rather than individually. The Company monitors its estimates of transaction price to depict conditions that exist at each reporting date. If the Company subsequently determines that it will collect more consideration than it originally estimated for a contract with a patient, it will account for the change as an increase in the estimate of the transaction price in the period identified. Similarly, if the Company subsequently determines that the amount it expects to collect from a patient is less than it originally estimated, it will generally account for the change as a decrease in the estimate of the transaction price, provided that such downward adjustment does not result in a significant reversal of cumulative revenue recognized.

The Company's performance obligations are satisfied at one point in time when test reports are delivered. The Company also provides services to patients with whom the Company does not have contracts as defined in Topic 606. The Company recognizes revenue for these patients when contracts as defined in Topic 606 are established at the amount of consideration to which it expects to be entitled or when the Company receives substantially all of the consideration subsequent to the performance obligations being satisfied.

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During the first half of 2018, cash collections for certain tests delivered during the three months ended March 31, 2018 came in at rates higher than originally accrued. As a result, the Company changed its estimate of the amounts to be recognized for these tests and recognized an additional $884,000 of revenue for the three and six months ended June 30, 2018. These changes in estimates resulted in increases in net income per share of approximately $0.02 for the three and six months ended June 30, 2018.

The following table presents the Company's product revenues disaggregated by revenue source:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	(In thousands)		(In thousands)	
Invasive breast cancer test	$ 86,478	$ 78,517	$ 171,029	$ 156,575
Prostate cancer test	6,777	4,154	12,617	7,504
Other	2,364	2,816	4,598	5,388
Total product revenues	$ 95,619	$ 85,487	$ 188,244	$ 169,467

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. The Company typically uses an input method that recognizes revenue based on the Company's efforts to satisfy the performance obligation relative to the total expected inputs to the satisfaction of that performance obligation. Advance payments received in excess of revenues recognized are classified as deferred revenue until such time as the revenue recognition criteria have been met.

Note 3. Net Income (Loss) Per Share

Basic net income (loss) per share is calculated by dividing net income (loss) for the period by the weighted-average number of common shares outstanding for the period without consideration of potential common shares. Diluted earnings per share is calculated using the weighted-average number of common shares outstanding including the dilutive effect of stock awards as determined under the treasury stock method. In periods when the Company has a net loss, stock awards are excluded from the calculation of diluted net loss per share as their inclusion would have an antidilutive effect.

	Three Months Ended	Six Months Ended

	June 30, 2018	2017	June 30, 2018	2017
Numerator:				
Net income (loss)	$ 8,317	$ (2,739)	$ 4,542	$ (3,545)
Denominator:				
Weighted-average shares of common stock outstanding used in the calculation of basic net income (loss) per share	35,544	34,428	35,372	34,219
Effect of dilutive securities:				
Options to purchase common stock	840	—	660	—
Restricted stock units	308	—	309	—
ESPP	24	—	19	—
Total	1,172	—	988	—
Weighted-average shares of common stock outstanding used in the calculation of diluted net income (loss) per share	36,716	34,428	36,360	34,219
Basic net income (loss) per share	$ 0.23	$ (0.08)	$ 0.13	$ (0.10)
Diluted net income (loss) per share	$ 0.23	$ (0.08)	$ 0.12	$ (0.10)

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The Company excluded stock awards of 666,000 and 566,000 for the three and six months ended June 30, 2018 from the computation of diluted net income per share because their effect was anti-dilutive.

The Company excluded potentially dilutive stock awards of 788,000 and 774,000 for the three and six months ended June 30, 2017 from the computation of diluted net loss per share because they were anti-dilutive.

Note 4. Cash and Cash Equivalents, and Marketable Securities

The following tables set forth the Company's cash and cash equivalents, and marketable securities as of the dates indicated:

	June 30, 2018	December 31, 2017
	(In thousands)	
Cash and cash equivalents		
Cash	$ 33,821	$ 35,303
Money market deposits	10,552	10,215
Commercial paper	9,474	-
Total cash and cash equivalents	53,847	45,518
Marketable securities		
Commercial paper	52,918	30,272
Corporate debt securities	42,529	50,260
Corporate equity securities	3,651	3,525
Total marketable securities	99,098	84,057
Total cash and cash equivalents, and marketable securities	$ 152,945	$ 129,575

The following tables summarize the Company's available-for-sale securities that are measured at fair value as of the dates indicated:

	June 30, 2018			
	Cost or Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Total Estimated Fair Value
	(In thousands)			
Commercial paper	$ 52,928	$ 8	$ (18)	$ 52,918
Corporate debt securities	42,585	—	(56)	42,529
Total	$ 95,513	$ 8	$ (74)	$ 95,447

	December 31, 2017			
	Cost or Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Total Estimated Fair Value
	(In thousands)			
Commercial paper	$ 30,315	$ —	$ (43)	$ 30,272
Corporate debt securities	50,331	2	(73)	50,260
Corporate equity securities	4,020	—	(495)	3,525
Total	$ 84,666	$ 2	$ (611)	$ 84,057

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All of the Company's marketable securities had contractual maturities of one year or less as of June 30, 2018 and December 31, 2017.

The following table provides the breakdown of the available-for-sale marketable securities with unrealized losses as of the dates indicated:

	In a Loss Position for Less Than 12 Months	
	Gross Unrealized Losses	Estimated Fair Value
	(In thousands)	
As of June 30, 2018:		
Commercial paper	$ (18)	$ 30,406
Corporate debt securities	(56)	41,193
Total	(74)	$ 71,599
As of December 31, 2017:		
Commercial paper	$ (43)	$ 30,272
Corporate debt securities	(73)	45,110
Corporate equity securities	(495)	3,525
Total	$ (611)	$ 78,907

Marketable Equity Securities

Prior to January 1, 2018, the Company accounted for its marketable equity securities at fair value with unrealized gains and losses recognized in accumulated other comprehensive income on the balance sheet. Realized gains and losses on marketable equity securities sold or impaired were recognized in other income (expense), net.

On January 1, 2018, the Company adopted the ASU No. 2016-01 which changed the way the Company accounts for marketable equity securities. The Company's marketable equity securities are measured at fair value and starting January 1, 2018, unrealized gains and losses are recognized in other income (expense), net. Upon adoption, the Company reclassified $180,000 of unrealized loss related to marketable equity securities from accumulated other comprehensive income to opening accumulated deficit.

In December 2017, the Company invested €3.4 million or $4.0 million in 270,000 shares of the common stock of Biocartis, a public company listed on the Euronext exchange. This corporate equity security investment was accounted for as an available-for-sale marketable security and valued at €3.0 million or $3.5 million at December 31, 2017.

During the year ended December 31, 2017, $180,000 of unrealized losses relating to changes in the fair value of this investment were recorded in other comprehensive income. These securities are subject to a lock-up agreement which expires in December 2018. In accordance with ASU No 2016-01, the Company recorded an increase in fair value of $90,000 and $218,000 and a foreign currency revaluation loss of $231,000 and $91,000, in other income (expense), net for the three and six months ended June 30, 2018, respectively.

During the three months ended March 31, 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. There were no shares sold during the three and six months ended June 30, 2018. During the three months ended March 31, 2017, $1.1 million of unrealized gain, net of tax of $821,000 related to the shares sold was reclassified out of accumulated other comprehensive income into earnings.

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Note 5. 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, 2018 or December 31, 2017. The following tables set forth the Company's financial instruments that were measured at fair value on a recurring basis at June 30, 2018 and December 31, 2017 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, 2018

	(In thousands)			
As of June 30, 2018:				
Assets				
Money market deposits	$ 10,552	$ —	$ —	$ 10,552
Commercial paper	—	62,392	—	62,392
Corporate debt securities	—	42,529	—	42,529
Corporate equity securities	—	3,651	—	3,651
Total	$ 10,552	$ 108,572	$ —	$ 119,124

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	Actively Quoted Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	Balance at December 31, 2017
	(In thousands)			
As of December 31, 2017:				
Assets				
Money market deposits	$ 10,215	$ —	$ —	$ 10,215
Commercial paper	—	30,272	—	30,272
Corporate debt securities	—	50,260	—	50,260
Corporate equity securities	—	3,525	—	3,525
Convertible promissory note	—	—	1,329	1,329
Total	$ 10,215	$ 84,057	$ 1,329	$ 95,601

The Company's commercial paper and corporate debt securities are classified as Level 2 as they are valued using multi-dimensional relational pricing models that use observable market inputs, including benchmark yields, reported trades, broker-dealer quotes, issuer spreads, benchmark securities, bids, offers and reference data. Not all inputs listed are available for use in the evaluation process on any given day for each security evaluation. In addition, market indicators and industry and economic events are monitored and may serve as a trigger to acquire further corroborating market data. The Company's corporate equity securities are classified as Level 2 while subject to certain restrictions on sale.

The Company estimated its investment in a convertible promissory note of Cleveland Diagnostics to be approximately $1.3 million at December 31, 2017. The convertible promissory note was classified as Level 3 as it was valued using unobservable inputs that were primarily based on the Company's estimate of the fair value of the underlying preferred stock into which the note would be convertible. In June 2018, the Company made a business decision to terminate its milestone-based collaboration with Cleveland Diagnostics and wrote off the convertible promissory note. See Note 6, "Collaboration and Commercial Technology Licensing Agreements," for additional information.

Note 6. 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 $3.2 million and $3.8 million for the three and six months ended June 30, 2018, respectively, and $912,000 and $1.8 million for the three and six months ended June 30, 2017, 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 has specified options and rights relating to joint inventions arising out of these 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 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 $66,000 and $135,000 for the three and six months ended June 30, 2018, respectively, and $94,000 and $190,000 for the three and six months ended June 30, 2017, respectively, which were included in cost of product revenues.

In June 2016, the Company entered into a collaboration agreement with Epic Sciences, under which the Company was granted exclusive distribution rights to commercialize Epic Sciences' AR-V7 Nucleus Detect test in the United States, which is marketed 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, claims appeals, customer support, and providing and maintaining order management systems for the test. Epic Sciences is responsible for performing all tests, performing studies, including analytic and clinical validation studies, and seeking Medicare coverage and a Medicare payment rate from the Centers for Medicare and

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Medicaid Services ("CMS") for the test. Future revenues generated from the test will be shared by the Company and Epic Sciences in accordance with the terms of the agreement. During 2016 and 2017, the Company 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 estimated to be approximately $7.1 million while the difference of $375,000 was deferred as of December 31, 2017 and will be recognized as an additional cost of future purchases of Oncotype DX AR-V7 Nucleus Detect tests, which the Company believes will be at a discount to fair value. The Company originally agreed to invest an additional $2.5 million in Epic Sciences preferred stock, upon achievement of one of the milestones. In June 2018, prior to the achievement of the milestone, the Company invested an additional $2.5 million in Epic Sciences preferred stock and the milestone payment was waived by Epic Sciences. Additional terms of the agreement include the Company's obligation to pay Epic Sciences $4.0 million upon achievement of certain milestones. The collaboration agreement has a term of 10 years, unless terminated earlier under certain circumstances.

In September 2017, the Company entered into an exclusive license and development agreement with Biocartis, a molecular diagnostics company based in Belgium, to develop and commercialize an in vitro diagnostic ("IVD") version of the Oncotype DX breast cancer test on Biocartis' Idylla platform that can be performed locally by laboratory partners and in hospitals around the world. Under the terms of the license and development agreement, the Company has an exclusive, worldwide, royalty-bearing license to develop and commercialize an IVD version of the Oncotype DX breast cancer test on the Biocartis Idylla platform, and an option to expand the collaboration to include additional tests in oncology and urology. The Company has primary responsibility for developing, validating and obtaining regulatory authorizations and registrations for IVD Oncotype DX tests to be performed on the Idylla platform. The Company is also responsible for manufacturing and commercialization activities with respect to such tests. Pursuant to the license and development agreement, the Company recorded a one-time upfront license and option fee of €2.8 million, or $3.2 million, which is included in research and development expenses in the year ended December 31, 2017. In December 2017, the Company purchased 270,000 ordinary shares of Biocartis at the market price of €12.50 for a total cost of €3.4 million or $4.0 million. This investment is subject to a lock-up agreement that expires in December 2018. The investment has been recognized at fair value, which the Company believes to be $3.7 million and $3.5 million at June 30, 2018 and December 31, 2017, respectively. Additional terms of the license and development agreement include the Company's obligation to pay Biocartis an aggregate of €6.5 million in cash upon achievement of certain milestones, and royalties based primarily on the future sales volumes of the Company's test performed on the Idylla platform.

In November 2017, the Company entered into an exclusive licensing agreement with Cleveland Diagnostics to develop and commercialize new prostate cancer tests based on Cleveland Diagnostics' IsoPSA reagents and technology. During the year ended December 31, 2017, the Company invested $2.0 million in a convertible promissory note of Cleveland Diagnostics. The convertible promissory note has been recognized at fair value, which the Company estimated to be approximately $1.3 million at December 31, 2017 based on the Company's estimate of the fair value of the underlying preferred stock into which the note is convertible. In June 2018, the Company made a business decision to discontinue development of the IsoPSA assay and terminate its agreement with Cleveland Diagnostics following its internal review for advancing an early stage technology into the next phase of product development. As a result, the Company wrote off the convertible promissory note and interest accrued through the termination date in the aggregate amount of $1.4 million in the three months ended June 30, 2018.

Note 7. 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 $3.2 million for the three and six months ended June 30, 2018, respectively, and $1.6 million and $3.1 million for the three and six months ended June 30, 2017, respectively.

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Future non cancelable commitments under these operating leases at June 30, 2018 were as follows:

	Annual Payments (In thousands)
Years Ending December 31,	
2018 (remainder of year)	$ 3,130
2019	6,845
2020	7,008
2021	4,800
2022	4,176
2023 and thereafter	1,082
Total minimum payments	$ 27,041

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. Legal proceedings, including litigation, government investigations and enforcement actions, could result in material costs, occupy significant management resources and entail civil and criminal penalties, even if the Company ultimately prevails. Any of the foregoing consequences could result in serious harm to the Company’s business, results of operations and financial condition.

Note 8. Stock-Based Compensation

Stock Options

The following table summarizes the activities for stock options for the six months ended June 30, 2018:

	Outstanding Options	
	Number of	Weighted-Average

	Shares (In thousands)	Exercise Price
Balance at December 31, 2017	3,460	$ 26.42
Options granted	659	$ 34.89
Options exercised	(436)	$ 22.92
Options forfeited	(111)	$ 29.68
Options expired	—	$ 27.00
Balance at June 30, 2018	3,572	$ 28.31
Exercisable at June 30, 2018	2,268	$ 26.60
Vested and expected to vest at June 30, 2018	3,471	$ 28.22

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Restricted Stock Units

The following table summarizes the activities for restricted stock units ("RSU"s) for the six months ended June 30, 2018:

	Number of Shares (In thousands)	Weighted-Average Grant Date Fair Value
Balance at December 31, 2017	964	$ 28.25
RSUs granted	512	$ 33.31
RSUs vested	(400)	$ 28.38
RSUs cancelled	(177)	$ 30.13
Balance at June 30, 2018	899	$ 30.70

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, 2018, the Company issued 3,055 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 $32.68 per share.

Employee Stock Purchase Plan

During the six months ended June 30, 2018, 98,916 shares of common stock were issued pursuant to the Employee Stock Purchase Plan ("ESPP"). As of June 30, 2018, there was $657,000 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 was allocated as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	(In thousands)		(In thousands)	
Cost of product revenues	$ 224	$ 170	$ 451	$ 361
Research and development	1,070	1,443	2,333	2,831
Selling and marketing	1,345	1,478	2,632	2,989
General and administrative	2,516	2,106	4,925	4,121
Total	$ 5,155	$ 5,197	$ 10,341	$ 10,302

Note 9. 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, 2018, 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 Company adopted the requirements of Topic 606 on January 1, 2018 using the modified retrospective method, therefore there is a lack of comparability to the prior period presented. See Recently Adopted Accounting Pronouncements in Note 1 for additional information.

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,	
	2018	2017	2018	2017
	(In thousands)		(In thousands)	
United States	$ 81,440	$ 72,409	$ 160,307	$ 142,998
Outside of the United States	14,179	13,078	27,937	26,469
Total revenues	$ 95,619	$ 85,487	$ 188,244	$ 169,467

Note 10. Income Taxes

The Company recognized income tax expense of $218,000 and $458,000 for the three and six months ended June 30, 2018, respectively, and $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, 2018 was primarily comprised of foreign income tax expense. 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.

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, 2018 and December 31, 2017. 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 $2.6 million and $2.4 million of unrecognized tax benefits at June 30, 2018 and December 31, 2017, 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 remains open for the years 2001 through 2018 in U.S. federal and state jurisdictions, and for the years 2012 through 2018 in foreign jurisdictions.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 (the Act) was signed into law. Accounting Standards Codification 740, Income Taxes, requires companies to recognize the effect of the tax law changes in the period of enactment. However, the SEC staff issued Staff Accounting Bulletin 118, which allows companies to record provisional amounts during a measurement period that is similar to the measurement period used when accounting for business combinations. The Company adjusted its deferred tax assets and liabilities based on the reduction of the U.S. federal corporate tax rate from 35% to 21% as of December 31, 2017 and assessed the realizability of its deferred tax assets based on the current understanding of the provisions of the new law. As of June 30, 2018, the Company still considers its accounting for the impacts of the new law to be provisional and will continue to assess the impact of the recently enacted tax law on its business and condensed consolidated financial statements over the next six months.

Note 11. Restructuring Costs

On March 8, 2018, the Company announced its decision to no longer provide its commercial offering of Oncotype SEQ Liquid Select or any further investment in next generation sequencing (NGS) panels due to a decision to focus the Company's efforts to develop in vitro diagnostic test solutions and other tests with more predictable reimbursement,

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higher proprietary value and better prospects for global adoption. With this shift in strategic direction, the Company announced a reduction of its workforce of approximately 10%.

In March 2018, the Company recorded charges of $8.5 million consisting of $4.8 million in non-cash asset impairments and $3.7 million in employee separation charges, all of which were recorded as operating expenses in the condensed consolidated statements of operations. During the three months ended June 30, 2018, the Company recorded an additional separation charge of $69,000 and adjustments to reduce non-cash asset impairments for $80,000.

Of the $3.7 million of employee separation charges, the Company paid $628,000 during the three months ended March 31, 2018 and paid the remaining $3.1 million during the three months ended June 30, 2018.

There were no restructuring costs for the three and six months ended June 30, 2017.

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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 and our efforts to hedge such effects; our beliefs with respect to the benefits and attributes of our tests or collaborations 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 salesforce's 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 additional tests will result from our collaborations or license agreements; the applicability of clinical results to actual outcomes; our estimates and assumptions with respect to disease incidence and potential market opportunities; the occurrence, timing, outcome or success of clinical trials or studies; our expectations regarding timing of the announcement or publication of research results; the benefits of our technology platform; the economic benefits of our tests to the healthcare system; the ability of our tests to impact treatment decisions; our beliefs regarding our competitive position; our expectations regarding new and future technologies, including non-invasive test technology, and their potential benefits; our 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 billing and collections; 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, including the risk that we may lose Medicare coverage for our tests; the risk that reimbursement pricing or coverage for our tests may change; the risks and uncertainties associated with the regulation of our tests by the FDA or regulatory agencies outside of the U.S.; risks associated with the outcome

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of any legal proceeding, including litigation, government investigations and enforcement actions against us; the success of our new technology; the results of clinical studies; the applicability of clinical results to actual outcomes; the impact of new legislation or regulations, or of judicial decisions, on our business; our ability to compete against third parties; 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, Genomic Prostate 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 and intermediate risk disease. In February 2018, the Oncotype DX AR-V7 Nucleus Detect test for men with metastatic castration-resistant prostate cancer, or mCPRC, became commercially available. As of July 31, 2018, 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 the Oncotype DX AR-V7 Nucleus Detect test was $3,950. 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, 2018, more than 33,590 and 66,030 Oncotype test reports were delivered for use in treatment planning, compared to more than 31,550 and 63,130 test reports delivered for the same periods in 2017. All of our internally-developed tests are conducted at our clinical reference laboratory in Redwood City, California, which is accredited under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and certified by the College of American Pathologists, or CAP. 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 our tests, excluding Oncotype DX AR-V7 Nucleus Dectect, 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.

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We have expanded our clinical laboratory facilities and processing capacity to accommodate future test processing, research and development and general use office space. 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.

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. In August 2017, Palmetto GBA, a Medicare Administrative Contractor that processes Medicare claims and sets Medicare coverage and payment policies for certain tests performed by our laboratory, issued its final local coverage determination, or LCD, recommending Medicare coverage for use of our prostate cancer test in qualified patients with favorable intermediate-risk prostate cancer. Effective October 2017, Palmetto expanded their reimbursement coverage of our Oncotype DX prostate cancer test to include qualified patients with favorable intermediate-risk prostate cancer.

On December 16, 2015, Palmetto 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. 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 expanded our business in both the United States and international markets. Operational requirements generally vary from country to country, and different countries may have a public healthcare system, a combination of public and private healthcare system or a cash-based payment system. We have a direct commercial presence with employees in Canada, Japan and certain European countries, including our European headquarters in Geneva, Switzerland. Additionally, we have exclusive distribution agreements for the sale of our breast and colon cancer tests with distributors covering more than 90 countries outside of the United States.

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

We expect that international sales of our Oncotype 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

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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. 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 Tests

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.

In June 2018, the results of the Trial Assigning IndividuaLized Options for Treatment (Rx), or TAILORx, were published in The New England Journal of Medicine and presented at the plenary session of the 2018 American Society of Clinical Oncology annual meeting. The TAILORx trial was independently designed and led by ECOG-ACRIN Cancer Research Group under the sponsorship of the National Cancer Institute, or NCI. TAILORx represents the largest breast cancer treatment trial ever conducted, and thousands of investigators enrolled more than 10,000 women across approximately 1,200 sites in six countries. With regard to the primary endpoint, TAILORx enrolled approximately 7,000 women with Oncotype DX Breast Recurrence Score results of 11 to 25. This primary

study group was randomized to receive hormonal therapy with or without chemotherapy in order to more precisely define the benefit of chemotherapy, if any. These randomized patients with Oncotype DX Breast Recurrence Score results of 11 to 25 comprised approximately two-thirds of all TAILORx patients and were followed long-term, with nine-year outcomes reported. This group of women represents approximately 260,000 breast cancer patients diagnosed in major global markets each year. The TAILORx study definitively established that chemotherapy can be spared in at least 70 percent of patients. Tumor size or tumor grade did not predict chemotherapy benefit. Thus, the TAILORx trial established that chemotherapy treatment

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should be guided using the Oncotype DX breast cancer test as the genomic classifier. We anticipate that the results of the TAILORx study will have a positive impact on our invasive breast cancer revenue growth.

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 invasive breast cancer test in more than 90% 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 this test.

Oncotype DX Colon Cancer Test

We expect to continue to pursue adoption of and reimbursement for our Oncotype DX colon cancer test. 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. 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 August 2017, Palmetto issued its final LCD, recommending Medicare coverage for use of our prostate cancer test in qualified patients with favorable intermediate-risk prostate cancer. Effective October 2017, Palmetto expanded their reimbursement coverage of our Oncotype DX prostate cancer test to include qualified patients with favorable intermediate-risk prostate cancer.

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

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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 DX AR-V7 Nucleus Detect Test

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 the Oncotype DX AR-V7 Nucleus Detect test in the United States.

The Oncotype DX AR-V7 Nucleus Detect test is performed by Epic Sciences in its centralized laboratory in San Diego, California, which is accredited under CLIA and certified by CAP. This blood-based test detects the V7 variant of the androgen receptor, or AR, protein in the nucleus of CTCs, 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 began making the Oncotype DX AR-V7 Nucleus Detect test available through a clinical utility program in July 2017 and commercially available in February 2018.

We believe that this collaboration is complementary to our product development efforts for our other Oncotype 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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Commercial Collaborations

In September 2017, we entered into an exclusive license and development agreement with Biocartis N.V., or Biocartis, a molecular diagnostics company based in Belgium, to develop and commercialize an in vitro diagnostic, or IVD, version of the Oncotype DX breast cancer test on Biocartis' Idylla platform that can be performed locally by laboratory partners and in hospitals around the world. The Idylla platform offers a unique solution in the localization of complex molecular diagnostics. Using the sample-to-answer, real-time PCR-based cartridge of the Idylla platform, we intend to enable local pathology labs to generate Oncotype DX breast recurrence score results. Under the terms of the license and development agreement, we have an exclusive, worldwide, royalty-bearing, license to develop and commercialize an IVD version of our Oncotype DX breast cancer test on Biocartis' Idylla platform, and an option to expand the collaboration to include additional tests in oncology and urology. We have primary responsibility for developing, validating and registering IVD tests to be performed on the Idylla platform, and are also responsible for manufacturing and commercialization activities with respect to such tests.

In November 2017, we entered into an exclusive license agreement with Cleveland Diagnostics, Inc., or Cleveland Diagnostics, a biotechnology company based in Cleveland, Ohio, whereby we were granted exclusive global rights to develop and commercialize early- and late-stage cancer diagnostic tests based on Cleveland Diagnostics' proprietary IsoPSA reagent and solvent interaction analysis technology platform. In June 2018, we discontinued development of the IsoPSA assay and terminated our agreement with Cleveland Diagnostics. The decision to terminate was based on internal review of advancing an early stage product into the next phase of development.

See Note 6 in the Notes to Condensed Consolidated Financial Statements for additional information regarding the financial terms of our commercial collaboration agreements.

Product Development Opportunities

In addition to developing products to address new cancer areas, we seek to expand the clinical utility and addressable patient populations for our existing tests, including expanding our current test offerings to include tests that are performed as IVDs. 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 next-generation sequencing, or NGS, and digital PCR. Additionally, we believe potential new products can be implemented in the form of non invasive tests performed on blood or urine, similar to the Oncotype DX AR-V7 Nucleus Detect test.

We have also begun development of an IVD version of the Oncotype DX breast cancer test on Biocartis' Idylla platform that we believe will be able to be performed locally by laboratory partners and in hospitals around the world.

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.

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. We may pursue additional research and development opportunities and leverage our existing and future collaborations using other analytes such as circulating tumor cells, or CTCs, RNA, and proteins. Additionally, we may also use a number of other technologies across our various development programs and to implement our products.

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While early stage cancer continues to represent a significant opportunity with near term revenue potential, we believe we also have an opportunity to expand our business further along the patient's cancer journey, both through our research and development process and strategic collaborations.

We are also working with a number of different technologies, such as digital PCR and detection and capture methods for CTCs, and circulating tumor DNA, or ctDNA, to expand our capabilities, and continue to develop methods to enable genomic testing using a variety of biological materials such as blood and urine.

We have developed computer programs to automate our RT-PCR 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.

Economic Environment

Continuing concerns over entitlement and health care reform efforts, including efforts to repeal, replace or reduce the impact of the Affordable Care Act, or ACA, regulatory changes and taxation issues, and geopolitical issues have contributed to uncertain expectations both for the U.S. and global economies. These factors, combined with uncertainties in business and consumer confidence and continued concerns regarding the stability of some European Union member countries, have contributed to the expectations of slower domestic and global economic growth in the near term. We periodically evaluate the impact of the economic environment on our cash management, cash collection activities and volume of tests delivered.

As of the date of this report, we have not experienced a loss of principal on any of our short-term marketable securities, and we expect that we will continue to be able to access or liquidate these investments as needed to support our business activities. We periodically monitor the financial position of our significant third-party payors, which include Medicare and managed care companies. As of the date of this report, we do not expect the current economic environment to have a material negative impact on our ability to collect payments from third-party payors in the foreseeable future. We believe the economic environment and changes in the healthcare system continued to impact product payment cycles, growth in tests delivered and product revenue generated during the three and six months ended June 30, 2018. 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, both in the U.S. and in many foreign countries. The effect of the implementation of the ACA or any future changes to the ACA on our business is uncertain and, 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. Additionally, the ACA 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 through 2019, but is scheduled for re-imposition in 2020. Various proposals have been put forth, including by the FDA to regulate laboratory developed tests, or LDTs, as medical devices. Although none of our LDTs, such as our Oncotype DX breast, colon and prostate cancer tests, are currently listed with the FDA, we cannot assure you that the tax will not apply to services such as ours in the future.

In addition, the Protecting Access to Medicare Act of 2014, or PAMA, requires CMS to implement a substantial new payment system for certain clinical laboratory tests which became effective 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. CMS will use the rates and volumes reported

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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. As a result, effective January 1, 2018, our Medicare reimbursement rate for our invasive breast cancer test increased by more than 10%. This rate will be reassessed every three years.

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 for the Physician Quality Reporting System, the Value-based modifier program and the Electronic Health Record Meaningful Use program, and incentivizes physicians to enroll in alternative payment methods. At this time, we do not know whether these changes to the physician payment systems will have any impact on orders or payments for our tests.

Changes in Medicare Administrative Contractor (MAC) services

On a five-year rotational basis, Medicare requests bids for its regional MAC services. In September 2013, the claims processing function for our jurisdiction transitioned from Palmetto GBA, to Noridian, our current MAC. Palmetto GBA under their MolDx Program is continuing to establish coverage and coding 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 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, 2017. During the first quarter of 2018, we adopted new accounting guidance related to revenue recognition, accounting for financial instruments and presentation of restricted cash in the statement of cash flows, each of which is described below at “Recently Adopted Accounting Pronouncements.” There have been no other significant changes in our accounting policies during the six months ended June 30, 2018 as compared to the significant accounting policies described in our Annual Report on Form 10-K for the year ended December 31, 2017.

Results of Operations

Three and Six Months Ended June 30, 2018 and 2017

We recognized net income of $8.3 million and $4.5 million for the three and six months ended June 30, 2018, respectively, compared to a net loss of $2.7 million and $3.5 million for the three and six months ended June 30, 2017, respectively. On a basic and diluted per share basis, net income per share was $0.23 and $0.23, respectively, for the three months ended June 30, 2018, and $0.13 and $0.12, respectively, for the six months ended June 30, 2018. 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. 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, 2018, the substantial majority of our product revenues have been derived

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from the sale of our Oncotype DX breast cancer test. Payors are billed upon generation and delivery of test results to the ordering physician.

Revenues are recognized when control of the promised goods or services is transferred to customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods or services.

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2018	2017	2018	2017
	(In thousands)		(In thousands)	
Invasive breast cancer test	$ 86,478	$ 78,517	$ 171,029	$ 156,575
Prostate cancer test	6,777	4,154	12,617	7,504
Other	2,364	2,816	4,598	5,388
Product revenues	$ 95,619	$ 85,487	$ 188,244	$ 169,467
Period over period dollar increase in product revenues	$ 10,132		$ 18,777	
Period over period percentage increase in product revenues	12 %		11 %	

The period over period increase in product revenues resulted, in part, from increased adoption, as well as favorable rate increases resulting from new Medicare pricing and private payor contract renewals, and the January 1, 2018 adoption of the new revenue accounting standard ASC 606 as described in Note 2 in the Notes to the Condensed Consolidated Financial Statements and below at “Recently Adopted Accounting Pronouncements.” We adopted ASC 606 using the modified retrospective method, which applies the new standard prospectively, and therefore does not impact prior years’ reported revenue.

Test volume increased by 6% and 5% for the three and six months ended June 30, 2018 compared to the three and six months ended June 30, 2017. Of the growth in test volume, our U.S. invasive breast cancer and prostate cancer tests increased by 4% and 32%, respectively, for the three months ended June 30, 2018 compared to the same period in 2017. For the six months ended June 30, 2018 compared to the same period in 2017, test volume of our U.S. invasive breast cancer and prostate cancer tests increased 4% and 29%, respectively, offset by a 3% decrease in our international test volume.

International product revenues were $14.2 million, or 15% and $27.9 million or 15%, of product revenues for the three and six months ended June 30, 2018, respectively, compared to $13.1 million, or 15% and $26.5 million or 16%, respectively, of product revenues for the three and six months ended June 30, 2017.

Product revenues related to Medicare patients for the three and six months ended June 30, 2018 comprised 24% and 25%, respectively, of product revenues compared to 22% and 23% for each of the same periods in 2017. There were

no other third-party payors comprising product revenues of 10% or more for those periods.

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Cost of Product Revenues

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2018	2017	2018	2017
	(In thousands)		(In thousands)	
Tissue sample processing costs	$ 14,093	$ 13,534	$ 32,540	$ 26,920
Stock-based compensation	224	170	451	361
Total tissue sample processing costs	14,317	13,704	32,991	27,281
License fees	66	94	125	190
Total cost of product revenues	$ 14,383	$ 13,798	$ 33,116	$ 27,471
Period over period dollar increase in tissue sample processing costs	$ 559		$ 5,620	
Period over period percentage increase in tissue sample processing costs	4 %		21 %	

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.

Total tissue sample processing costs increased $559,000 for the three months ended June 30, 2018 compared to the three months ended June 30, 2017. Total tissue sample processing costs increased $5.6 million for the six months ended June 30, 2018 compared to the six months ended June 30, 2017. The increase for the six month period was primarily due to our March 2018 cessation of Oncotype SEQ, including Oncotype SEQ Liquid Select test, product development and commercialization activities, including a one-time write-off of fixed assets and inventory totaling $3.6 million as well as a $1.3 million increase in personnel-related expenses and stock-based compensation due to increased headcount and contract labor and an $86,000 increase in net cost allocations, also primarily due to increased headcount. We expect the cost of product revenues may 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,

	2018	2017	2018	2017
	(In thousands)		(In thousands)	
Personnel-related expenses	$ 8,425	$ 9,157	$ 20,092	$ 18,332
Stock-based compensation	1,070	1,443	2,333	2,831
Collaboration expenses	2,829	686	3,148	1,507
Reagents and laboratory supplies	1,249	1,218	1,961	1,995
Allocated information technology, facilities and other costs	282	1,636	381	3,112
Other costs	1,457	1,641	4,204	2,878
Total research and development expenses	$ 15,312	$ 15,781	$ 32,119	$ 30,655
Period over period dollar increase (decrease)	$ (469)		$ 1,464	
Period over period percentage increase (decrease)	(3) %		5 %	

Research and development expenses represent costs incurred to develop our technology, our pipeline products and continuous process improvement, and carry out clinical studies, primarily related to our ongoing work in breast 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.

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The $469,000, or 3%, decrease in research and development expenses for the three months ended June 30, 2018 compared to the three months ended June 30, 2017 was primarily due to a $1.4 million decrease in allocated information technology, facilities and other costs, a $732,000 decrease in personnel-related expense and a $373,000 decrease in stock-based compensation expense partially offset by a $2.1 million increase in collaboration expenses. The decreases in personnel-related expense and allocations are primarily due to the reduction in personnel as a result of our cessation of Oncotype SEQ in March 2018. The $2.1 million increase in collaboration expense is primarily due to a $990,000 milestone payment to Biocartis and a $1.3 million write-off of a convertible promissory note in connection with the termination of our collaboration with Cleveland Diagnostics.

The $1.5 million, or 5%, increase in research and development expenses for the six months ended June 30, 2018 compared to the six months ended June 30, 2017 was primarily due to a $1.6 million increase in collaboration expenses, a $1.8 million increase in personnel-related expense and a $1.3 million increase in other costs partially offset by a $2.8 million decrease in allocated information technology, facilities and other costs and a $498,000 decrease in stock-based compensation expense.

The $1.8 million increase in personnel-related expense and the $1.3 million increase in other costs for the six months ended June 30, 2018, was primarily attributable to $1.8 million in severance and other personnel-related costs and a $1.3 million write-off of assets related to our cessation of Oncotype SEQ, including the Oncotype SEQ Liquid Select test, product development and commercialization activities. The $1.8 million increase in collaboration expense includes a $990,000 milestone payment to Biocartis and a $1.3 million write-off of a convertible promissory note in connection with the termination of our collaboration with Cleveland Diagnostics. The offsetting decreases in allocations and stock-based compensation expense are primarily due to the reduction in personnel as a result of our cessation of Oncotype SEQ in March 2018.

We expect our research and development expenses to increase in future periods due to increased investment in our new product pipeline for breast, prostate and other cancers.

Selling and Marketing Expenses

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2018	2017	2018	2017
	(In thousands)		(In thousands)	
Personnel-related expenses	$ 20,082	$ 20,455	$ 42,218	$ 41,836
Stock-based compensation	1,345	1,478	2,632	2,989
Promotional and marketing materials	3,753	3,991	5,927	8,121
Travel, meetings and seminars	3,709	3,911	8,259	8,458

Collaboration expenses	413	226	666	340
Allocated information technology, facilities and other costs	9,915	9,512	20,108	18,262
Other costs	1,120	1,083	2,282	2,157
Total selling and marketing expenses	$ 40,337	$ 40,656	$ 82,092	$ 82,163
Period over period dollar decrease	$ (319)		$ (71)	
Period over period percentage decrease	(1) %		(0) %	

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.

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The $319,000, or 1%, decrease in selling and marketing expenses for the three months ended June 30, 2018 compared to the three months ended June 30, 2017 was primarily due to a $373,000 decrease in personnel-related expense, a $238,000 decrease in promotional marketing materials expense and a $202,000 decrease in travel expenses partially offset by a $403,000 increase in allocated information technology, facilities and other occupancy costs. The increase in allocations is primarily due to information technology-related projects to improve efficiencies for processing domestic and international orders of our tests.

Selling and marketing expenses for the six months ended June 30, 2018 compared to the six months ended June 30, 2017 were substantially flat and include a $1.8 million increase in allocated information technology, facilities and other occupancy costs and a $382,000 increase in personnel-related expense offset by a $2.2 million decrease in promotional marketing materials expense. The increase in personnel-related expense includes $1.0 million in severance and other personnel-related costs related to our cessation of Oncotype SEQ, including the Oncotype SEQ Liquid Select test, product development and commercialization activities offset by a decrease in expense from the reduction in personnel as a result of our cessation of Oncotype SEQ in March 2018. The increase in allocations is primarily due to information technology-related projects to improve efficiencies for processing domestic and international orders of our tests. The decrease in promotional and marketing materials is due to a combination of delayed programs in the first half of 2018 and non-recurring marketing programs in the first half of 2017.

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

General and Administrative Expenses

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2018	2017	2018	2017
	(In thousands)		(In thousands)	
Personnel-related expenses	$ 12,955	$ 13,490	$ 28,282	$ 26,668
Stock-based compensation	2,516	2,106	4,925	4,121
Occupancy and equipment expenses	8,733	8,583	17,091	16,334
Billing and collection fees	3,155	3,218	6,114	6,138
Bad debt expense	—	1,187	—	1,599
Professional fees and other expenses	3,361	3,117	6,452	5,744
Information technology, facilities and other cost allocations	(12,233)	(13,306)	(24,659)	(25,458)
Total general and administrative expenses	$ 18,487	$ 18,395	$ 38,205	$ 35,146
Period over period dollar increase	$ 92		$ 3,059	
Period over period percentage increase	1 %		9 %	

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

General and administrative expenses for the three months ended June 30, 2018 compared to the three months ended June 30, 2017 were substantially flat and included a $1.2 million decrease in bad debt expense and a $535,000 decrease in personnel-related expenses offset by a $1.1 million increase in allocated information technology, facilities and other occupancy costs allocated to other functional areas, a $410,000 increase in stock-based compensation expense and a $244,000 increase in professional fees and other expenses. The $1.1 million increase in allocated information technology, facilities and other occupancy costs allocated to other functional areas is primarily due to depreciation and amortization on equipment and facilities not in place in the prior year. There was no bad debt expense for the three months ended June 30, 2018 due to our implementation of the new revenue guidance on January 1, 2018, on a modified retrospective basis. However, we may incur bad debt expense in the future.

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The $3.1 million, or 9%, increase in general and administrative expenses for the six months ended June 30, 2018 compared to the six months ended June 30, 2017 was primarily due to a $1.6 million increase in personnel-related expenses, a $804,000 increase in stock-based compensation expense, a $799,000 increase in allocated information technology, facilities and other occupancy costs allocated to other functional areas, a $757,000 increase in occupancy and equipment expenses, and a $708,000 increase in professional fees and other expenses. These increases were partially offset by a $1.6 million decrease in bad debt expense. The $1.6 million increase in personnel-related expenses includes $909,000 in severance and other personnel-related costs related to our cessation of the Oncotype SEQ, including Oncotype SEQ Liquid Select test, product development and commercialization activities in March 2018, and a $793,000 increase in contract labor and consulting services related to evaluation of our business for process improvements and information technology enhancements. The $757,000 increase in occupancy and equipment expenses is primarily due to depreciation and amortization on equipment and facilities not in place in the prior year. There was no bad debt expense for the six months ended June 30, 2018 due to our implementation of the new revenue guidance on January 1, 2018, on a modified retrospective basis. However, we may incur bad debt expense in the future.

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.

Interest Income

Interest income was $400,000 and $817,000 for the three and six months ended June 30, 2018, respectively, compared to $206,000 and $364,000 for the three and six months ended June 30, 2017, respectively. The $194,000 and $453,000 increases in interest income for the three and six months ended June 30, 2018, respectively, over the comparable periods in 2017 were primarily due to increase in short-term investments held in commercial paper and corporate bonds. 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 in connection with the sale of our common stock of Invitae Corporation, or Invitae. As of June 30, 2017, we had sold all of our remaining shares of common stock of Invitae. There was no such activity for the comparable periods of 2018.

Unrealized gain on equity securities

For the three and six months ended June 30, 2017, we had unrealized gain on equity securities of $1.3 million and $1.4 million. There was no such activity for the comparable periods of 2018.

Other Income (Expense), Net

Other expense, net was $248,000 and other income, net was $61,000 for the three and six months ended June 30, 2018, respectively, compared to other income, net of $357,000 and $452,000 for the three and six months ended June 30, 2017. Other expense, net for the three months ended June 30, 2018 and other income, net for the six months ended June 30, 2018 was primarily related to $228,000 and $34,000 of net foreign currency losses and gains, 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, 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.

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Income Tax Expense (Benefit)

We recognized income tax expense of $218,000 and $458,000 for the three months ended June 30, 2018, respectively, which was computed using the “discrete” (or “cut-off”) method. Income tax expense for the three and six months ended June 30, 2018 was primarily composed of foreign income tax expense.

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.

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, 2018 and December 31, 2017. We will continue to maintain a full valuation allowance until there is sufficient evidence to support recoverability of our deferred tax assets.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 (the Act) was signed into law. Accounting Standards Codification 740, Income Taxes, requires companies to recognize the effect of the tax law changes in the period of enactment. However, the SEC staff issued Staff Accounting Bulletin 118, which allows companies to record provisional amounts during a measurement period that is similar to the measurement period used when accounting for business combinations. We adjusted our deferred tax assets and liabilities based on the reduction of the U.S. federal corporate tax rate from 35% to 21% as of December 31, 2017 and assessed the realizability of our deferred tax assets based on the current understanding of the provisions of the new law. As of June 30, 2018, we still consider our accounting for the impacts of the new law to be provisional and will continue to assess the impact of the recently enacted tax law on our business and condensed consolidated financial statements over the next six months.

Liquidity and Capital Resources

As of June 30, 2018, we had an accumulated deficit of $227.5 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, 2018	December 31, 2017
	(in thousands)	
Cash, cash equivalents and short-term marketable securities	$ 152,945	$ 129,575
Working capital	175,389	134,744

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, 2018, we had cash, cash equivalents and short-term investments of $152.9 million compared to $129.6 million at December 31, 2017. The $23.4 million increase was primarily attributable to an increase in cash generated from operations, 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. 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, 2018 and December 31, 2017, $49.0 million, or 18%, and $31.2 million, or 13%, respectively, of our total assets consisted of accounts receivable. The $17.8 million increase in accounts receivable from December 31, 2017 to

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June 30, 2018 was primarily due to the change in revenue recognition for certain payors who were not accrual payors prior to our adoption of the new revenue guidance.

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, 2018 and December 31, 2017, our weighted average DSOs were 68 days and 62 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, 2018 and December 31, 2017:

	June 30, 2018							
	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	$ 43,620	85 %	$ 25,713	$ 4,102	$ 3,803	$ 2,978	$ 2,998	4,026
Medicare	7,546	15	7,118	76	69	71	68	144
Total	51,166	100 %	$ 32,831	$ 4,178	$ 3,872	$ 3,049	$ 3,066	$ 4,170
Allowance for doubtful accounts	(2,184)							
Net accounts receivable	$ 48,982							

	December 31, 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	$ 27,017	77 %	$ 12,501	$ 5,028	$ 2,225	$ 1,771	$ 1,775	$ 3,717
Medicare	8,028	23	6,170	564	94	258	467	475
Total	35,045	100 %	$ 18,671	$ 5,592	$ 2,319	$ 2,029	$ 2,242	$ 4,192
Allowance for doubtful accounts	(3,884)							
Net accounts receivable	$ 31,161							

Cash Flows

The following table summarizes our cash flow activities:

	2018	2017
	(In thousands)	
For the six months ended June 30,		
Cash provided by (used in):		
Operating activities	$ 22,241	$ 11,899
Investing activities	(21,591)	(18,298)
Financing activities	7,757	8,208
Capital expenditures (included in investing activities above)	$ (4,225)	$ (8,057)

Cash Provided by Operating Activities

Cash provided by operating activities was $22.2 million for the six months ended June 30, 2018 and consisted primarily of net income of $4.5 million adjusted for non-cash items of $21.0 million and $3.3 million related to changes in operating assets and liabilities.

Cash provided by operating activities was $11.9 million for the six months ended June 30, 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 $1.6 million related to changes in operating assets and liabilities.

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Cash Used in Investing Activities

Cash used in investing activities for the six months ended June 30, 2018 was $21.6 million, consisting of $14.9 million net purchases of marketable securities, $4.2 million in capital expenditures related to the expansion of our business and an additional $2.5 million investment in preferred stock of Epic Sciences.

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 (Used in) Provided by Financing Activities

Cash used in financing activities for the six months ended June 30, 2018 was $7.8 million, consisting primarily of $12.5 million of proceeds from the issuance of our common stock upon the exercise of stock options offset by $4.8 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, 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.

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, 2017.

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 our research and development programs, our commercialization efforts related to Oncotype DX AR-V7 Nucleus Detect, our efforts to expand adoption of and reimbursement for our tests, our international expansion efforts

and our development of our IVD product and capabilities. We expect to spend approximately $10 million over the next 12 months for planned laboratory equipment, information technology and facilities expansion. We may also use cash to acquire or invest in complementary businesses, technologies, services or products. We expect that our cash, cash equivalents and short term marketable securities will also be used to fund working capital and for other general corporate purposes, such as licensing technology rights, distribution arrangements for our tests both within and outside of the United States or expanding our direct sales capabilities worldwide.

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

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

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

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

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

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

Off-Balance Sheet Arrangements

As of June 30, 2018, we had no off-balance sheet arrangements.

Recently Adopted Accounting Pronouncements

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In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or 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. We adopted Topic 606 as of January 1, 2018 using the modified retrospective transition method applied to those contracts which were not completed as of January 1, 2018. We recorded a one-time increase to opening accounts receivable, net, and a one-time reduction to opening accumulated deficit of $14.1 million as of January 1, 2018 due to the cumulative impact of adopting Topic 606, primarily related to certain payors who were not previously accrual payors. See Note 1 to the Condensed Consolidated Financial Statements for additional information.

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. We adopted the ASU as of January 1, 2018 using the modified retrospective method for marketable equity securities and the prospective method for non-marketable equity securities. We recorded a reduction to accumulated deficit of $180,000 as of January 1, 2018 due to the cumulative impact of adopting the ASU, with the impact related to unrealized loss on Biocartis common stock at December 31, 2017. We have elected to use the measurement alternative for our non-marketable equity securities, defined as cost adjusted for changes from observable transactions for identical or similar investments of the same issuer, less impairment. The adoption of ASU 2016-01 increases the volatility of our other income (expense), net, as a result of the remeasurement of our equity securities.

In November 2016, the FASB issued ASU Nos. 2016-15 and 2016-18 amending the presentation of restricted cash within the statement of cash flows. The guidance requires that restricted cash be included within cash and cash equivalents on the statement of cash flows. The ASU became effective retrospectively for reporting periods beginning after December 15, 2017. We adopted these standards effective January 1, 2018.

Recently Issued Accounting Pronouncements Not Yet Adopted

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 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.

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, 2018, we had cash, cash equivalents and short-term marketable securities of $152.9 million. We currently do not utilize derivative financial instruments to hedge interest rate exposure. The securities in our investment portfolio

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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, 2018, 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 (losses) of $(228,000) and $34,000 for the three and six months ended June 30, 2018, respectively and $347,000 and $424,000 for the three and six months ended June 30, 2017, respectively. The functional currency of our wholly-owned subsidiaries is the U.S. dollar, so we are not currently subject to gains and losses from foreign currency translation of the subsidiary financial statements. We use forward contracts to mitigate the impact of adverse movements in foreign exchange rates related to the remeasurement of monetary assets and liabilities and hedge our foreign currency exchange rate exposure. As of June 30, 2018 and December 31, 2017, we had foreign currency contracts with notional amounts of $20.6 million and $16.1 million, respectively. Although the impact of currency fluctuations on our financial results has been immaterial in the past, there can be no guarantee that the impact of currency fluctuations related to our international activities will not be material in the future.

ITEM 4. CONTROLS AND PROCEDURES.

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

in achieving its stated goals under all potential future 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 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, the Company may be subject to various legal proceedings and claims arising in the ordinary course of business. Legal proceedings, including litigation, government investigations and enforcement actions could result in material costs, occupy significant management resources and entail civil and criminal penalties, even if we ultimately prevail. The Company is currently being investigated by the United States Department of Justice related to its compliance with the Medicare Date of Service billing regulation. The Company received a civil investigative demand ("CID") in connection with this matter and has produced specific documents in response to the CID. An adverse outcome could include the Company being required to pay treble damages, and incur attorneys' fees, penalties and other adverse actions that could materially and adversely affect the Company's business, financial condition and results of operations. The Company is unable to predict the outcome and is unable to make a meaningful estimate of the amount or range of loss, if any, that could result from any unfavorable outcome.

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 and enter into collaborations, 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, 2018, we had an accumulated deficit of $227.5 million. We expect to continue to invest in our product pipeline, including our current Oncotype DX tests and future commercialized products, and to invest in our global commercial infrastructure, our laboratory operations, commercial collaborations, and other technologies. For the three and six months ended June 30, 2018, our research and development expenses were $15.3 million and $32.1 million, respectively, and our selling and marketing expenses were $40.3 million and $82.1 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 DX AR-V7 Nucleus Detect and the in-vitro diagnostic, or IVD, version of our Oncotype DX breast cancer test. As a result, we will need to generate significant growth in revenues in order to achieve sustained profitability. Our failure to achieve increased revenue or sustained profitability in the future could cause the market price of our common stock to decline.

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

Physicians and patients might not order our tests unless third party payors, such as managed care organizations as well as government payors such as Medicare and Medicaid and government 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 invasive 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 tests, 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

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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 and for favorable intermediate risk patients. However, we may not be able to obtain Medicare reimbursement coverage for our prostate cancer test for patients with different risk profiles 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 and maintain broad adoption of and reimbursement for all of our tests and any future tests we may develop, our reputation could be harmed and our future prospects and our business could suffer.

Under the terms of the coverage determinations for our Oncotype DX prostate cancer test, coverage for the test for patients with certain risk profiles 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 Medicare Administrative Contractor, or MAC, services. In September 2013, the claims processing function for our jurisdiction transitioned from Palmetto to Noridian Healthcare Solutions, although coverage determinations for our tests remain with Palmetto at this time through the MolDx Program. Future changes in the MAC with jurisdiction over our tests may affect our ability to obtain Medicare coverage and reimbursement for products for which we have coverage, for products for which we do not yet have coverage or for any products we may launch in the future or delay payments.

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

Our financial results depend largely on the sales of one test, our Oncotype DX 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. 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 or product enhancements to our currently commercialized tests, our revenues and our ability to achieve sustained profitability would be impaired.

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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 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, as well as an increase in the administrative requirements for reimbursement of claims. Noridian Healthcare Solutions and Palmetto GBA, the MACs that process Medicare claims and set Medicare coverage policies, respectively, for most tests billed by our laboratory and other MACs review coverage and decisions regularly.

The Protecting Access to Medicare Act of 2014, or PAMA, implements a substantial new payment system for clinical laboratory tests under the Clinical Laboratory Fee Schedule, or CLFS. Under PAMA, Medicare payment rates for tests are equal to the volume-weighted median of the private payor payment rates for such tests. The payment rates calculated under PAMA apply to our tests effective 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. Laboratories that fail to report or erroneously report the required payment information may be subject to substantial civil money penalties. We believe our Oncotype DX tests each meet the criteria to be considered advanced diagnostic laboratory tests. 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 under PAMA that 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, and patient self pay. In many countries outside of the United States, various coverage, pricing and reimbursement approvals are required for our tests to be available to patients. 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, or the reimbursement may be conditioned upon local performance of the tests or other requirements we may have difficulty satisfying. Reimbursement levels outside of the United States may vary considerably from the domestic reimbursement amounts we receive. In addition, because we rely on distributors to obtain reimbursement for our tests outside of the United States, 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, if a distributor fails to pay us or 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 24% and 25% of our product revenues for the three and six months ended June 30, 2018, respectively, and 22% and 23% of our product revenues for the three and six months ended June 30, 2017, respectively. Accounts receivable on behalf of patients directly covered by Medicare represented 15% and 23% of our total accounts receivable at June 30, 2018 and December 31, 2017, 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, 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

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payable to us. Any such action could have a negative impact on our business, financial condition and results of operations. In addition, as described in Item 1 – Legal Proceedings, we are being investigated by the United States Department of Justice related to our compliance with a Medicare billing regulation related to the date of service for our tests. An adverse outcome could include us being required to pay treble damages, and incur attorneys' fees, penalties and other adverse actions, that could materially and adversely affect our business, financial condition and results of operations.

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 Medicare billing rules, payment for our Oncotype DX tests performed on Medicare beneficiaries who were hospital patients at the time the tumor tissue samples were obtained and whose tests were ordered less than 14 days from discharge must be bundled into the payment that the hospital receives for the services provided. Effective January 1, 2018, this Medicare rule changed such that we may now bill Medicare directly for tests performed on Medicare beneficiaries who were hospital outpatients at the time the tumor tissue samples were obtained following an outpatient encounter. The rule remains unchanged with respect to payment for our Oncotype DX tests performed on Medicare beneficiaries who were hospital inpatients at the time the tumor tissue or blood samples were obtained and whose tests were ordered less than 14 days from discharge – payment for those tests must be bundled into the payment that the hospital receives for its services provided. 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. We refer to this rule, as has been in effect and most recently amended as of January 1, 2018, as the Medicare Date of Service billing regulation.

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 payors 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. In addition, as described in Item 1 – Legal Proceedings, we are being investigated by the United States Department of Justice related to our compliance with the Medicare Date of Service billing regulation. An adverse outcome could include us being required to pay treble damages, and incur attorneys' fees, penalties and other adverse actions, that could materially and adversely affect our business, financial condition and results of operations.

If our 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 DX 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. Our 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 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

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reasonable terms, or that it would be able to meet our quality or regulatory 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 resume 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 or other collaborations. 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 only recent 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, and we are determined to be the primary beneficiary of that 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.

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:

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difficulties in complying with multiple, conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, data protection 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;

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- 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 salesforce 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, or similar anti-bribery or anti-corruption laws or regulations, such as the U.K. Anti-bribery Act and the U.K. Criminal Finances Act.

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 months ended June 30, 2018, approximately 9% of our product revenues came from foreign denominated currencies. If the U.S. dollar strengthens against foreign currencies, the translation of these foreign currency denominated transactions will result in decreased revenues and operating expenses and increased net losses. We may not be able to offset adverse foreign currency impact with increased revenues. Beginning in September 2017, we enter into forward contracts to mitigate the impact of adverse movements in foreign exchange rates related to the re-measurement of monetary assets and liabilities and hedge our foreign currency exchange rate exposure. Even with this strategy in place to mitigate balance sheet foreign currency risk, we will not eliminate our exposure to foreign exchange rate fluctuations on our financial results.

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

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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. Unexpected errors or delays could also harm our ability to operate certain aspects of our business or to file our periodic reports in a timely manner.

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

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

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

In the ordinary course of our business, we and our third-party billing and collections provider collect and store sensitive data, including legally protected health information, sensitive personal data, 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

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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 ability 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 therein 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, similar U.S. state data protection regulations, the E.U. General Data Protection Regulation, or GDPR, and other regulations, the breach of which could result in significant penalties. Unauthorized access, loss or disclosure 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. We have self-certified with the Department of Commerce for compliance with the U.S.-E.U. Privacy Shield as of August 1, 2016, 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 prior Safe Harbor data transfer 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. Compliance with Privacy Shield requirements does not, in addition, equate to compliance with the stringent requirements of the GDPR. European data protection authorities could interpret or apply European data protection law in a manner that is inconsistent with our practices. If so, this could result in prohibitions on processing of data required to perform our tests in Europe or government-imposed fines, or both, which could adversely affect our business. Complying with these various laws could in addition cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business.

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

The marketing, sale and use of our tests could lead to the filing of product liability claims if someone were to allege that our tests failed to perform as designed. We may also be subject to liability for errors in the test results we provide to physicians or for a misunderstanding of, or inappropriate reliance upon, the information we provide. For example, physicians sometimes order our Oncotype DX breast cancer test for patients who do not have the specific clinical attributes indicated on the report form as those for whom the test provides clinical information validated by 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.

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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. 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 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. Notably, Congress enacted legislation in 2017 that eliminates the ACA’s individual insurance mandate beginning in 2019, which may significantly impact the number of covered lives participating in exchange plans. 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.

Although individual states' reimbursement methodology has not materially affected the payment rate for our tests recently, we cannot be certain that future changes will not affect payment rates. We also cannot predict whether future

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healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which we may do business, or the effect any future legislation or regulation will have on us. The taxes imposed by new legislation, cost reduction measures and the expansion in government's role in the U.S. healthcare industry may result in decreased profits to us, lower reimbursements by payors for our products or reduced medical procedure volumes, all of which may adversely affect our business, financial condition and results of operations. In addition, sales of our tests outside the United States make us subject to foreign regulatory requirements and cost reduction measures, which may also change over time.

If the FDA were to begin regulating our laboratory developed 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. It is unclear at this time if or when the FDA will finalize its plans to end enforcement discretion for LDTs; 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 for our current LDTs, 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

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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 and limiting or prohibiting the purchase of reagents necessary to perform testing.

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

If the FDA decides to regulate any of our LDTs, 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 those trials. We may also depend on clinical investigators, medical institutions and contract research organizations to perform certain aspects of 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 LDTs, 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 and certain laboratories with whom we collaborate, including Epic Sciences, Inc., or Epic Sciences, 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 and Epic Sciences each have a current certificate of accreditation under CLIA to perform testing through our accreditations by the College of American Pathologists, or CAP. To renew a CLIA certificate, laboratories are subject to survey and inspection every two years and inspectors may also make random inspections of clinical reference laboratories.

Although we and Epic Sciences are required to hold a certificate of accreditation or compliance under CLIA to perform high complexity testing, laboratories are not required to hold a certificate of accreditation through CAP. We and Epic Sciences 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 accreditation under CAP were to terminate, either voluntarily or involuntarily, it would be necessary to convert from a certification under CLIA to a certificate of compliance (or to a certificate of accreditation with another accreditation organization)

in order to maintain our ability to perform clinical tests and to continue commercial operations. Whether we or Epic Sciences would be able to successfully maintain operations through either of these alternatives would depend upon the facts and circumstances surrounding the termination of the 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).

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We and certain laboratories with whom we collaborate, including Epic Sciences, 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 clinical reference laboratories, including the training and skills required of personnel and quality control.

In addition, clinical reference laboratories are 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 licenses are maintained to test specimens from patients in those states. Other states may have similar requirements or may adopt similar requirements in the future. Finally, we may be subject to regulation in foreign jurisdictions as we seek to expand international distribution of our tests, which may require regulatory review of our tests in order for them to be offered, 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 or any laboratory with whom we collaborate, including Epic Sciences, were to lose 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. Additionally, if we or any laboratory with whom we collaborate were to lose a license in New York or in other states where a license is required, specimens from those states would not be able to be tested.

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, the European Data Protection Directive, the GDPR, and the E.U. In Vitro Diagnostic Device Regulation, all of which apply or will 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.

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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. As described further in Item 1 – Legal Proceedings, we are being investigated by the United States Department of Justice related to our compliance with the Medicare Date of Service billing regulation. An adverse outcome could include our being required to pay treble damages, and incur attorneys' fees, penalties and other adverse actions that could materially and adversely affect our business, financial condition and results of operations.

We have adopted policies and procedures designed to comply with these laws. In the ordinary course of our business, we conduct internal reviews of our compliance with these laws. Our compliance is also subject to governmental review. The growth of our business and sales organization and our expansion outside of the United States may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including civil and criminal penalties, damages and fines, we could be required to refund payments received by us, and we could lose the ability to bill for our tests 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, including an IVD version of our invasive breast cancer test, and devote considerable resources to research and development. There can be no assurance that our new Oncotype tests or IVD versions of our current 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 products we launch will attain use among the intended target of community oncologists and pathologists. 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

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- develop and scale our infrastructure including our operational systems such as order-to-cash, supply chain, and inventory management, and customer service to establish and add new capabilities.

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

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

Few research and development projects result in commercial products, and success in early clinical trials often is not replicated in later studies. At any point, we may abandon development of a product candidate or we may be required to expend considerable resources repeating clinical trials, which would adversely impact the timing for generating potential revenues from those product candidates. If a clinical validation study fails to demonstrate the prospectively defined endpoints of the study, we might choose to abandon the development of the product or product feature that was the subject of the clinical trial, which could harm our business. In addition, competitors may develop and commercialize competing products faster than we are able to do so.

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 and we examine additional means through which we can provide our tests, 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 salesforce. In addition, we will need to demonstrate our ability to obtain and maintain adequate reimbursement coverage from third party payors.

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.

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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 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, 2018, 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. Despite contractual obligations, 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

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Biosciences Inc., Hologic Inc., Myriad Genetics Inc. (and its Sividon Diagnostics subsidiary), NanoString Technologies Inc., NeoGenomics, Inc. and Qiagen N.V. As we look to expand our research, development and commercialization efforts, we may face competition from companies such as Danaher Corporation (and its Cepheid, Inc. subsidiary), Exosome Diagnostics, Inc., Grail, MDxHealth, Metamark Genetics, Inc., Natera Inc. and Personal Genome Diagnostics, Inc. Historically, our principal competition for our Oncotype tests has also come from existing diagnostic methods used by pathologists and oncologists, and such 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, and Siemens AG, as well as other companies and academic and research institutions.

In our more recently 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 test and the recently launched Oncotype DX AR-V7 Nucleus Detect 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. 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 agreements with alternate collaborators 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. We have found the publication of clinical data in peer reviewed journals to be 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 only recent experience in commercializing products through collaborations with third parties, which includes our commercial collaboration with Epic Sciences and our license and development agreement with Biocartis. The collaboration with Epic Sciences 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 legal, regulatory, quality and governmental risks with regards to the performance and delivery of Oncotype DX AR-V7 Nucleus Detect tests, due to the fact 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
31.1	Rule 13a-14(a) Certification of Chief Executive Officer.
31.2	Rule 13a-14(a) Certification of Chief Financial Officer.
32.1#	Statement of Chief Executive Officer under Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. §1350).
32.2#	Statement of Chief Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. §1350).
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase.
101.DEF	XBRL Taxonomy Extension Definition Linkbase.
101.LAB	XBRL Taxonomy Extension Label Linkbase.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase.

#In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release No. 34-47986, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10-Q and will not be deemed "filed" for purposes of Section 18 of the 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 7, 2018 By: /s/ Kimberly J. Popovits
Kimberly J. Popovits
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 7, 2018 By: /s/ G. Bradley Cole

G. Bradley Cole
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)