UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2017.

OR

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

For the transition period from _____ to _____.

Commission File Number 001-16537

ORASURE TECHNOLOGIES, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**36-4370966**
(State or Other Jurisdiction of Incorporation or Organization)	**(IRS Employer Identification No.)**
220 East First Street, Bethlehem, Pennsylvania	**18015**
(Address of Principal Executive Offices)	**(Zip code)**

(610) 882-1820
(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 (§232.405 of this chapter) 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, a 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.

Large accelerated filer	☐		
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☐
Accelerated filer	☒	Emerging growth company	☐

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. ☐

Indicate by checkmark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

Number of shares of Common Stock, par value $.000001 per share, outstanding as of May 4, 2017: 57,762,761 shares.

PART I. FINANCIAL INFORMATION

PART II. OTHER INFORMATION

Item 1. FINANCIAL STATEMENTS

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(Unaudited)
(in thousands, except per share amounts)

	March 31, 2017	December 31, 2016
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 120,851	$ 107,959
Restricted cash	1,831	1,831
Short-term investments	18,776	11,160
Accounts receivable, net of allowance for doubtful accounts of $588 and $484	24,005	19,827
Inventories	12,707	11,799
Prepaid expenses	1,732	1,722
Other current assets	633	2,143
Total current assets	180,535	156,441
PROPERTY AND EQUIPMENT, net	20,134	20,033
INTANGIBLE ASSETS, net	9,779	10,337
GOODWILL	18,971	18,793
OTHER ASSETS	3,173	2,331
	$ 232,592	$ 207,935
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 7,286	$ 4,633
Deferred revenue	1,306	1,388
Accrued expenses	9,685	11,314
Total current liabilities	18,277	17,335
OTHER LIABILITIES	3,160	2,304
DEFERRED INCOME TAXES	2,330	2,446
COMMITMENTS AND CONTINGENCIES (Note 7)		
STOCKHOLDERS' EQUITY		
Preferred stock, par value $.000001, 25,000 shares authorized, none issued	—	—
Common stock, par value $.000001, 120,000 shares authorized, 57,664 and 56,001 shares issued and outstanding	—	—
Additional paid-in capital	360,612	350,528
Accumulated other comprehensive loss	(13,770)	(14,220)
Accumulated deficit	(138,017)	(150,458)
Total stockholders' equity	208,825	185,850
	$ 232,592	$ 207,935

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF INCOME
(Unaudited)
(in thousands, except per share amounts)

	Three Months Ended March 31,	
	2017	2016
NET REVENUES:		
Product	$ 31,482	$ 25,245
Other	1,064	3,844
	32,546	29,089
COST OF PRODUCTS SOLD	12,236	8,776
Gross profit	20,310	20,313
OPERATING EXPENSES:		
Research and development	2,970	2,366
Sales and marketing	6,877	8,706
General and administrative	7,092	6,542
Gain on litigation settlement	(12,500)	—
	4,439	17,614
Operating income	15,871	2,699
OTHER INCOME (EXPENSE)	467	(192)
Income before income taxes	16,338	2,507
INCOME TAX EXPENSE	3,897	61
NET INCOME	$ 12,441	$ 2,446
EARNINGS PER SHARE:		
BASIC	$ 0.22	$ 0.04
DILUTED	$ 0.21	$ 0.04
SHARES USED IN COMPUTING EARNINGS PER SHARE:		
BASIC	56,929	55,451
DILUTED	58,772	56,079

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(Unaudited)
(in thousands)

	Three Months Ended March 31,	
	2017	2016
NET INCOME	$ 12,441	$ 2,446
OTHER COMPREHENSIVE INCOME		
Currency translation adjustments	450	2,867
COMPREHENSIVE INCOME	$ 12,891	$ 5,313

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(in thousands)

	Three Months Ended March 31,	
	2017	2016
OPERATING ACTIVITIES:		
Net income	$ 12,441	$ 2,446
Adjustments to reconcile net income to net cash provided by operating activities:		
Stock-based compensation	1,518	1,452
Depreciation and amortization	1,408	1,354
Amortization of lease incentives	(20)	(19)
Amortization of debt issue costs	31	—
Unrealized foreign currency (gain) loss	(1)	141
Deferred income taxes	(139)	(18)
Changes in assets and liabilities		
Accounts receivable	(4,143)	2,489
Inventories	(893)	990
Prepaid expenses and other assets	1,505	26
Accounts payable	2,619	758
Deferred revenue	(84)	(2,504)
Accrued expenses and other liabilities	(1,623)	(2,371)
Net cash provided by operating activities	12,619	4,744
INVESTING ACTIVITIES:		
Purchases of short-term investments	(7,514)	(7,689)
Proceeds from maturities of short-term investments	—	7,689
Purchases of property and equipment	(878)	(1,593)
Net cash used in investing activities	(8,392)	(1,593)
FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	9,417	—
Repurchase of common stock	(851)	(3,187)
Net cash provided by (used in) financing activities	8,566	(3,187)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	99	500
NET INCREASE IN CASH AND CASH EQUIVALENTS	12,892	464
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	107,959	94,094
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 120,851	$ 94,558
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for income taxes	$ 1,949	$ 84
Noncash investing activities (accrued property and equipment purchases)	$ 297	$ 444

See accompanying notes to the consolidated financial statements.

1. The Company

We develop, manufacture, market and sell diagnostic products and specimen collection devices using our proprietary technologies, as well as other diagnostic products, including immunoassays and other *in vitro* diagnostic tests that are used on other specimen types. Our diagnostic products include tests that are performed on a rapid basis at the point-of-care, tests that are processed in a laboratory, and include a rapid point-of-care HIV in-home test approved for use in the domestic consumer retail or over-the-counter ("OTC") market and a rapid point-of-care HIV self-test used in certain international markets. We also manufacture and sell devices used to collect, stabilize, transport and store samples of genetic material for molecular testing in the consumer genetic, clinical genetic, academic research, pharmacogenomic, personalized medicine, microbiome and animal genetic markets. Lastly, we manufacture and sell medical devices used for the removal of benign skin lesions by cryosurgery, or freezing. Our products are sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations, public health organizations, research and academic institutions, distributors, government agencies, physicians' offices, commercial and industrial entities, retail pharmacies and mass merchandisers, and to consumers over the internet.

2. Summary of Significant Accounting Policies

Principles of Consolidation and Basis of Presentation. The consolidated financial statements include the accounts of OraSure Technologies, Inc. ("OraSure") and its wholly-owned subsidiary, DNA Genotek, Inc. ("DNAG"). All intercompany transactions and balances have been eliminated. References herein to "we," "us," "our," or the "Company" mean OraSure and its consolidated subsidiary, unless otherwise indicated.

The accompanying consolidated financial statements are unaudited and, in the opinion of management, include all adjustments (consisting only of normal and recurring adjustments) necessary for a fair presentation of our financial position and results of operations for these interim periods. These financial statements should be read in conjunction with the financial statements and notes thereto included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016. Results of operations for the three months ended March 31, 2017 are not necessarily indicative of the results of operations expected for the full year.

Use of Estimates. The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions about future events. These estimates and underlying assumptions affect the amounts of assets and liabilities reported, disclosures about contingent assets and liabilities, and reported amounts of revenues and expenses. Such estimates include the valuation of accounts receivable and inventories and assumptions utilized in impairment testing for intangible assets and goodwill, as well as calculations related to contingencies, accruals, and performance- based compensation expense, among others. These estimates and assumptions are based on management's best estimates and judgment. Management evaluates its estimates and assumptions on an ongoing basis, using historical experience and other factors, which management believes to be reasonable under the circumstances, including the current economic environment. We adjust such estimates and assumptions when facts and circumstances dictate. Illiquid credit markets, volatile equity and foreign currency markets, reductions in government funding, and declines in consumer spending have combined to increase the uncertainty inherent in such estimates and assumptions. As future events and their effects cannot be determined with precision, actual results could differ significantly from these estimates. Changes in those estimates resulting from continuing changes in the economic environment and other factors will be reflected in the financial statements in those future periods.

Short-Term Investments. We consider all short-term investments to be available-for-sale securities. These securities are comprised of guaranteed investment certificates with purchased maturities greater than ninety days. Available-for-sale securities are carried at fair value, based upon quoted market prices, with unrealized gains and losses, if any, reported in stockholders' equity as a component of accumulated other comprehensive loss.

Our available-for-sale securities as of March 31, 2017 and December 31, 2016 consisted of guaranteed investment certificates with amortized cost and fair value of $18,776 and $11,160, respectively.

Fair Value of Financial Instruments. As of March 31, 2017 and December 31, 2016, the carrying values of cash and cash equivalents, accounts receivable, and accounts payable approximate their respective fair values based on their short-term nature.

Fair value measurements of all financial assets and liabilities that are being measured and reported on a fair value basis are required to be classified and disclosed in one of the following three categories:

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2: Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability; and

Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

Included in cash and cash equivalents at March 31, 2017 and December 31, 2016, was $82,142 and $83,704 invested in government money market funds. These funds have investments in government securities and are Level 1 instruments.

We offer a nonqualified deferred compensation plan for certain eligible employees and members of our Board of Directors. The assets of the plan are held in the name of the Company at a third-party financial institution. Separate accounts are maintained for each participant to reflect the amounts deferred by the participant and all earnings and losses on those deferred amounts. The assets of the plan are held in mutual funds and Company stock. The fair value of the plan assets as of March 31, 2017 and December 31, 2016 was $2,828 and $1,980, respectively, and was calculated using the quoted market prices of the assets as of those dates. All investments in the plan are classified as trading securities and measured as Level 1 instruments. The fair value of plan assets is included in other assets with the same amount included in other liabilities in the accompanying consolidated balance sheets.

All of our available-for-sale securities are measured as Level 1 instruments as of March 31, 2017 and December 31, 2016.

In 2017, we purchased certificates of deposit (“CD”) from a commercial bank. The CDs bear interest at an annual rate ranging from 0.28% to 0.44% and mature monthly through February 28, 2018. The carrying values of the CDs approximate their fair value. These CDs serve as collateral for certain standby letters of credit and are reported as restricted cash on the accompanying consolidated balance sheets. Also see Note 7 – Commitments and Contingencies.

Inventories. Inventories are stated at the lower of cost and net realizable value determined on a first-in, first-out basis and are comprised of the following:

	March 31, 2017	December 31, 2016
Raw materials	$ 5,024	$ 5,399
Work in process	1,035	1,034
Finished goods	6,648	5,366
	$ 12,707	$ 11,799

Property and Equipment. Property and equipment are stated at cost. Additions or improvements are capitalized, while repairs and maintenance are charged to expense. Depreciation and amortization are provided using the straight-line method over the estimated useful lives of the related assets. Buildings are depreciated over twenty to

forty years, while computer equipment, machinery and equipment, and furniture and fixtures are depreciated over two to ten years. Building improvements are amortized over their estimated useful lives. When assets are sold, retired, or discarded, the related property amounts are relieved from the accounts, and any gain or loss is recorded in the consolidated statements of income. Accumulated depreciation of property and equipment as of March 31, 2017 and December 31, 2016 was $36,856 and $36,067, respectively.

Intangible Assets. Intangible assets consist of a customer list, patents and product rights, acquired technology and tradenames. Patents and product rights consist of costs associated with the acquisition of patents, licenses, and product distribution rights. Intangible assets are amortized using the straight-line method over their estimated useful lives of seven to fifteen years. Accumulated amortization of intangible assets as of March 31, 2017 and December 31, 2016 was $15,944 and $15,197, respectively. The change in intangibles from $10,337 as of December 31, 2016 to $9,779 as of March 31, 2017 is a result of $637 in amortization expense and $79 in foreign currency translation gains.

Goodwill. Goodwill represents the excess of the purchase price we paid over the fair value of the net tangible and identifiable intangible assets acquired and liabilities assumed in our acquisition of DNAG in August 2011. Goodwill is not amortized but rather is tested annually for impairment or more frequently if we believe that indicators of impairment exist. Current U.S. generally accepted accounting principles permit us to make a qualitative evaluation about the likelihood of goodwill impairment. If we conclude that it is more likely than not that the fair value of a reporting unit is greater than its carrying amount, then we would not be required to perform the two-step quantitative impairment test. Otherwise, performing the two-step impairment test is necessary. The first step of the two-step quantitative impairment test involves comparing the fair values of the applicable reporting unit with its aggregate carrying value, including goodwill. If the carrying value of a reporting unit exceeds the reporting unit's fair value, we perform the second step of the test to determine the amount of the impairment loss, if any. The second step involves measuring any impairment by comparing the implied fair values of the affected reporting unit's goodwill and intangible assets with the respective carrying values.

We performed our last annual impairment assessment as of July 31, 2016 utilizing a qualitative evaluation and concluded that it was more likely than not that the fair value of our DNAG reporting unit is greater than its carrying value. We believe we have made reasonable estimates and assumptions to calculate the fair value of our reporting unit. If actual future results are not consistent with management's estimates and assumptions, we may have to take an impairment charge in the future related to our goodwill. Future impairment tests will continue to be performed annually in the fiscal third quarter, or sooner if a triggering event occurs. As of March 31, 2017, we believe no indicators of impairment exist.

The change in goodwill from $18,793 as of December 31, 2016 to $18,971 as of March 31, 2017 is a result of foreign currency translation.

Revenue Recognition. We recognize product revenues when there is persuasive evidence that an arrangement exists, the price is fixed or determinable, title has passed and collection is reasonably assured. Product revenues are recorded net of allowances for any discounts or rebates. Other than for sales of our OraQuick® In-Home HIV test to the retail trade, we do not grant price protection or product return rights to our customers except for warranty returns. Historically, returns arising from warranty issues have been infrequent and immaterial. Accordingly, we expense warranty returns as incurred.

Our net revenues recorded on sales of the OraQuick® In-Home HIV test represent total gross revenues, less an allowance for expected returns, and customer allowances for cooperative advertising, discounts, rebates, and chargebacks. The allowance for expected returns is an estimate established by management, based upon currently available information, and is adjusted to reflect known changes in the factors that impact this estimate. Other customer allowances are at contractual rates and are recorded as a reduction of gross revenue when recognized in our consolidated statements of income.

We record shipping and handling charges billed to our customers as product revenue and the related expense as cost of products sold. Taxes assessed by governmental authorities, such as sales or value-added taxes, are excluded from product revenues.

In June 2014, we entered into a Master Program Services and Co-Promotion Agreement with AbbVie Bahamas Ltd., a wholly-owned subsidiary of AbbVie Inc. ("AbbVie"), to co-promote our OraQuick® HCV test in the United

States. On June 30, 2016, we mutually agreed to terminate our agreement with AbbVie effective December 31, 2016. Following the termination of the agreement, AbbVie was relieved of its co-promotion obligations, including its obligation to detail the OraQuick® HCV Rapid Test into physician offices, and has no further financial obligations to us. We are no longer obligated to compensate AbbVie for product detailing activities and are free to pursue arrangements with other pharmaceutical companies to market and promote our OraQuick® HCV Rapid Antibody Test in the U.S. Accordingly, during the first quarter of 2017 we did not record any revenue from this co-promotion agreement. During the first quarter of 2016, $3,362 in exclusivity revenue was recognized and was recorded as other revenue in our consolidated statements of income.

On June 12, 2015, we were awarded a grant for up to $10,400 in total funding from the U.S. Department of Health and Human Services ("HHS") Office of the Assistant Secretary for Preparedness and Response's Biomedical Advanced Research and Development Authority ("BARDA") related to our OraQuick® Ebola Rapid Antigen test. The three-year, multi-phased grant includes an initial commitment of $1,800 and options for up to an additional $8,600 to fund certain clinical and regulatory activities. In September 2015, BARDA exercised an option to provide $7,200 in additional funding for the development of our OraQuick® Ebola Rapid Antigen test. Amounts related to this grant are recorded as other revenue in our consolidated statements of income as the activities are being performed and the related costs are incurred. During the first quarters of 2017 and 2016, $420 and $482, respectively, was recognized in connection with this grant.

In August 2016, we were awarded a contract for up to $16,600 in total funding from BARDA related to our rapid Zika test. The six-year, multi-phased contract includes an initial commitment of $7,000 and options for up to an additional $9,600 to fund the evaluation of additional product enhancements, and clinical and regulatory activities. Funding received under this contract is recorded as other revenue in our consolidated statements of income as the activities are being performed and the related costs are incurred. During the first quarter of 2017, $644 was recognized in connection with this grant.

Customer Sales Returns and Allowances. We do not grant return rights to our customers for any product, except for our OraQuick® In-Home HIV test. Accordingly, we have recorded an estimate of expected returns as a reduction of gross OraQuick® In-Home HIV product revenues in our consolidated statements of income. This estimate reflects our historical sales experience to retailers and consumers, as well as other retail factors, and is reviewed regularly to ensure that it reflects potential product returns. As of March 31, 2017 and December 31, 2016, the reserve for sales returns and allowances was $235 and $217, respectively. If actual product returns differ materially from our reserve amount, or if a determination is made that this product's distribution would be discontinued in whole or in part by certain retailers, then we would need to adjust our reserve. Should the actual level of product returns vary significantly from our estimates, our operating and financial results could be materially affected.

Deferred Revenue. We record deferred revenue when funds are received prior to the recognition of the associated revenue. Deferred revenue as of March 31, 2017 and December 31, 2016 includes customer prepayments of $1,306 and $1,388, respectively.

Customer and Vendor Concentrations. One of our customers accounted for 22% of our accounts receivable as of March 31, 2017. Another customer accounted for 15% of our accounts receivable as of December 31, 2016. We had no significant concentrations in net consolidated revenues for the three months ended March 31, 2017. One of our customers accounted for approximately 12% of our net consolidated revenues for the three months ended March 31, 2016.

We currently purchase certain products and critical components of our products from sole-supply vendors. If these vendors are unable or unwilling to supply the required components and products, we could be subject to increased costs and substantial delays in the delivery of our products to our customers. Also, our subsidiary, DNAG, uses two third-party suppliers to manufacture its products. Our inability to have a timely supply of any of these components and products could have a material adverse effect on our business, as well as our financial condition and results of operations.

Earnings Per Share. Basic earnings per share is computed by dividing net income by the weighted-average number of shares of common stock outstanding during the period. Diluted earnings per share is computed in a manner similar to basic earnings per share except that the weighted average number of shares outstanding is increased to

include shares from the assumed vesting or exercise of dilutive securities, such as common stock options, unvested restricted stock, and performance stock units, unless the impact is antidilutive. The number of incremental shares is calculated by assuming that outstanding stock options were exercised and unvested restricted shares and performance stock units were vested, and the proceeds from such exercises or vesting were used to acquire shares of common stock at the average market price during the reporting period.

The computations of basic and diluted earnings per share are as follows:

	Three Months Ended March 31,	
	2017	2016
Net income	$12,441	$ 2,446
Weighted average shares of common stock outstanding:		
Basic	56,929	55,451
Dilutive effect of stock options and restricted stock	1,843	628
Diluted	58,772	56,079
Earnings per share:		
Basic	$ 0.22	$ 0.04
Diluted	$ 0.21	$ 0.04

For the three-month periods ended March 31, 2017 and 2016, outstanding common stock options, unvested restricted stock, and unvested performance units representing 666 and 4,843 shares, respectively, were excluded from the computation of diluted earnings per share as their inclusion would have been anti-dilutive.

Foreign Currency Translation. The assets and liabilities of our foreign operations are translated into U.S. dollars at current exchange rates as of the balance sheet date, and revenues and expenses are translated at average exchange rates for the period. Resulting translation adjustments are reflected in accumulated other comprehensive loss, which is a separate component of stockholders' equity.

Transaction gains and losses resulting from exchange rate changes on transactions denominated in currencies other than functional currency are included in our consolidated statements of income in the period in which the change occurs. Net foreign exchange losses resulting from foreign currency transactions that are included in other income (expense) in our consolidated statements of income were $(200) and $(346) for the three months ended March 31, 2017 and 2016, respectively.

Accumulated Other Comprehensive Income (Loss). We classify items of other comprehensive income (loss) by their nature and disclose the accumulated balance of other comprehensive income (loss) separately from accumulated deficit and additional paid-in capital in the stockholders' equity section of our consolidated balance sheet.

We have defined the Canadian dollar as the functional currency of our Canadian subsidiary, DNAG, and as such, the results of its operations are translated into U.S. dollars, which is the reporting currency of the Company. The $450 and $2,867 currency translation adjustments recorded in the first three months of 2017 and 2016, respectively, are largely the result of the translation of our Canadian operation's balance sheets into U.S. dollars.

Recent Accounting Pronouncements. In May 2014, the Financial Accounting Standards Board ("FASB") issued converged guidance on recognizing revenue in contracts with customers, ASU 2014-09, *Revenue from Contracts with Customers*. The intent of the new standard is to improve financial reporting and comparability of revenue globally. The core principle of the standard is for a company to recognize revenue in a manner that depicts the transfer of goods or services to customers in an amount that reflects the consideration which the company expects to receive in exchange for those goods or services. The standard will be effective for the first interim period within annual reporting periods beginning after December 15, 2017, at which point we plan to adopt the standard.

The FASB allows two adoption methods under ASU 2014-09. We plan to adopt the standard using the “modified retrospective method.” Under that method, we will apply the rules to all contracts existing as of January 1, 2018, recognizing in beginning retained earnings an adjustment for the cumulative effective of the change and providing additional disclosures comparing results to previous accounting standards.

Upon initial evaluation, we believe the key changes in the standard that impact our revenue recognition relate to the allocation of the transaction price to performance obligations related to our device and lab services for drug testing. This revenue stream amounts to less than 1% of total consolidated revenues. We will continue to evaluate the impact that the adoption of ASU 2014-09 will have on our consolidated financial statements and related disclosures, but do not anticipate the adoption to have a material impact on our financial results.

In July 2015, the FASB issued ASU 2015-11, *Simplifying the Measurement of Inventory*, which requires an entity that uses the first-in, first-out method for inventory measurement to report inventory cost at the lower of cost and net realizable value versus the current measurement principle of lower of cost or market. The ASU requires prospective adoption for inventory measurements for fiscal years beginning after December 15, 2016. We adopted ASU 2015-11 on January 1, 2017. The adoption of this standard did not have a material impact on our consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU 2016-02, *Leases*, which requires entities to begin recording assets and liabilities from leases on the balance sheet. The new guidance will also require significant additional disclosures about the amount, timing and uncertainty of cash flows from leases. The standard will be effective for the first interim period within annual reporting periods beginning after December 15, 2018, using a modified retrospective approach. Early adoption is permitted. We are evaluating the effect that ASU 2016-02 may have on our consolidated financial statements and related disclosures.

In March 2016, the FASB issued authoritative guidance under ASU 2016-09, *Compensation-Stock Compensation (Topic 718) Improvements to Employee Share-Based Payment Accounting*. ASU 2016-09 provides for simplification of several aspects of the accounting for share-based payment transactions, including income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. We adopted ASU 2016-09 on January 1, 2017. Since we have a full valuation allowance against our net deferred tax assets, the adoption of this standard for recognition of tax effects of deductions for employee share awards in excess of compensation costs (‘windfall”) did not have a material impact on our consolidated financial statements and related disclosures. See Note 6 – Income Taxes, for additional information. Should the full valuation allowance be reversed in future periods the adoption of this new guidance will introduce more volatility to our effective tax rate depending on the Company’s share price at exercise or vesting of share-based awards compared to grant date. The other provisions of ASU 2016-09 did not have a material impact on our consolidated financial statements and related disclosures.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*, which provides guidance related to cash flows presentation and is effective for annual reporting periods beginning after December 15, 2017, subject to early adoption. The majority of the guidance in ASU 2016-15 is consistent with our current cash flow classifications and we do not expect the adoption of this standard will have a material impact on our consolidated financial statements.

In January 2017, the FASB issued ASU 2017-04, *Intangibles-Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment*, which requires an entity to no longer perform a hypothetical purchase price allocation to measure goodwill impairment. Instead, impairment will be measured using the difference between the carrying amount and the fair value of the reporting unit. This update will be effective for annual and interim periods in fiscal years beginning after December 15, 2019. Early adoption is permitted. We are currently assessing the impact of the future adoption of this standard on our consolidated financial statements and related disclosures.

3. Accrued Expenses

	March 31, 2017	December 31, 2016
Payroll and related benefits	$ 3,905	$ 7,685
Income taxes payable	2,045	(39)
Royalties	688	982
Professional fees	686	715
Other	2,361	1,971
	$ 9,685	$ 11,314

4. Credit Facility

On September 30, 2016, we entered into a credit agreement (the "Credit Agreement") with a commercial bank. The Credit Agreement provides for revolving extensions of credit in an initial aggregate amount of up to $10,000 (inclusive of a letter of credit subfacility of $2,500), with an option to request, prior to the second anniversary of the closing date, that the lender, at its election, provide up to $5,000 of additional revolving commitments. Obligations under the Credit Agreement are secured by a first priority security interest in certain eligible accounts receivable, 65% of the equity of our subsidiary, DNAG, and certain related assets. There were no borrowings outstanding under the Credit Agreement at March 31, 2017 and December 31, 2016.

Borrowings under the Credit Agreement are subject to compliance with borrowing base limitations tied to eligibility of accounts receivable. Interest under the Credit Agreement is payable at the London Interbank Offered Rate for one, two, three or six-month loans, as selected by the Company, plus 2.50% per year. The Credit Agreement is subject to an unused line fee of 0.375% per year on the unused portion of the commitment under the Credit Agreement during the revolving period. The maturity date of the Credit Agreement is September 30, 2019.

In connection with the Credit Agreement, under certain circumstances, we must comply with a minimum fixed charge coverage ratio of 1.10 to 1.00, measured as of the last day of each fiscal month and for the twelve-fiscal month period ending on such date. As of March 31, 2017 and December 31, 2016, we were in compliance with all applicable covenants in the Credit Agreement.

5. Stockholders' Equity

Stock-Based Awards

We grant stock-based awards under the OraSure Technologies, Inc. Stock Award Plan, as amended (the "Stock Plan"). The Stock Plan permits stock-based awards to employees, outside directors and consultants or other third-party advisors. Awards which may be granted under the Stock Plan include qualified incentive stock options, nonqualified stock options, stock appreciation rights, restricted awards, performance awards and other stock-based awards. We recognize compensation expense for stock option and restricted stock awards issued to employees and directors on a straight-line basis over the requisite service period of the award. We recognize compensation expense related to performance-based restricted stock units based on assumptions as to what percentage of each performance target will be achieved. We evaluate these target assumptions on a quarterly basis and adjust compensation expense related to these awards, as appropriate. To satisfy the exercise of options or to issue restricted stock, or redeem performance-based restricted stock units, we issue new shares rather than purchase shares on the open market.

Total compensation cost related to stock options for the three months ended March 31, 2017 and 2016 was $502 and $733, respectively. Net cash proceeds from the exercise of stock options were $9,417 and $0 for the three months ended March 31, 2017 and 2016, respectively. As a result of the Company's net operating loss carryforward position, no actual income tax benefit was realized from stock option exercises during these periods.

The following table summarizes the stock option activity for the first three months ended March, 31, 2017:

	Options
Outstanding on January 1, 2017	5,456
Granted	191
Exercised	(1,462)
Expired	(27)
Forfeited	(19)
Outstanding on March 31, 2017	4,139

Compensation cost of $655 and $719 related to restricted shares was recognized during the three months ended March 31, 2017 and 2016, respectively. In connection with the vesting of restricted shares and exercise of stock options during the three months ended March 31, 2017 and 2016, we purchased and immediately retired 96 and 98 shares with aggregate values of $851 and $527, respectively, in satisfaction of minimum tax withholding and exercise obligations.

The following table summarizes restricted stock award activity for the three months ended March 31, 2017:

	Shares
Issued and unvested, January 1, 2017	750
Granted	288
Vested	(297)
Forfeited	(4)
Issued and unvested, March 31, 2017	737

Commencing in 2016, we granted to certain executives performance-based restricted stock units (“PSUs”). Vesting of these PSUs is dependent upon achievement of performance-based metrics during a one-year or three-year period, from the date of grant. Assuming achievement of each performance-based metric, the executive must also remain in our service for three years from the grant date. Performance during the one-year period will be based on a one-year earnings per share target. If the one-year target is achieved, the PSUs will then vest three years from grant date. Performance during the three-year period will be based on achievement of a three-year compound annual growth rate for consolidated product revenues. If the three-year target is achieved, the corresponding PSUs will then vest three years from grant date. PSUs are converted into shares of our common stock once vested. Upon grant of the PSUs, we recognize compensation expense related to these awards based on assumptions as to what percentage of each target will be achieved. The Company evaluates these assumptions on a quarterly basis and adjusts compensation expense related to these awards, as appropriate.

Compensation cost of $361 related to PSUs was recognized during the three months ended March 31, 2017. No compensation cost related to the PSUs was recognized during the three months ended March, 31, 2016.

The following table summarizes PSU activity for the three months ended March 31, 2017:

	Units
Issued and unvested, January 1, 2017	456
Granted	229
Vested	—
Forfeited	—
Issued and unvested, March 31, 2017	685

Stock Repurchase Program

On August 5, 2008, our Board of Directors approved a share repurchase program pursuant to which we are permitted to acquire up to $25,000 of our outstanding common shares. No shares were purchased and retired during the three months ended March 31, 2017. During the three months ended March 31, 2016, we purchased and retired 423 shares of common stock at an average price of $6.29 per share for a total cost of $2,660, respectively.

6. Income Taxes

During the three months ended March 31, 2017 and 2016, we recorded tax expense of $3,897 and $61, respectively.

Tax expense reflects taxes due to state and Canadian taxing authorities and the tax effects of temporary differences between the basis of assets and liabilities recognized for financial reporting and tax purposes, and net operating loss and tax credit carryforwards. The significant components of our total deferred tax liability as of March 31, 2017 relate to the tax effects of the basis difference between the intangible assets acquired in the DNAG acquisition for financial reporting and tax purposes. Tax expense in the first quarter of 2017 reflects the additional Canadian taxes due as a result of the $12,500 gain from the settlement of the Ancestry litigation.

In 2008, we established a full valuation allowance against our U.S. deferred tax asset. Management believes the full valuation allowance is still appropriate as of both March 31, 2017 and December 31, 2016 since the facts and circumstances necessitating the allowance have not changed. As a result, no U.S. federal or state deferred income tax expense or benefit was recorded for the three-month periods ended March 31, 2017 and 2016.

The new accounting guidance under ASU 2016-09 allows for the recognition of excess tax benefits regardless of whether the deduction reduces taxes payable. On January 1, 2017, we recorded a cumulative-effect adjustment to retained earnings of $3,391 to recognize the increase in our net operating loss carryforwards from the cumulative excess tax benefits not recognized in periods prior to January 1, 2017. A corresponding $3,391 increase to our valuation allowance associated with this tax benefit was also recorded to retained earnings thereby recording a net impact to retained earnings of $0.

7. Commitments and Contingencies

Standby Letters of Credit

In 2016, we established four standby letters of credit in the aggregate amount of $1,831, naming international customers as the beneficiaries. These letters of credit were required as a performance guarantee of our obligations under our product supply contracts with those customers and are collateralized by certificates of deposit maintained at a commercial bank.

Litigation

From time to time, we are involved in certain legal actions arising in the ordinary course of business. In management’s opinion, the outcomes of such actions, either individually or in the aggregate, are not expected to have a material adverse effect on our future financial position or results of operations.

In May 2015, our subsidiary DNAG filed a complaint in the United States District Court for the District of Delaware against Ancestry.com DNA LLC (“Ancestry”) relating to the manufacture and sale by Ancestry of its oral fluid DNA collection device (the “Ancestry Device”). Ancestry previously purchased DNAG’s patented oral fluid DNA collection devices. The complaint alleged that the manufacture and sale by Ancestry of the Ancestry Device infringes U.S. Patent No. 8,221,381 B2, which is owned by DNAG. In addition, the complaint alleged that Ancestry has breached the terms of agreements under which Ancestry previously purchased DNAG products. The complaint also included an action to quiet title to the Ancestry Device and related patent applications. DNAG requested the court to grant injunctive relief and damages.

On October 20, 2015, Ancestry filed with the United States Patent and Trademark Office (“USPTO”) a Petition for *Inter Partes* Review (“IPR”) of some, but not all, claims of U.S. Patent No. 8,221,381 B2. On April 8, 2016, the USPTO instituted an IPR of some, but not all, of the claims raised in Ancestry’s petition. On June 3, 2016, Ancestry filed a second Petition for IPR of some, but not all, of the claims of U.S. Patent No. 8,221,381 B2.

In July 2015, DNAG filed a complaint in the United States District Court for the District of Delaware against Spectrum DNA, Spectrum Solutions L.L.C. and Spectrum Packaging L.L.C. (collectively "Spectrum") relating to the manufacture and sale by Spectrum of an oral fluid DNA collection device (the "Spectrum Device"). The Spectrum Device is the same as the Ancestry device mentioned above and Spectrum is the manufacturer of the Ancestry Device for Ancestry. The complaint alleged that the manufacture and sale by Spectrum of the Spectrum Device infringes U.S. patent number 8,221,381 B-2, which is owned by DNAG. DNAG requested the court to grant injunctive relief and damages. Spectrum filed a motion to dismiss this lawsuit on the grounds that the Delaware District Court lacked jurisdiction over Spectrum. The Court granted Spectrum's motion to dismiss for lack of personal jurisdiction.

On June 20, 2016, DNAG filed a complaint in the United States District Court for the Southern District of California against Spectrum relating to the manufacture and sale of the Spectrum Device. The complaint alleged that the manufacture and sale by Spectrum of the Spectrum Device infringes U.S. Patent No. 9,207,164, which is owned by DNAG. DNAG requested the court to grant injunctive relief and damages. On June 21, 2016, DNAG filed a motion for preliminary injunction. On July 21, 2016, Spectrum filed a motion to stay the case pending resolution by the PTO of a Petition for IPR of U.S. Patent No. 9,207,164, which was filed by Ancestry in July 2016. On October 6, 2016, the Court issued an order denying DNAG's motion for preliminary injunction and on October 7, 2016, the Court issued an order staying the case pending resolution of the IPR of U.S. Patent No. 9,207,164.

Effective February 6, 2017, DNAG settled the foregoing litigation with Ancestry and Spectrum. Under a Settlement and License Agreement executed by the parties, Ancestry agreed to pay DNAG a settlement fee of $12,500. This settlement amount has been recorded as a separate line item and a reduction of our operating expenses in our consolidated statements of income. In addition, DNAG granted Ancestry a royalty-bearing, non-exclusive, worldwide license to certain patents and patent applications related to the collection of DNA in human saliva. The license granted to Ancestry is limited to saliva DNA collection kits sold or used as part of Ancestry's genetic testing service offerings and does not cover the sale or use of collection kits outside of Ancestry's business. The Settlement and License Agreement also provides DNAG with a royalty-free, non-exclusive license to patents related to Ancestry's existing saliva DNA collection kit and certain modifications thereto.

The parties have each agreed to a mutual release of claims and other provisions typical for settlement agreements of this type. Pursuant to the terms of the Settlement and License Agreement, the pending federal lawsuits in the District of Delaware and the Southern District of California have been dismissed and the IPR proceedings before the USPTO involving the DNAG patents asserted in the litigation have been terminated.

8. Business Segment Information

We operate our business within two reportable segments: our "OSUR" business, which consists of the development, manufacture and sale of diagnostic products, specimen collection devices and medical devices; and our molecular collection systems or "DNAG" business, which primarily consists of the manufacture, development and sale of oral fluid collection devices that are used to collect, stabilize and store samples of genetic material for molecular testing. OSUR revenues are derived primarily from products sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations, public health organizations, distributors, government agencies, physicians' offices, commercial and industrial entities, retail pharmacies and mass merchandisers, and to consumers over the internet. OSUR also derives other revenues, including exclusivity payments for co-promotion rights and other licensing and product development activities. DNAG revenues result primarily from products sold into the commercial market which consists of customers engaged in consumer genetics, clinical genetic testing, pharmacogenomics, personalized medicine, microbiome, and animal genetic testing. DNAG products are also sold into the academic research market, which consists of research laboratories, universities and hospitals.

We organized our operating segments according to the nature of the products included in those segments. The accounting policies of the segments are the same as those described in the summary of significant accounting

policies (see Note 2). We evaluate performance of our operating segments based on revenue and operating income (loss). We do not allocate interest income, interest expense, other income, other expenses or income taxes to our operating segments. Reportable segments have no inter-segment revenues and inter-segment expenses have been eliminated.

The following table summarizes operating segment information for the three months ended March 31, 2017 and 2016, and asset information as of March 31, 2017 and December 31, 2016:

	Three Months Ended March 31,	
	2017	2016
Net revenues:		
OSUR	$ 21,840	$ 22,199
DNAG	10,706	6,890
Total	$ 32,546	$ 29,089
Operating income (loss):		
OSUR	$ (219)	$ 1,608
DNAG	16,090	1,091
Total	$ 15,871	$ 2,699
Depreciation and amortization:		
OSUR	$ 625	$ 639
DNAG	783	715
Total	$ 1,408	$ 1,354
Capital expenditures:		
OSUR	$ 784	$ 447
DNAG	94	1,146
Total	$ 878	$ 1,593

	March 31, 2017	December 31, 2016
Total assets:		
OSUR	$ 161,730	$ 151,719
DNAG	70,862	56,216
Total	$ 232,592	$ 207,935

Our products are sold principally in the United States and Europe.

The following table represents total net revenues by geographic area, based on the location of the customer:

	Three Months Ended March 31,	
	2017	2016
United States	$ 20,854	$ 22,170
Europe	3,125	3,879
Other regions	8,567	3,040
	$ 32,546	$ 29,089

The following table represents total long-lived assets by geographic area:

	March 31, 2017	December 31, 2016
United States	$ 15,886	$ 15,737
Canada	4,238	4,286
Other regions	10	10
	$ 20,134	$ 20,033

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

Statements below regarding future events or performance are "forward-looking statements" within the meaning of the Federal securities laws. These may include statements about our expected revenues, earnings/loss per share, net income (loss), expenses, cash flow or other financial performance or developments, clinical trial or development activities, expected regulatory filings and approvals, planned business transactions, views of future industry, competitive or market conditions, and other factors that could affect our future operations, results of operations or financial position. These statements often include the words "believes," "expects," "anticipates," "intends," "plans," "estimates," "may," "will," "should," "could," or similar expressions. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include, but are not limited to: ability to market and sell products, whether through our internal, direct sales force or third parties; ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements; ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; ability to comply with applicable regulatory requirements; ability to effectively resolve warning letters, audit observations and other findings or comments from the FDA or other regulators; changes in relationships, including disputes or disagreements, with strategic partners or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements; impact of increased reliance on U.S. government contracts; failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our products; impact of replacing distributors; inventory levels at distributors and other customers; ability of the Company to achieve its financial and strategic objectives and continue to increase its revenues, including the ability to expand international sales; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; impact of negative economic conditions, high unemployment levels and poor credit conditions; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products; market acceptance of oral fluid testing or other products; changes in market acceptance of products based on product performance or other factors, including changes in testing guidelines, algorithms or other recommendations by the Centers for Disease Control and Prevention ("CDC") or other agencies; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical products and components; availability of related products produced by third parties or products required for use of our products; history of losses and ability to achieve sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of the Company's stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to meet financial covenants in credit agreements; ability to attract and retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; and general political, business and economic conditions. These and other factors are discussed more fully in our Securities and Exchange Commission ("SEC") filings, including our registration statements, Annual Report on Form 10-K for the year ended December 31, 2016, Quarterly Reports on Form 10-Q, and other filings with the SEC. Although forward-looking statements help to provide information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. The forward-looking statements are made as of the date of this Report, and we undertake no duty to update these statements.

Investors should also be aware that while we do, from time to time, communicate with securities analysts, it is against our policy to disclose any material non-public information or other confidential commercial information. Accordingly, stockholders should not assume that we agree with any statement or report issued by any analyst irrespective of the content of the statement or report. Furthermore, we have a policy against issuing or confirming financial forecasts or projections issued by others. Thus, to the extent that reports issued by securities analysts contain any projections, forecasts or opinions, such reports are not the responsibility of OraSure.

The following discussion should be read in conjunction with our consolidated financial statements contained herein and the notes thereto, along with the Section entitled “Critical Accounting Policies and Estimates,” set forth below.

Overview

We develop, manufacture, market and sell diagnostic products and specimen collection devices using our proprietary technologies, as well as other diagnostic products, including immunoassays and other *in vitro* diagnostic tests that are used on other specimen types. Our diagnostic products include tests that are performed on a rapid basis at the point-of-care, tests that are processed in a laboratory, a rapid point-of-care HIV test approved for use in the domestic consumer retail or over-the-counter (“OTC”) market and a rapid point-of-care HIV self-test used in certain interational markets. We also manufacture and sell collection devices used to collect, stabilize, transport and store samples of genetic material for molecular testing in the consumer genetic, clinical genetic, academic research, pharmacogenomic, personalized medicine, microbiome and animal genetic markets. Lastly, we manufacture and sell medical devices used for the removal of benign skin lesions by cryosurgery, or freezing. Our products are sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations, public health organizations, research and academic institutions, distributors, government agencies, physicians’ offices, commercial and industrial entities, retail pharmacies and mass merchandisers, and to consumers over the internet.

Recent Developments

Litigation Settlement

Effective February 6, 2017, we settled our patent infringement and breach of contract litigation against Ancestry.com DNA LLC (“Ancestry”) and its contract manufacturer. Under a Settlement and License Agreement executed by the parties, Ancestry agreed to pay a settlement fee of $12.5 million which we received in the first quarter of 2017 and recorded as a gain on litigation settlement in our consolidated statements of income. In addition, we granted Ancestry a royalty-bearing, non-exclusive, worldwide license to certain patents and patent applications related to the collection of DNA in human saliva. The license granted to Ancestry is limited to saliva DNA collection kits sold or used as part of Ancestry’s genetic testing service offerings and does not cover the sale or use of collection kits outside of Ancestry’s business. The Settlement and License Agreement also provides us with a royalty-free, non-exclusive license to patents related to Ancestry’s existing saliva DNA collection kit and certain modifications thereto.

New Genomics Contract

We recently entered into a contract to supply over $20 million of our DNA saliva collection kits over a period greater than 12 months with one of our genomics customers. This is the largest product supply contract in the history of our molecular business.

Current Consolidated Financial Results

During the three months ended March 31, 2017, our consolidated net revenues were $32.5 million, compared to $29.1 million for the three months ended March 31, 2016. Net product revenues during the three months ended March 31, 2017 increased 25% when compared to the first three months of 2016, primarily due to higher sales of our molecular products and higher international sales of our professional OraQuick® HIV self-test and OraQuick® HCV product, partially offset by lower domestic sales of our OraQuick® HIV and HCV products and our cryosurgical products. Other revenues for the first three months of 2017 were $1.1 million compared to $3.8 million in the same period of 2016. Other revenues in the first quarter of 2017 represent revenue recognized in connection with funding received from the U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response’s Biomedical Advanced Research and Development Authority (“BARDA”) for our Ebola and Zika products. Other revenues in the first quarter of 2016 included $482,000 of BARDA funding and $3.4 million of exclusivity revenues recognized under our HCV co-promotion agreement with AbbVie, which terminated effective December 31, 2016.

Our consolidated net income for the three months ended March 31, 2017 was $12.4 million, or $0.21 per share on a fully-diluted basis, compared to consolidated net income of $2.4 million, or $0.04 per share on a fully-diluted basis, for the three months ended March 31, 2016. Results for the current quarter include a pre-tax gain of $12.5 million associated with the Ancestry settlement, as described above.

Cash provided by operating activities for the three months ended March 31, 2017 was $12.6 million and included the $12.5 million litigation settlement noted above. Cash provided by operating activities during the three months ended March 31, 2016 was $4.7 million. As of March 31, 2017, we had $141.5 million in cash (including restricted cash), cash equivalents, and short-term investments compared to $120.9 million at December 31, 2016.

Business Segments

We operate our business within two reportable segments: our "OSUR" business, which consists of the development, manufacture and sale of diagnostic products, specimen collection devices, and medical devices, and our "DNAG" or molecular collection systems business, which consists primarily of the development, manufacture and sale of oral fluid collection devices that are used to collect, stabilize, transport, and store samples of genetic material for molecular testing. OSUR revenues are derived primarily from products sold into the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations, public health organizations, distributors, government agencies, physicians' offices, commercial and industrial entities, retail pharmacies, mass merchandisers and consumers over the internet. DNAG revenues result from products sold into the commercial market, which consists of customers engaged in consumer genetics, clinical genetic testing, pharmacogenomics, personalized medicine, microbiome and animal genetic testing, as well as products sold into the academic research market which consists of research laboratories, universities and hospitals.

Results of Operations

Three months ended March 31, 2017 compared to March 31, 2016

CONSOLIDATED NET REVENUES

The table below shows a breakdown of total consolidated net revenues (dollars in thousands) generated by each of our business segments for the three months ended March 31, 2017 and 2016.

	Three Months Ended March 31,				
	Dollars			Percentage of Total Net Revenues	
	2017	2016	% Change	2017	2016
OSUR	$20,776	$18,355	13%	64%	63%
DNAG	10,706	6,890	55	33	24
Net product revenues	31,482	25,245	25	97	87
Other	1,064	3,844	(72)	3	13
Net revenues	$32,546	$29,089	12%	100%	100%

Consolidated net product revenues increased 25% to $31.5 million in the first quarter of 2017 from $25.2 million in the comparable period of 2016. Higher sales of our molecular products and increased international sales of our OraQuick® HIV self-test and OraQuick® HCV product, were partially offset by lower domestic sales of our OraQuick® HIV and HCV products and lower sales of our cryosurgical products. In the first quarter of 2017, we recognized $1.1 million as other revenues in connection with funding from BARDA related to our Ebola and Zika products. Other revenues in the first quarter of 2016 were $3.8 million and included $3.4 million in exclusivity payments received under our HCV co-promotion agreement with AbbVie and $482,000 recognized in connection with funding from BARDA. Our co-promotion agreement with AbbVie was terminated effective as of December 31, 2016 and no further revenues under this agreement will be recognized.

Consolidated net revenues derived from products sold to customers outside of the United States were $11.7 million and $6.9 million, or 36% and 24% of total net revenues, in the first quarters of 2017 and 2016, respectively. Because the majority of our international sales are denominated in U.S. dollars, the impact of fluctuating foreign currency exchange rates was not material to our total consolidated net revenues.

Net Revenues by Segment

OSUR Segment

The table below shows a breakdown of total net revenues (dollars in thousands) generated by our OSUR segment.

	Three Months Ended March 31,				
	Dollars			Percentage of Total Net Revenues	
Market	2017	2016	% Change	2017	2016
Infectious disease testing	$14,583	$11,368	28%	67%	51%
Risk assessment testing	3,130	3,105	1	14	14
Cryosurgical	3,063	3,882	(21)	14	18
Net product revenues	20,776	18,355	13	95	83
Other	1,064	3,844	(72)	5	17
Net revenues	$21,840	$22,199	(2)%	100%	100%

Infectious Disease Testing Market

Sales to the infectious disease testing market increased 28% to $14.6 million in the first quarter of 2017 from $11.4 million in the first quarter of 2016. This increase resulted from higher international sales of our OraQuick® HIV self-test and OraQuick® HCV product, partially offset by a decline in domestic sales of our OraQuick® HIV and HCV products.

The table below shows a breakdown of our total net OraQuick® HIV and HCV product revenues (dollars in thousands) during the first quarters of 2017 and 2016.

	Three Months Ended March 31,		
Market	2017	2016	% Change
Domestic HIV	$ 3,812	$ 5,703	(33)%
International HIV	2,644	854	210
Domestic OTC HIV	1,542	1,523	1
Net HIV revenues	7,998	8,080	(1)
Domestic HCV	1,709	1,900	(10)
International HCV	4,402	1,001	340
Net HCV revenues	6,111	2,901	111
Net OraQuick® HIV and HCV product revenues	$14,109	$10,981	28%

Domestic OraQuick® HIV sales decreased 33% to $3.8 million for the three months ended March 31, 2017 from $5.7 million for the three months ended March 31, 2016. This decrease was primarily the result of customer ordering patterns and continued price and product competition. We anticipate that future domestic sales of our professional HIV product will continue to be negatively affected as a result of Centers for Disease Control and Prevention (“CDC”) testing guidelines recommending the use of competing fourth generation automated HIV immunoassays performed in a laboratory, changes in government funding and continued product and price

competition. International sales of our OraQuick® HIV test during the first quarter of 2017 rose 210% to $2.6 million from $854,000 in the first quarter of 2016. This increase was largely due to the continued shipment of product in support of a HIV self-testing program in Africa, higher sales into the Middle East, and customer ordering patterns.

Sales of our OraQuick® In-Home HIV test remained consistent at $1.5 million during the first quarters of 2017 and 2016.

Domestic OraQuick® HCV sales decreased 10% to $1.7 million in the first quarter of 2017 from $1.9 million in the first quarter of 2016 primarily due to customer ordering patterns. International OraQuick® HCV sales increased 340% to $4.4 million in the first quarter of 2017 from $1.0 million in the first quarter of 2016, largely due to continued shipments of product to a foreign government to support a nationwide HCV testing and treatment program that began in November 2016, and increased sales in Africa.

International orders for both our HIV and HCV products can be sporadic in nature and are often predicated upon the availability of governmental funding, the impact of competition and other factors. As such, there is no assurance that such sales will continue at the same levels in future periods.

Risk Assessment Market

Sales to the risk assessment market remained consistent at $3.1 million in the first quarters of 2017 and 2016.

Cryosurgical Market

Sales of our cryosurgical products (which includes sales in both the physicians' office and OTC markets) decreased 21% to $3.1 million in the first quarter of 2017 from $3.9 million in the first quarter of 2016.

The table below shows a breakdown of our total net cryosurgical revenues (dollars in thousands) generated in each market during the first quarters of 2017 and 2016.

	Three Months Ended March 31,		
Market	2017	2016	% Change
Domestic professional	$1,496	$1,554	(4)%
International professional	130	235	(45)
Domestic OTC	285	378	(25)
International OTC	1,152	1,715	(33)
Net cryosurgical revenues	$3,063	$3,882	(21)%

Sales of our Histofreezer® product to physicians' offices in the United States decreased 4% to $1.5 million in the first quarter of 2017 from $1.6 million in the first quarter of 2016, primarily due to distributor ordering patterns. International sales of Histofreezer® decreased to $130,000 in the first quarter of 2017 from $235,000 in the same period of the prior year largely due to lower sales into Asia and Europe.

Sales of our private-label wart removal product in the U.S. retail market decreased to $285,000 in the first quarter of 2017 from $378,000 in the first quarter of 2016. Sales volume in the first quarter of 2016 was at a higher level as a result of inventory stocking at a new large pharmacy chain in that period. Sales levels in the first quarter of 2017 are more reflective of typical quarterly sales of the product in the U.S. retail market.

Sales of our international OTC cryosurgical products during the first quarter of 2017 decreased 33% to $1.2 million compared to $1.7 million in the first quarter of 2016, largely due to lower sales into Europe and Latin America.

Other revenues

Other revenues in the first quarter of 2017 decreased 72% to $1.1 million from $3.8 million in the first quarter of 2016.

Other revenues in the first quarter of 2016 included AbbVie exclusivity revenues of $3.4 million. There are no similar revenues in the first quarter of 2017 due to the termination of our co-promotion agreement with AbbVie on December 31, 2016. Funding from BARDA increased to $1.1 million in the first quarter of 2017 compared to $482,000 in the first quarter of 2016.

DNAG Segment

Molecular Market

Net molecular revenues increased 55% to $10.7 million in the first quarter of 2017 from $6.9 million in the first quarter of 2016. Sales of our Oragene® product in the commercial market rose 119% in the first quarter of 2017 compared to the first quarter of 2016, primarily as a result of higher customer demand and increased sales from new customer accounts won in the second half of 2016. Sales of our Oragene® product in the academic market decreased 20% in the first quarter of 2017 compared to the first quarter of 2016, largely due to ordering patterns of existing customers and the absence of a one-time order which occurred in the first quarter of 2016 and did not repeat in 2017. The higher revenues in the first quarter of 2017 also included $767,000 in sales of our microbiome product compared to $162,000 in the same period of 2016. We believe interest in our microbiome product offering continues to grow with both new and existing customers.

CONSOLIDATED OPERATING RESULTS

Consolidated gross margin was 62% for the first quarter of 2017 compared to 70% for the first quarter of 2016. Gross margin in the first quarter of 2017 was negatively impacted by the absence of exclusivity revenues under our HCV co-promotion agreement with AbbVie, increased scrap and spoilage costs, and an increase in lower margin product sales in the first quarter of 2017 compared to the first quarter of 2016.

Consolidated operating income for the first quarter of 2017 was $15.9 million, a $13.2 million improvement from $2.7 million of operating income reported in the first quarter of 2016. The operating income for the first quarter of 2017 benefited from the Ancestry litigation settlement gain and lower sales and marketing costs, partially offset by higher research and development and general and administrative expenses.

OPERATING INCOME (LOSS) BY SEGMENT

OSUR Segment

OSUR’s gross margin was 60% in the first quarter of 2017 compared to 69% in the first quarter of 2016. OSUR’s gross margin in the first quarter of 2017 was negatively impacted by the absence of exclusivity revenues under our HCV co-promotion agreement with AbbVie ($3.4 million was recorded in the first quarter of 2016 and none in 2017), increased scrap and spoilage costs, and an increase in lower margin product sales in the first quarter of 2017 compared to the first quarter of 2016.

Research and development expenses increased 36% to $2.4 million in the first quarter of 2017 from $1.7 million in the first quarter of 2016, largely due to higher supply costs associated with the development of our Ebola and Zika products and increased staffing expenses. Sales and marketing expenses decreased 28% to $4.7 million in the first quarter of 2017 from $6.5 million in the first quarter of 2016. This decrease was primarily the result of the termination of our OraQuick® HCV co-promotion agreement with AbbVie on December 31, 2016 and lower staffing costs. General and administrative expenses increased 14% to $6.3 million in the first quarter of 2017 from $5.5 million in the first quarter of 2016 due to increased staffing costs.

All of the above contributed to OSUR's first quarter 2017 operating loss of $219,000, which included non-cash charges of $625,000 for depreciation and amortization and $1.4 million for stock-based compensation.

DNAG Segment

DNAG's gross margin was 67% in the first quarter of 2017 compared to 73% in the first quarter of 2016. This decline was attributable to an increase in lower margin sales in the first quarter of 2017 compared to the first quarter of 2016.

Research and development expenses decreased 4% to $603,000 in the first quarter of 2017 from $627,000 in the first quarter of 2016, largely due to lower supply costs. Sales and marketing expenses remained consistent at $2.2 million in the first quarters of each of 2017 and 2016. General and administrative expenses decreased 22% to $831,000 in the first quarter of 2017 compared to $1.1 million in the first quarter of 2016 primarily due to lower legal costs. Operating expenses in the first quarter of 2017 were offset by the $12.5 million pre-tax gain associated with the settlement of our Ancestry litigation.

All of the above contributed to DNAG's first quarter 2017 operating income of $16.1 million, which included non-cash charges of $783,000 for depreciation and amortization and $97,000 for stock-based compensation.

CONSOLIDATED INCOME TAXES

We continue to believe the full valuation allowance established in 2008 against OSUR's total U.S. deferred tax asset is appropriate as the facts and circumstances necessitating the allowance have not changed. For the three months ended March 31, 2017, state income tax expense of $31,000 was recorded compared to $0 in the three months ended March 31, 2016. Canadian income tax expense of $3.9 million and $61,000 was recorded in the first quarters of 2017 and 2016, respectively. Taxes in the first quarter of 2017 included the additional taxes due as a result of the $12.5 million Ancestry litigation settlement payment.

Liquidity and Capital Resources

	March 31, 2017	December 31, 2016
	(In thousands)	
Cash and cash equivalents	$122,682	$ 109,790
Short-term investments	18,776	11,160
Working capital	162,258	139,106

Our cash, cash equivalents, and short-term investment balances increased to $141.5 million at March 31, 2017 from $120.9 million at December 31, 2016. Our working capital increased to $162.2 million at March 31, 2017 from $139.1 million at December 31, 2016.

During the first three months of 2017, we generated $12.6 million in cash from operating activities. Our net income of $12.4 million benefitted from non-cash stock-based compensation expense of $1.5 million and depreciation and amortization expense of $1.4 million, partially offset by a net reduction of other non-cash charges of $129,000. Additional sources of cash included an increase in accounts payable of $2.6 million largely due to consulting services and inventory purchases that were invoiced at the end of the quarter, and a decrease in prepaid and other assets of $1.5 million largely due to the receipt of $1.4 million as payment of a claim from one of our raw material suppliers. This settlement was recorded as a receivable at December 31, 2016. Uses of cash in operating activities during the period include an increase in accounts receivable of $4.1 million largely resulting from longer collection periods associated with our international contracts, a decrease in accrued expenses and other liabilities of $1.6 million associated with payment of our 2016 management incentive bonuses partially offset by an increase in our Canadian income taxes payable, an increase in inventory balances of $893,000 required to meet expected demand, and a decrease in deferred revenue of $84,000.

Net cash used in investing activities was $8.4 million for the three months ended March 31, 2017, which reflects $7.5 million used to purchase short-term investments and $878,000 to acquire property and equipment.

Net cash provided by financing activities was $8.6 million for the three months ended March 31, 2017, which resulted from $9.4 million in proceeds received from the exercise of stock options partially offset by $851,000 used for the repurchase of common stock to satisfy withholding taxes related to the vesting of restricted shares.

On September 30, 2016, we entered into a credit agreement (the "Credit Agreement") with a commercial bank. The Credit Agreement provides for revolving extensions of credit in an initial aggregate amount of up to $10,000,000 (inclusive of a letter of credit subfacility of $2,500,000), with an option to request, prior to the second anniversary of the closing date, that lenders, at their election, provide up to $5,000,000 of additional revolving commitments. Obligations under the Credit Agreement are secured by a first priority security interest in certain eligible accounts receivable, 65% of the equity of our subsidiary, DNAG, and certain related assets. There were no borrowings outstanding at March 31, 2017 or December 31, 2016.

Borrowings under the Credit Agreement are subject to compliance with borrowing base limitations tied to eligibility of accounts receivable. Interest under the Credit Agreement is payable at the London Interbank Offered Rate for one, two, three or six-month loans, as selected by the Company, plus 2.50% per annum. The Credit Agreement will be subject to an unused line fee of 0.375% per annum on the unused portion of the commitment under the Credit Agreement during the revolving period. The maturity date of the Credit Agreement is September 30, 2019.

In connection with the Credit Agreement, under certain circumstances, we must comply with a minimum fixed charge coverage ratio of 1.10 to 1.00, measured as of the last day of each fiscal month and for the twelve-fiscal month period ending on such date. As of March 31, 2017 and December 31, 2016, we were in compliance with all applicable covenants under the Credit Agreement.

Our current cash and cash equivalents balance and available borrowing capacity are expected to be sufficient to fund our current operating and capital needs for the foreseeable future. Our cash requirements, however, may vary materially from those now planned due to many factors, including, but not limited to, the scope and timing of future strategic acquisitions, the progress of our research and development programs, the scope and results of clinical testing, the cost of any future litigation, the magnitude of capital expenditures, changes in existing and potential relationships with business partners, the timing and cost of obtaining regulatory approvals, the timing and cost of future stock purchases, the costs involved in obtaining and enforcing patents, proprietary rights and any necessary licenses, the cost and timing of expansion of sales and marketing activities, market acceptance of new products, competing technological and market developments, the impact of the current economic environment and other factors.

Summary of Contractual Obligations

A summary of our obligations to make future payments under contracts existing at December 31, 2016 is included in Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations, of our Annual Report on Form 10-K for the year ended December 31, 2016. As of March 31, 2017, there were no significant changes to this information, including the absence of any off-balance sheet arrangements.

Critical Accounting Policies and Estimates

This Management's Discussion and Analysis of Financial Condition and Results of Operations discusses our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these consolidated financial statements requires that we make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. On an on-going basis, we evaluate our judgments and estimates, including those related to the valuation of accounts receivable, inventories and intangible assets, as well as calculations related to contingencies and accruals. We base our judgments and estimates on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

A more detailed review of our critical accounting policies is contained in our Annual Report on Form 10-K for the year ended December 31, 2016 filed with the SEC. During the first three months of 2017, there were no material changes in our critical accounting policies.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We do not hold any amounts of derivative financial instruments or derivative commodity instruments and, accordingly, we have no material derivative risk to report under this Item.

As of March 31, 2017, we did not have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. Sales denominated in foreign currencies comprised 5.2% of our total revenues for the three months ended March 31, 2017. We do have foreign currency exchange risk related to our operating subsidiary in Canada. While the majority of this subsidiary's revenues are recorded in U.S. dollars, almost all of this subsidiary's operating expenses are denominated in Canadian dollars. Fluctuations in the exchange rate between the U.S. dollar and the Canadian dollar could affect year-to-year comparability of operating results and cash flows. Our Canadian subsidiary had net assets, subject to translation, of $78.4 million CDN ($58.9 million USD), which are included in the Company's consolidated balance sheet as of March 31, 2017. A 10% unfavorable change in the Canadian-to-U.S. dollar exchange rate would have decreased our comprehensive income by $5.9 million in the three months ended March 31, 2017.

Item 4. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures. The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) as of March 31, 2017. Based on that evaluation, the Company's management, including such officers, concluded that the Company's disclosure controls and procedures were effective as of March 31, 2017 to provide reasonable assurance that material information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act of 1934 was accumulated and communicated to the Company's management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure and was recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission.

(b) Changes in Internal Control Over Financial Reporting. There was no change in the Company's internal control over financial reporting that occurred during the three months ended March 31, 2017 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

From time to time, we are involved in certain legal actions arising in the ordinary course of business. In management's opinion, based upon the advice of counsel, the outcomes of such actions are not expected, individually or in the aggregate, to have a material adverse effect on our future financial position or results of operations.

In May 2015, our subsidiary DNAG filed a complaint in the United States District Court for the District of Delaware against Ancestry.com DNA LLC ("Ancestry") relating to the manufacture and sale by Ancestry of its oral fluid DNA collection device (the "Ancestry Device"). Ancestry previously purchased DNAG's patented oral fluid DNA collection devices. The complaint alleged that the manufacture and sale by Ancestry of the Ancestry Device infringes U.S. Patent No. 8,221,381 B2, which is owned by DNAG. In addition, the complaint alleged that Ancestry has breached the terms of agreements under which Ancestry previously purchased DNAG products. The complaint also included an action to quiet title to the Ancestry Device and related patent applications. DNAG requested the court to grant injunctive relief and damages.

On October 20, 2015, Ancestry filed with the United States Patent and Trademark Office ("USPTO") a Petition for *Inter Partes* Review ("IPR") of some, but not all, claims of U.S. Patent No. 8,221,381 B2. On April 8, 2016, the USPTO instituted an IPR of some, but not all, of the claims raised in Ancestry's petition. On June 3, 2016, Ancestry filed a second Petition for IPR of some, but not all, of the claims of U.S. Patent No. 8,221,381 B2.

In July 2015, DNAG filed a complaint in the United States District Court for the District of Delaware against Spectrum DNA, Spectrum Solutions L.L.C. and Spectrum Packaging L.L.C. (collectively "Spectrum") relating to the manufacture and sale by Spectrum of an oral fluid DNA collection device (the "Spectrum Device"). The Spectrum Device is the same as the Ancestry device mentioned above and Spectrum is the manufacturer of the Ancestry Device for Ancestry. The complaint alleged that the manufacture and sale by Spectrum of the Spectrum Device infringes U.S. patent number 8,221,381 B-2, which is owned by DNAG. DNAG is requesting the court to grant injunctive relief and damages. Spectrum filed a motion to dismiss this lawsuit on the grounds that the Delaware District Court lacked jurisdiction over Spectrum. The Court granted Spectrum's motion to dismiss for lack of personal jurisdiction.

On June 20, 2016, DNAG filed a complaint in the United States District Court for the Southern District of California against Spectrum relating to the manufacture and sale of the Spectrum Device. The complaint alleged that the manufacture and sale by Spectrum of the Spectrum Device infringes U.S. Patent No. 9,207,164, which is owned by DNAG. DNAG requested the court to grant injunctive relief and damages. On June 21, 2016, DNAG filed a motion for preliminary injunction. On July 21, 2016, Spectrum filed a motion to stay the case pending resolution by the PTO of a Petition for IPR of U.S. Patent No. 9,207,164, which was filed by Ancestry in July 2016. On October 6, 2016, the Court issued an order denying DNAG's motion for preliminary injunction and on October 7, 2016, the Court issued an order staying the case pending resolution of the IPR of U.S. Patent No. 9,207,164.

Effective February 6, 2017, DNAG settled the foregoing litigation with Ancestry and Spectrum. Under a Settlement and License Agreement executed by the parties, Ancestry agreed to pay DNAG a settlement fee of $12.5 million. This settlement amount has been recorded as a separate line item and a reduction of our operating expenses in our statements of income in 2017. In addition, DNAG granted Ancestry a royalty-bearing, non-exclusive, worldwide license to certain patents and patent applications related to the collection of DNA in human saliva. The license granted to Ancestry is limited to saliva DNA collection kits sold or used as part of Ancestry's genetic testing service offerings and does not cover the sale or use of collection kits outside of Ancestry's business. The Settlement and License Agreement also provides DNAG with a royalty-free, non-exclusive license to patents related to Ancestry's existing saliva DNA collection kit and certain modifications thereto.

The parties have each agreed to a mutual release of claims and other provisions typical for settlement agreements of this type. Pursuant to the terms of the Settlement and License Agreement, the pending federal lawsuits in the District of Delaware and the Southern District of California have been dismissed and the IPR proceedings before the USPTO involving the DNAG patents asserted in the litigation have been terminated

Item 1A. RISK FACTORS

There have been no material changes to the factors disclosed in Item 1A., entitled “Risk Factors,” in our Annual Report on Form 10-K for the year ended December 31, 2016.

Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Period	Total number of shares purchased	Average price paid per Share	Total number of shares purchased as part of publicly announced plans or programs	Maximum number (or approximate dollar value) of shares that may yet be repurchased under the plans or programs (2, 3)
January 1, 2017 - January 31, 2017	—	—	—	11,984,720
February 1, 2017 - February 28, 2017	—	—	—	11,984,720
March 1, 2017 - March 31, 2017	96,105 (1)	$ 8.85	N/A	11,984,720
	96,105		—	

(1) Pursuant to the OraSure Technologies, Inc. Stock Award Plan, and in connection with the vesting of restricted shares, these shares were retired to satisfy minimum tax withholdings.

(2) On August 5, 2008, our Board of Directors approved a share repurchase program pursuant to which we are permitted to acquire up to $25.0 million of outstanding shares. This share repurchase program may be discontinued at any time.

(3) This column represents the amount that remains available under the $25.0 million repurchase plan, as of the period indicated. We have made no commitment to purchase any shares under this plan.

Item 3. DEFAULTS UPON SENIOR SECURITIES

None

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable

ITEM 5. OTHER INFORMATION

None

Item 6. EXHIBITS

Exhibits are listed on the Exhibit Index following the signature page of this Report.

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.

ORASURE TECHNOLOGIES, INC.

/s/ Ronald H. Spair

Date: May 9, 2017

Ronald H. Spair
Chief Operating Officer and
Chief Financial Officer
(Principal Financial Officer)

/s/Mark L. Kuna

Date: May 9, 2017

Mark L. Kuna
Senior Vice President, Finance and Controller
(Principal Accounting Officer)

EXHIBIT INDEX

Exhibit Number	Exhibit
10.1	Description of the OraSure Technologies, Inc. 2017 Management Incentive Plan is incorporated by reference to Item 5.02 to the Company's Current Report on Form 8-K filed February 24, 2017.*
10.2	Description of Long-Term Incentive Policy, as amended, is incorporated by reference to Item 5.02 to the Company's Current Report on Form 8-K filed February 24, 2017.*
10.3	Description of Non-Employee Director Compensation Policy, as amended, is incorporated by reference to Item 5.02 to the Company's Current Report on Form 8-K filed February 24, 2017. *
31.1	Certification of Douglas A. Michels required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Ronald H. Spair required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
32.1	Certification of Douglas A. Michels required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Ronald H. Spair required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Management contract or compensatory plan or arrangement.

Exhibit 31.1

Certification

I, Douglas A. Michels, certify that:

1. I have reviewed this report on Form 10-Q of OraSure Technologies, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d –15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within the entity, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2017

/s/ Douglas A. Michels
Douglas A. Michels
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification

I, Ronald H. Spair, certify that:

1. I have reviewed this report on Form 10-Q of OraSure Technologies, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d –15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within the entity, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2017

/s/ Ronald H. Spair
Ronald H. Spair
Chief Operating Officer and
Chief Financial Officer
(Principal Financial Officer)

CERTIFICATION PURSUANT TO
18 U.S.C. §1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of OraSure Technologies, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Douglas A. Michels, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Douglas A. Michels

Douglas A. Michels
President and Chief Executive Officer

May 9, 2017

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. §1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of OraSure Technologies, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ronald H. Spair, Chief Operating Officer and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Ronald H. Spair

Ronald H. Spair
Chief Operating Officer and Chief Financial Officer

May 9, 2017