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 June 30, 2016.

OR

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

For the transition period from ________ to ________.

Commission File Number 001-16537

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

Delaware **(State or Other Jurisdiction of Incorporation or Organization)**	**36-4370966** **(IRS Employer Identification No.)**
220 East First Street, Bethlehem, Pennsylvania **(Address of Principal Executive Offices)**	**18015** **(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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☐

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 August 3, 2016: 55,600,580 shares.

PART I. FINANCIAL INFORMATION

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Item 1. FINANCIAL STATEMENTS

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

	June 30, 2016	December 31, 2015
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 105,701	$ 94,094
Short-term investments	7,736	7,225
Accounts receivable, net of allowance for doubtful accounts of $755 and $798	18,436	19,265
Inventories	11,366	13,242
Prepaid expenses	1,942	1,533
Other current assets	1,194	1,355
Total current assets	146,375	136,714
PROPERTY AND EQUIPMENT, net	20,200	20,083
INTANGIBLE ASSETS, net	12,020	12,591
GOODWILL	19,541	18,250
OTHER ASSETS	1,784	1,683
	$ 199,920	$ 189,321
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 3,956	$ 5,087
Deferred revenue	13,822	9,735
Accrued expenses	8,293	10,412
Total current liabilities	26,071	25,234
OTHER LIABILITIES	2,018	1,768
DEFERRED INCOME TAXES	3,043	2,883
COMMITMENTS AND CONTINGENCIES (Note 6)		
STOCKHOLDERS' EQUITY		
Preferred stock, par value $.000001, 25,000 shares authorized, none issued	—	—
Common stock, par value $.000001, 120,000 shares authorized, 55,601 and 55,705 shares issued and outstanding	—	—
Additional paid-in capital	345,093	345,253
Accumulated other comprehensive loss	(12,409)	(15,639)
Accumulated deficit	(163,896)	(170,178)
Total stockholders' equity	168,788	159,436
	$ 199,920	$ 189,321

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 June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
NET REVENUES:				
Product	$ 27,582	$ 26,313	$ 52,827	$ 50,078
Other	3,777	4,075	7,621	7,398
	31,359	30,388	60,448	57,476
COST OF PRODUCTS SOLD	10,274	9,692	19,050	19,782
Gross profit	21,085	20,696	41,398	37,694
OPERATING EXPENSES:				
Research and development	2,985	2,996	5,351	6,436
Sales and marketing	7,397	8,904	16,103	16,788
General and administrative	6,354	6,075	12,896	12,040
	16,736	17,975	34,350	35,264
Operating income	4,349	2,721	7,048	2,430
OTHER INCOME (EXPENSE)	(340)	(95)	(532)	314
Income before income taxes	4,009	2,626	6,516	2,744
INCOME TAX EXPENSE	173	658	234	663
NET INCOME	$ 3,836	$ 1,968	$ 6,282	$ 2,081
EARNINGS PER SHARE:				
BASIC	$ 0.07	$ 0.03	$ 0.11	$ 0.04
DILUTED	$ 0.07	$ 0.03	$ 0.11	$ 0.04
SHARES USED IN COMPUTING EARNINGS PER SHARE:				
BASIC	55,543	56,453	55,497	56,398
DILUTED	56,208	56,687	56,144	56,678

See accompanying notes to the consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
NET INCOME	$ 3,836	$ 1,968	$ 6,282	$ 2,081
OTHER COMPREHENSIVE INCOME (LOSS)				
Currency translation adjustments	363	633	3,230	(3,178)
COMPREHENSIVE INCOME (LOSS)	$ 4,199	$ 2,601	$ 9,512	$ (1,097)

See accompanying notes to the consolidated financial statements.

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

	Six Months Ended June 30, 2016	Six Months Ended June 30, 2015
OPERATING ACTIVITIES:		
Net income	$ 6,282	$ 2,081
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		
Stock-based compensation	2,942	3,008
Depreciation and amortization	2,778	2,849
Amortization of lease incentives	(40)	—
Unrealized foreign currency loss	115	266
Deferred income taxes	(44)	366
Changes in assets and liabilities		
Accounts receivable	893	(524)
Inventories	1,949	35
Prepaid expenses and other assets	17	(42)
Accounts payable	(782)	(2,453)
Deferred revenue	4,083	(6,256)
Accrued expenses and other liabilities	(1,452)	(2,751)
Net cash provided by (used in) operating activities	16,741	(3,421)
INVESTING ACTIVITIES:		
Purchases of short-term investments	(15,335)	(11,960)
Proceeds from maturities of short-term investments	15,335	8,999
Purchases of property and equipment	(2,729)	(1,145)
Net cash used in investing activities	(2,729)	(4,106)
FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	209	124
Repurchase of common stock	(3,311)	(883)
Net cash used in financing activities	(3,102)	(759)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	697	(1,178)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	11,607	(9,464)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	94,094	92,867
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 105,701	$ 83,403
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for income taxes	$ 556	$ 81
Noncash investing activities (accrued property and equipment purchases)	$ 287	$ 128

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
Notes to the Consolidated Financial Statements
(Unaudited)
(in thousands, except per share amounts, unless otherwise indicated)

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 a rapid point-of-care HIV test approved for use in the domestic consumer retail or over-the-counter ("OTC") market. 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.

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, 2015. Results of operations for the three and six months ended June 30, 2016 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 and accruals, 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 income (loss).

Our available-for-sale securities as of June 30, 2016 and December 31, 2015 consisted of guaranteed investment certificates with amortized cost and fair value of $7,736 and $7,225, respectively.

Fair Value of Financial Instruments. As of June 30, 2016 and December 31, 2015, 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 June 30, 2016 and December 31, 2015, was $84,229 and $65,509 invested in money market funds. These funds 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 June 30, 2016 and December 31, 2015 was $1,589 and $1,324, 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 June 30, 2016 and December 31, 2015.

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

	June 30, 2016	December 31, 2015
Raw materials	$ 6,085	$ 7,895
Work in process	497	333
Finished goods	4,784	5,014
	$ 11,366	$ 13,242

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 June 30, 2016 and December 31, 2015 was $34,479 and $33,013, respectively.

Intangible Assets. Intangible assets consist of the following:

	Amortization Period (Years)	June 30, 2016 Gross	Accumulated Amortization	Net
Customer list	10	$ 9,692	$ (4,552)	$ 5,140
Patents and product rights	10	5,400	(3,583)	1,817
Acquired technology	7	7,528	(4,974)	2,554
Tradename	15	3,715	(1,206)	2,509
		$26,335	$ (14,315)	$12,020

	Amortization Period (Years)	December 31, 2015 Gross	Accumulated Amortization	Net
Customer list	10	$ 9,051	$ (3,818)	$ 5,233
Patents and product rights	10	5,400	(3,358)	2,042
Acquired technology	7	7,030	(4,172)	2,858
Tradename	15	3,469	(1,011)	2,458
		$24,950	$ (12,359)	$12,591

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, 2015 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 June 30, 2016, we believe no indicators of impairment exist.

The change in goodwill from $18,250 as of December 31, 2015 to $19,541 as of June 30, 2016 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 for cooperative advertising, discounts, rebates, and chargebacks are contractual in nature. These allowances 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.

On June 10, 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.

Pursuant to the agreement, we granted exclusive co-promotion rights for the OraQuick® HCV test in certain markets to AbbVie and we agreed to develop, implement, administer and maintain a patient care database for the exclusive use of AbbVie. This patient care database is being used to compile patient information regarding new individuals who have tested positive for HCV using our OraQuick® HCV test. We also jointly agreed with AbbVie to co-promote our OraQuick® HCV test in certain market segments.

Under the terms of this agreement, we are eligible to receive up to $75,000 in aggregate payments. We are recognizing this revenue ratably on a monthly basis over the term of the agreement which was to terminate on December 31, 2019. During the second quarter and first six months of 2016, $3,360 and $6,722, respectively, in exclusivity revenue was recognized and was recorded as other revenue in our consolidated statements of income.

Effective June 30, 2016, we mutually agreed to an early termination of this agreement with AbbVie and it will now end on December 31, 2016. Following the termination of the agreement, AbbVie will be relieved of its co-promotion obligations, including its obligation to detail the OraQuick® HCV Rapid Test into physician offices, and will have no further financial obligations to us. We will no longer be obligated to compensate AbbVie for product detailing activities and will be free to pursue arrangements with other pharmaceutical companies to market and promote our OraQuick® HCV Rapid Antibody Test in the U.S. As a result of the shortened term, the remaining associated deferred revenue of $12.2 million at June 30, 2016, will be recognized ratably as other revenue over the remaining six months of 2016 as there are no substantive on-going obligations remaining beyond December 31, 2016.

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 the development of 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 second quarter and first six months of 2016, $417 and $899, respectively, 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 June 30, 2016 and December 31, 2015, the reserve for sales returns and allowances was $328 and $310, 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 June 30, 2016 and December 31, 2015 includes customer prepayments of $1,593 and $784, respectively. Deferred revenue as of June 30, 2016 and December 31, 2015 also includes $12,229 and $8,951, respectively, from AbbVie, which represents the excess of the payments received from AbbVie over the amounts earned and recognized ratably in our consolidated statements of income.

Customer and Vendor Concentrations. One of our customers accounted for approximately 13% of our accounts receivable as of June 30, 2016. We had no significant concentrations in accounts receivable as of December 31, 2015. Another customer accounted for approximately 11% of our net revenues for the three and six months ended June 30, 2016, respectively. The same customer accounted for approximately 11% and 12% of our net revenues for the three and six months ended June 30, 2015, respectively.

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 incremental shares from the assumed vesting or exercise of dilutive securities, such as common stock options and unvested restricted stock, unless the impact is antidilutive. The number of incremental shares is calculated by assuming that outstanding stock options were exercised and unvested restricted shares 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 June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Net income	$ 3,836	$ 1,968	$ 6,282	$ 2,081
Weighted average shares of common stock outstanding:				
Basic	55,543	56,453	55,497	56,398
Dilutive effect of stock options and restricted stock	665	234	647	280
Diluted	56,208	56,687	56,144	56,678
Earnings per share:				
Basic	$ 0.07	$ 0.03	$ 0.11	$ 0.04
Diluted	$ 0.07	$ 0.03	$ 0.11	$ 0.04

For the three-month periods ended June 30, 2016 and 2015, outstanding common stock options and unvested restricted stock representing 2,459 and 5,010 shares, respectively, were excluded from the computation of diluted earnings per share as their inclusion would have been anti-dilutive. For the six months ended June 30, 2016 and 2015, outstanding common stock options and unvested restricted stock representing 3,191 and 3,856 shares, respectively, were similarly excluded from the computation of diluted earnings per share.

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 gains (losses) resulting from foreign currency transactions that are included in other income (expense) in our consolidated statements of income were $(302) and $(47) for the three months ended June 30, 2016 and 2015, respectively. Net foreign exchange gains (losses) were $(648) and $541 for the six months ended June 30, 2016 and 2015, 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 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 $3,230 and $(3,178) currency translation adjustments recorded in the first six months of 2016 and 2015, 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, with early adoption permitted. We are still evaluating the effects, if any, which adoption of this guidance will have on our consolidated financial statements.

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. Early adoption is permitted. We are evaluating the effect that ASU 2015-11 may have 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. The Company is required to adopt this new authoritative guidance in the first quarter of fiscal 2018. Early adoption is permitted. The Company is currently evaluating the potential impact of adoption of this standard on its consolidated financial statements.

3. Accrued Expenses

	June 30, 2016	December 31, 2015
Payroll and related benefits	$ 4,172	$ 6,311
Professional Fees	1,177	1,014
Royalties	830	819
Other	2,114	2,268
	$ 8,293	$ 10,412

4. Stockholders' Equity

Stock-Based Awards

We grant stock-based awards under the OraSure Technologies, Inc. Stock Award Plan, as amended and restated (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. To satisfy the exercise of options or vesting of restricted stock and performance awards, we issue new shares rather than purchase shares on the open market.

Commencing in 2016, we have granted to certain executives performance-based restricted stock units ("PSUs"). Vesting of these PSUs is dependent upon achievement of a performance-based metric 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, commencing with the grant date. Performance during the one-year period will be based on a one-year earnings per share target. Upon achievement of the one-year target, 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. Upon achievement of the three-year target, the corresponding PSUs will vest in full. PSUs are converted into shares of our common stock once vested. Upon grant of the PSUs, the Company recognizes compensation expense related to these awards based on assumptions as to what percentage of each target will be achieved. The Company evaluates these target assumptions on a quarterly basis and adjusts compensation expense related to these awards, as appropriate.

Total compensation cost related to stock options for the six months ended June 30, 2016 and 2015 was $1,387 and $1,690, respectively. Net cash proceeds from the exercise of stock options were $209 and $124 for the six months ended June 30, 2016 and 2015, 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.

Compensation cost of $1,401 and $1,318 related to restricted shares was recognized during the six months ended June 30, 2016 and 2015, respectively. In connection with the vesting of restricted shares and exercise of stock options during the six months ended June 30, 2016 and 2015, we purchased and immediately retired 117 and 132 shares with aggregate values of $651 and $883, respectively, in satisfaction of minimum tax withholding and exercise obligations.

Compensation cost of $154 related to the PSUs was recognized during the six months ended June 30, 2016.

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. During the six months ended June 30, 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. No shares were purchased and retired during the six months ended June 30, 2015, under this share repurchase program.

5. Income Taxes

During the three and six months ended June 30, 2016, we recorded tax expense of $173 and $234, respectively. During the three and six months ended June 30, 2015, we recorded tax expense of $658 and $663, respectively.

The following table summarizes the components of income tax expense:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Current taxes	$ 199	$ 292	$ 278	$ 297
Deferred taxes	(26)	366	(44)	366
Total	$ 173	$ 658	$ 234	$ 663

Current taxes reflect taxes due to state and provincial taxing authorities. Deferred income taxes reflect 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 June 30, 2016 relate to the tax effects of the basis differences between the intangible assets acquired in the DNAG acquisition for financial reporting and tax purposes.

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 June 30, 2016 and December 31, 2015 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 and six-month periods ended June 30, 2016 and 2015.

6. Commitments and Contingencies

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.

7. 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, 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, animal and livestock genetic testing, and microbiome 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.

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The following table summarizes operating segment information for the three and six months ended June 30, 2016 and 2015, and asset information as of June 30, 2016 and December 31, 2015:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Net revenues:				
OSUR	$ 22,926	$ 22,286	$ 45,125	$ 42,657
DNAG	8,433	8,102	15,323	14,819
Total	$ 31,359	$ 30,388	$ 60,448	$ 57,476
Operating income (loss):				
OSUR	$ 2,919	$ 685	$ 4,526	$ (836)
DNAG	1,430	2,036	2,522	3,266
Total	$ 4,349	$ 2,721	$ 7,048	$ 2,430
Depreciation and amortization:				
OSUR	$ 661	$ 734	$ 1,315	$ 1,460
DNAG	747	706	1,463	1,389
Total	$ 1,408	$ 1,440	$ 2,778	$ 2,849
Capital expenditures:				
OSUR	$ 661	$ 490	$ 1,123	$ 566
DNAG	460	218	1,606	579
Total	$ 1,121	$ 708	$ 2,729	$ 1,145

	June 30, 2016	December 31, 2015
Total assets:		
OSUR	$ 143,772	$ 137,082
DNAG	56,148	52,239
Total	$ 199,920	$ 189,321

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
United States	$ 24,021	$ 25,071	$ 46,191	$ 45,488
Europe	2,957	2,939	6,836	7,313
Other regions	4,381	2,378	7,421	4,675
	$ 31,359	$ 30,388	$ 60,448	$ 57,476

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

	June 30, 2016	December 31, 2015
United States	$ 15,665	$ 15,660
Canada	4,511	4,415
Other regions	24	8
	$ 20,200	$ 20,083

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 various arrangements; 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 DNA Genotek to achieve its financial and strategic objectives and continue to increase its revenues; 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 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 Centers for Disease Control and Prevention ("CDC") or other testing guidelines, algorithms or other recommendations; 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 OraSure'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 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, 2015, 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, and a rapid point-of-care HIV test approved for use in the domestic consumer retail or over-the-counter ("OTC") market. 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

HCV Co-Promotion Agreement

On June 10, 2014, we entered into an agreement with AbbVie to co-promote our OraQuick® HCV test in the United States. Pursuant to the agreement, we granted exclusive co-promotion rights for the OraQuick® HCV test in certain markets to AbbVie and we agreed to develop, implement, administer and maintain a patient care database for the exclusive use of AbbVie. This patient care database has been used to compile patient information regarding new individuals who have tested positive for HCV using our OraQuick® HCV test. We also jointly agreed with AbbVie to co-promote our OraQuick® HCV test in certain market segments.

Effective June 30, 2016, we mutually agreed to an early termination of this agreement with AbbVie and it will now end on December 31, 2016. Following the termination of the agreement, AbbVie will be relieved of its co-promotion obligations, including its obligation to detail the OraQuick® HCV Rapid Test into physician offices, and will have no further financial obligations to us. We will no longer be obligated to compensate AbbVie for product detailing activities and will be free to pursue arrangements with other pharmaceutical companies to market and promote our OraQuick® HCV Rapid Antibody Test in the U.S. As a result of the shortened term, the remaining associated deferred revenue of $12.2 million at June 30, 2016, which represents a portion of the exclusivity payments received from AbbVie, will be recognized ratably as other revenue over the remaining six months of 2016 as we will have no substantive on-going obligations after December 31, 2016.

Current Consolidated Financial Results

During the six months ended June 30, 2016, our consolidated net revenues were $60.4 million, compared to $57.5 million for the six months ended June 30, 2015. Net product revenues during the six months ended June 30, 2016 increased 5% when compared to the first six months of 2015, primarily due to higher sales of our OraQuick® HCV, cryosurgical systems, molecular collection systems, and OraQuick® HIV products. Other revenues for the first six months of 2016 were $7.6 million, of which $6.7 million represents the ratable recognition of payments for exclusive co-promotion rights and certain services provided under our HCV co-promotion agreement with AbbVie, and $899,000 represents revenue recognized in connection with the Ebola-related funding 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").

Our consolidated net income for the six months ended June 30, 2016 was $6.3 million, or $0.11 per share on a fully-diluted basis, compared to consolidated net income of $2.1 million, or $0.04 per share, for the six months ended June 30, 2015.

Cash provided by operating activities for the six months ended June 30, 2016 was $16.7 million, compared to $3.4 million used in operating activities during the six months ended June 30, 2015. As of June 30, 2016, we had $113.4 million in cash and cash equivalents and short-term investments compared to $101.3 million at December 31, 2015.

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 June 30, 2016 compared to June 30, 2015

CONSOLIDATED NET REVENUES

The table below shows a breakdown of total net revenues (dollars in thousands) generated by each of our business segments for the three months ended June 30, 2016 and 2015.

	Three Months Ended June 30,				
	Dollars			Percentage of Total Net Revenues	
	2016	2015	% Change	2016	2015
OSUR	$19,149	$18,211	5%	61%	60%
DNAG	8,433	8,102	4	27	27
Net product revenues	27,582	26,313	5	88	87
Other	3,777	4,075	(7)	12	13
Net revenues	$31,359	$30,388	3%	100%	100%

Consolidated net product revenues increased 5% to $27.6 million in the second quarter of 2016 from $26.3 million in the comparable period of 2015. Higher sales of our OraQuick® HCV, OraQuick® HIV and molecular collection systems products during the three months ended June 30, 2016, were partially offset by lower sales of our risk assessment products and the absence of sales of our OraQuick® Ebola Rapid Antigen test. Other revenues in the second quarter of 2016 were $3.8 million and included $3.4 million in exclusivity revenue recognized under our HCV co-promotion agreement with AbbVie and $417,000 recognized in connection with Ebola-related funding from BARDA. Other revenues in the second quarter of 2015 were $4.1 million and included $3.4 million in exclusivity payments from AbbVie and $714,000 of Ebola-related funding from BARDA.

Consolidated net revenues derived from products sold to customers outside of the United States were $7.3 million and $5.3 million, or 23% and 17% of total net revenues, in the second quarters of 2016 and 2015, 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 net revenues.

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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 June 30,				
	Dollars			Percentage of Total Net Revenues	
Market	**2016**	**2015**	**% Change**	**2016**	**2015**
Infectious disease testing	$12,949	$11,792	10%	57%	54%
Risk assessment testing	3,159	3,466	(9)	14	15
Cryosurgical systems	3,041	2,953	3	13	13
Net product revenues	19,149	18,211	5	84	82
Other	3,777	4,075	(7)	16	18
Net revenues	$22,926	$22,286	3%	100%	100%

Infectious Disease Testing Market

Sales to the infectious disease testing market increased 10% to $12.9 million in the second quarter of 2016 from $11.8 million in the second quarter of 2015. Increased sales of our OraQuick® HCV and OraQuick® HIV tests were partially offset by the absence of sales of our OraQuick® Ebola Rapid Antigen test during the three months ended June 30, 2016. Second quarter 2015 revenues included $396,000 in sales of our OraQuick® Ebola Rapid Antigen test to the CDC for field testing in Africa. There were no similar sales of this product in the second quarter of 2016.

The table below shows a breakdown of our total net OraQuick® HIV and HCV product revenues (dollars in thousands) during the second quarters of 2016 and 2015.

	Three Months Ended June 30,		
Market	**2016**	**2015**	**% Change**
Domestic HIV	$ 5,886	$ 6,593	(11)%
International HIV	1,969	596	230
Domestic OTC HIV	1,739	1,719	1
Net HIV revenues	9,594	8,908	8
Domestic HCV	1,788	1,693	6
International HCV	1,428	646	121
Net HCV revenues	3,216	2,339	37
Net OraQuick® HIV and HCV product revenues	$12,810	$11,247	14%

Domestic OraQuick® HIV sales decreased 11% to $5.9 million for the three months ended June 30, 2016 from $6.6 million for the three months ended June 30, 2015. This decrease was primarily the result of the continued loss of sales to competing fourth generation automated HIV immunoassays performed in a laboratory, as recommended under testing guidelines issued by the CDC, customer ordering patterns, and to a lesser extent the loss of sales to point-of-care HIV tests perceived to be more sensitive. We anticipate that future sales of our professional HIV product will continue to be negatively affected as a result of the CDC's testing guidelines, changes in government funding and continued product and price competition. International sales of our OraQuick® HIV test during the second quarter of 2016 increased 230% to $1.9 million from $596,000 in the second quarter of 2015. This increase was largely due to the continued shipment of product in support of a new HIV self-testing program in Africa, higher sales in Asia resulting from a new government sponsored testing project, and increased sales in Europe as a result of the addition of a new distributor in Russia.

Sales of our OraQuick® In-Home HIV test remained flat at $1.7 million in both the second quarters of 2016 and 2015.

Domestic OraQuick® HCV sales increased 6% to $1.8 million in the second quarter of 2016 from $1.7 million in the second quarter of 2015, primarily due to the expansion of existing HCV testing programs and the addition of new programs in the public health market. International OraQuick® HCV sales increased 121% to $1.4 million in the second quarter of 2016 from $646,000 in the second quarter of 2015, largely due to the expansion of our business in Asia and higher sales to a multi-national humanitarian organization primarily resulting from the timing of order placement by this organization. Sales to this organization can be variable, are influenced by its worldwide field activities, and therefore are difficult to predict.

We believe our OraQuick® HCV product represents an opportunity for future sales growth given the FDA approval of several new drug therapies for treating HCV. However, demand for our HCV product, particularly in the public health marketplace, may be somewhat tempered by the limited availability of government funding allocated to HCV testing efforts and the time and effort required to build awareness and demand for rapid HCV testing. Sales to physicians can also be adversely affected by the level of reimbursement available from insurance providers and competition from laboratory-based HCV tests. The intensely competitive market for new HCV therapies and the decisions by insurance providers and payors to grant preferred or exclusive formulary status to one HCV therapy over another have adversely affected our initiatives under the HCV co-promotion agreement with AbbVie. These and other factors could limit the future growth of our HCV business.

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

Commencing in 2016, we have combined the former substance abuse testing market and insurance risk assessment market categories under a single category referred to as the "risk assessment market." We combined revenues for these markets because they are similar in nature and testing modalities. Revenues for 2015 have been combined in a similar manner for presentation purposes.

Sales to the risk assessment market decreased 9% to $3.1 million in the second quarter of 2016 from $3.5 million in the second quarter of 2015, primarily as a result of a decline in sales of our OraSure® oral fluid collection device into the domestic life insurance market.

Cryosurgical Systems Market

Sales of our cryosurgical systems products (which includes sales in both the physicians' office and OTC markets) remained relatively flat at $3.0 million in both the second quarters of 2016 and 2015.

The table below shows a breakdown of our total net cryosurgical systems revenues (dollars in thousands) generated in each market during the second quarters of 2016 and 2015.

Market	Three Months Ended June 30, 2016	2015	% Change
Domestic professional	$1,145	$1,008	14%
International professional	211	142	49
Domestic OTC	345	108	219
International OTC	1,340	1,695	(21)
Net cryosurgical systems revenues	$3,041	$2,953	3%

Sales of our Histofreezer® product to physicians' offices in the United States increased 14% to $1.1 million in the second quarter of 2016 from $1.0 million in the second quarter of 2015, primarily due to the recovery of business previously lost to competition from private label brands as well as the initiation of a distributor expansion strategy. International sales of Histofreezer® increased to $211,000 in the second quarter of 2016 from $142,000 in the same period of the prior year largely due to higher sales into Europe.

Sales of our private-label wart removal product in the U.S. retail market increased to $345,000 in the second quarter of 2016 from $108,000 in the second quarter of 2015 due to the launch of private-label products in two additional large pharmacy chains earlier this year.

Sales of our international OTC cryosurgical products during the second quarter of 2016 decreased 21% to $1.3 million compared to $1.7 million in the second quarter of 2015, largely due to a decline in sales into Europe partially offset by higher sales in Latin America.

Other revenues

Other revenues in the second quarter of 2016 were $3.8 million and included $3.4 million in exclusivity revenue recognized under our HCV co-promotion agreement with AbbVie and $417,000 recognized in connection with Ebola-related funding from BARDA. Other revenues in the second quarter of 2015 were $4.1 million and included $3.4 million in AbbVie exclusivity revenue and $714,000 in Ebola-related funding from BARDA. Following the termination of our HCV co-promotion agreement with AbbVie on December 31, 2016, AbbVie will have no further financial obligations to us.

DNAG Segment

Molecular Collection Systems

Net molecular collection systems revenues increased 4% to $8.4 million in the second quarter of 2016 from $8.1 million in the second quarter of 2015. Sales of our Oragene® product in the commercial market increased 7% in the second quarter of 2016 compared to the second quarter of 2015, primarily as a result of the timing of purchases by two of our larger U.S. customers. The increase was partially offset by the absence of sales to two other large customers that have filed for bankruptcy protection. These other customers contributed approximately $1.1 million in sales in second quarter of 2015. The Company has no unreserved collections exposure related to these two customers. Sales of our Oragene® product in the academic market decreased 7% in the second quarter of 2016 compared to the second quarter of 2015, largely due to ordering patterns of existing customers partially offset by the first shipment of product to support a study on autism. The higher revenues in the second quarter of 2016 also included $218,000 in sales of our microbiome product compared to $84,000 in the same period of 2015. We believe interest in our microbiome product offering continues to grow with both new and existing customers.

CONSOLIDATED OPERATING RESULTS

Consolidated gross margin was 67% for the second quarter of 2016 compared to 68% for the second quarter of 2015. Gross margin for the second quarter of 2016 decreased primarily due to an unfavorable product mix partially offset by lower scrap and spoilage costs.

Consolidated operating income for the second quarter of 2016 was $4.3 million, a $1.6 million improvement from $2.7 million of operating income reported in the second quarter of 2015. The operating income for the second quarter of 2016 benefited from lower sales and marketing costs, partially offset by higher general and administrative expenses.

OPERATING INCOME BY SEGMENT

OSUR Segment

OSUR's gross margin was 67% in the second quarter of 2016 compared to 66% in the second quarter of 2015. OSUR's gross margin in the second quarter of 2016 was positively impacted by lower scrap and spoilage costs, partially offset by an unfavorable product mix.

Research and development expenses increased 7% to $2.3 million in the second quarter of 2016 from $2.2 million in the second quarter of 2015, largely due to higher supply costs associated with the development of our Ebola and Zika products and the additional costs associated with hiring our new Senior Vice President of Research and Development and Chief Science Officer. Sales and marketing expenses decreased 27% to $5.0 million in the second quarter of 2016 from $6.9 million in the second quarter of 2015. This decrease was primarily the result of lower detailing costs and other expenses associated with our OraQuick® HCV co-promotion agreement with AbbVie. General and administrative expenses remained flat at $5.1 million in both the second quarters of 2016 and 2015.

All of the above contributed to OSUR's second quarter 2016 operating income of $2.9 million, which included non-cash charges of $661,000 for depreciation and amortization and $1.4 million for stock-based compensation.

DNAG Segment

DNAG's gross margin was 68% in the second quarter of 2016 compared to 73% in the second quarter of 2015. This decline was attributable to an increase in lower margin sales experienced in the second quarter of 2016 when compared to the second quarter of 2015.

Research and development expenses decreased 21% to $639,000 in the second quarter of 2016 from $809,000 in the second quarter of 2015, largely due to lower staffing and validation costs. Sales and marketing expenses increased 18% to $2.4 million in the second quarter of 2016 from $2.1 million in the second quarter of 2015 due to an increase in our allowance for uncollectible accounts and higher commission and staffing costs, partially offset by a favorable foreign currency exchange rate impact of approximately $97,000. General and administrative expenses increased 29% to $1.3 million in the second quarter of 2016 compared to $989,000 in the second quarter of 2015 primarily due to higher legal fees.

All of the above contributed to DNAG's second quarter 2016 operating income of $1.4 million, which included non-cash charges of $747,000 for depreciation and amortization and $134,000 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 June 30, 2016, state income tax expense of $50,000 was recorded compared to $0 in the three months ended June 30, 2015. Canadian income tax expense of $123,000 and $658,000 was recorded in the second quarters of 2016 and 2015, respectively.

Six months ended June 30, 2016 compared to June 30, 2015

CONSOLIDATED NET REVENUES

The table below shows a breakdown of total net revenues (dollars in thousands) generated by each of our business segments for the six months ended June 30, 2016 and 2015.

	Six Months Ended June 30,				
	Dollars		% Change	Percentage of Total Net Revenues	
	2016	2015		2016	2015
OSUR	$37,504	$35,259	6%	62%	61%
DNAG	15,323	14,819	3	25	26
Net product revenues	52,827	50,078	5	87	87
Other	7,621	7,398	3	13	13
Net revenues	$60,448	$57,476	5%	100%	100%

Consolidated net product revenues increased 5% to $52.8 million in the first half of 2016 from $50.1 million in the comparable period of 2015. Higher sales of our OraQuick® HCV, cryosurgical systems, molecular collection systems, and OraQuick® HIV products in the six months ended June 30, 2016 were partially offset by lower sales of our risk assessment products and the absence of sales of our OraQuick® Ebola Rapid Antigen test. Other revenues in the first half of 2016 were $7.6 million and included $6.7 million in exclusivity revenue recognized under our HCV co-promotion agreement with AbbVie and $899,000 recognized in connection with Ebola-related funding from BARDA. Other revenues in the first half of 2015 were $7.4 million and included $6.7 million in exclusivity revenue from AbbVie and $714,000 of Ebola-related funding from BARDA.

Consolidated net revenues derived from products sold to customers outside of the United States were $14.3 million and $12.0 million, or 24% and 21% of total net revenues, during the six months ended June 30, 2016 and 2015, 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 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.

	Six Months Ended June 30,				
	Dollars		% Change	Percentage of Total Net Revenues	
Market	2016	2015		2016	2015
Infectious disease testing	$24,317	$23,288	4%	54%	55%
Risk assessment testing	6,265	6,473	(3)	14	15
Cryosurgical systems	6,922	5,498	26	15	13
Net product revenues	37,504	35,259	6	83	83
Other	7,621	7,398	3	17	17
Net revenues	$45,125	$42,657	6%	100%	100%

Infectious Disease Testing Market

Sales to the infectious disease testing market increased 4% to $24.3 million in the first half of 2016 from $23.3 million in the first half of 2015. Increased sales of our OraQuick® HCV and OraQuick® HIV tests were partially offset by the absence of sales of our OraQuick® Ebola Rapid Antigen test during the six months ended June 30, 2016. Revenues for the first six months of 2015 included $760,000 in sales of our OraQuick® Ebola Rapid Antigen test to the CDC for field testing in Africa. There were no similar sales of this product in the first half of 2016.

The table below shows a breakdown of our total net OraQuick® HIV and HCV product revenues (dollars in thousands) during the six months ended June 30, 2016 and 2015.

	Six Months Ended June 30,		
Market	**2016**	**2015**	**% Change**
Domestic HIV	$11,588	$12,601	(8)%
International HIV	2,824	1,544	83
Domestic OTC HIV	3,262	3,280	(1)
Net HIV revenues	17,674	17,425	1
Domestic HCV	3,689	2,889	28
International HCV	2,430	1,619	50
Net HCV revenues	6,119	4,508	36
Net OraQuick® revenues	$23,793	$21,933	8%

Domestic OraQuick® HIV sales decreased 8% to $11.6 million for the six months ended June 30, 2016 from $12.6 million for the six months ended June 30, 2015. This decrease was primarily the result of the continued loss of sales to competing fourth generation automated HIV immunoassays performed in a laboratory, as recommended under testing guidelines issued by the CDC, customer ordering patterns, and to a lesser extent the loss of sales to point-of-care HIV tests perceived to be more sensitive. We anticipate that future sales of our professional HIV product will continue to be negatively affected as a result of the CDC's testing guidelines, changes in government funding and continued product and price competition. International sales of our OraQuick® HIV test during the first half of 2016 increased 83% to $2.8 million from $1.5 million during the first half of 2015. This increase is largely due to the continued shipment of product in support of a new HIV self-testing program in Africa coupled with higher sales in Europe as a result of the addition of a new distributor in Russia.

Sales of our OraQuick® In-Home HIV test remained flat at $3.3 million in both the first halves of 2016 and 2015.

Domestic OraQuick® HCV sales increased 28% to $3.7 million in the first half of 2016 from $2.9 million in the first half of 2015, primarily due to the expansion of existing HCV testing programs and the addition of new programs in the public health market. International OraQuick® HCV sales increased 50% to $2.4 million in the first half of 2016 from $1.6 million in the first half of 2015, largely due to the expansion of our business in Asia and higher sales to a multi-national humanitarian organization primarily resulting from the timing of order placement by this organization. Sales to this organization can be variable, are influenced by its worldwide field activities, and therefore are difficult to predict.

We believe our OraQuick® HCV product represents an opportunity for future sales growth given the FDA approval of several new drug therapies for treating HCV. However, demand for our HCV product, particularly in the public health marketplace, may be somewhat tempered by the limited availability of government funding allocated to HCV testing efforts and the time and effort required to build awareness and demand for rapid HCV testing. Sales to physicians can also be adversely affected by the level of reimbursement available from insurance providers and competition from laboratory-based HCV tests. The intensely competitive market for new HCV therapies and the decisions by insurance providers and payors to grant preferred or exclusive formulary status to one HCV therapy over another have adversely affected our initiatives under the HCV co-promotion agreement with AbbVie. These and other factors could limit the future growth of our HCV business.

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

Commencing in 2016, we have combined the former substance abuse testing market and insurance risk assessment market categories under a single category referred to as the "risk assessment market." We combined revenues for these markets because they are similar in nature and testing modalities. Revenues for 2015 have been combined in a similar manner for presentation purposes.

Sales to the risk assessment market decreased 3% to $6.3 million for the six months ended June 30, 2016 from $6.5 million for the six months ended June 30, 2015, primarily as a result of a decline in sales of our OraSure® oral fluid collection device into the domestic life insurance market.

Cryosurgical Systems Market

Sales of our cryosurgical systems products (which includes sales in both the physicians' office and OTC markets) increased 26% to $6.9 million in the first half of 2016, compared to $5.5 million in the same period of the prior year.

The table below shows a breakdown of our total net cryosurgical systems revenues (dollars in thousands) generated in each market during the six months ended June 30, 2016 and 2015.

	Six Months Ended June 30,		
Market	**2016**	**2015**	**% Change**
Domestic professional	$2,699	$1,668	62%
International professional	446	498	(10)
Domestic OTC	723	163	344
International OTC	3,054	3,169	(4)
Net cryosurgical systems revenues	$6,922	$5,498	26%

Sales of our Histofreezer® product to physicians' offices in the United States increased 62% to $2.7 million in the first half of 2016 from $1.7 million in the first half of 2015, primarily due to the recovery of business previously lost to competition from private label brands, as well the initiation of a distributor expansion strategy. International sales of Histofreezer® remained relatively unchanged at $446,000 in the first six months of 2016, compared to $498,000 in the same period of the prior year.

Sales of our private-label wart removal product in the U.S. retail market increased to $723,000 in the first half of 2016 from $163,000 in the first half of 2015, due to the launch of private-label products in two additional large pharmacy chains earlier this year.

Sales of our international OTC cryosurgical products during the first six months of 2016 remained relatively flat at $3.0 million compared to $3.2 million in the same period of the prior year.

Other revenues

Other revenues in the first half of 2016 were $7.6 million and included $6.7 million in exclusivity revenue recognized under our HCV co-promotion agreement with AbbVie and $899,000 recognized in connection with Ebola-related funding from BARDA. Other revenues in the first half of 2015 were $7.4 million and included $6.7 million in AbbVie exclusivity revenue and $714,000 in Ebola-related funding from BARDA. Following the termination of our HCV co-promotion agreement with AbbVie on December 31, 2016, AbbVie will have no further financial obligations to us.

DNAG Segment

Molecular Collection Systems

Net molecular collection systems revenues increased 3% to $15.3 million in the first half of 2016 from $14.8 million in the first half of 2015. Sales of our Oragene® product in the academic market increased 14% in the first half of 2016 compared to the first half of 2015, due to the shipment of product to support a study on the epidemiology of aging and a study on autism. Sales of our Oragene® product in the commercial market decreased 5% in the first half of 2016 compared to the first half of 2015, primarily as a result of the loss of two U.S. customers that have filed for bankruptcy protection. These customers contributed approximately $1.9 million in sales during the first half of 2015. The Company has no unreserved collection exposure related to these two customers. The reduction in commercial revenue was partially offset by sales to new customers. Revenues in the first half of 2016 also included $381,000 in sales of our microbiome product compared to $121,000 in the same period of 2015. We believe interest in our microbiome product offering continues to grow with both new and existing customers.

CONSOLIDATED OPERATING RESULTS

Consolidated gross margin was 68% for the first half of 2016 compared to 66% for the first half of 2015. Gross margin for 2016 increased primarily due to lower scrap and spoilage expenses.

Consolidated operating income for the first half of 2016 was $7.0 million, a $4.6 million increase from $2.4 million of operating income reported in the first half of 2015. The current period operating income benefited from higher revenues, improved gross margins and lower research and development and sales and marketing costs, partially offset by higher general and administrative expenses.

OPERATING INCOME BY SEGMENT

OSUR Segment

OSUR's gross margin was 68% in the first half of 2016 compared to 64% in the first half of 2015. OSUR's gross margin in 2016 was positively impacted by lower scrap and spoilage costs, a more favorable product mix, decreased royalty expense, and an increase in Ebola-related funding from BARDA.

Research and development expenses decreased 18% to $4.1 million in the first half of 2016 from $5.0 million in the first half of 2015. During the first quarter of 2015, we conducted clinical studies related to the development of our fully-automated high-throughput drugs-of-abuse assays. In addition, we incurred certain program expenses related to the co-development agreement for these assays. These costs did not recur in 2016 and were partially offset by higher supply costs associated with the development of our Zika and Ebola products and the additional costs associated with hiring our new Senior Vice President of Research and Development and Chief Science Officer. Sales and marketing expenses decreased 12% to $11.4 million in the first half of 2016 from $13.0 million in the first half of 2015. This decrease was primarily the result of lower detailing costs and other expenses associated with our OraQuick® HCV co-promotion agreement with AbbVie as well as lower staffing costs. General and administrative expenses increased 5% to $10.5 million in the first half of 2016 compared to $10.0 million in the first half of 2015 largely due to higher consulting and staffing expenses.

All of the above contributed to OSUR's operating income of $4.5 million for the first half of 2016, which included non-cash charges of $1.3 million for depreciation and amortization and $2.7 million for stock-based compensation.

DNAG Segment

DNAG's gross margin was remained relatively unchanged at 70% in the first half of 2016 compared to 71% in the first half of 2015.

Research and development expenses decreased 12% to $1.3 million in the first half of 2016 from $1.4 million in the first half of 2015 largely due to lower staffing expenses and validation costs. Sales and marketing expenses increased 21% to $4.6 million in the first half of 2016 from $3.8 million in the first half of 2015 due to higher commission and staffing costs and an increase in our allowance for uncollectible accounts, partially offset by a favorable foreign currency exchange rate impact of approximately $237,000. General and administrative expenses increased 17% to $2.3 million in the first half of 2016 compared to $2.0 million in the first half of 2015 largely due to higher legal fees, partially offset by lower staffing expenses.

All of the above contributed to DNAG's second quarter 2016 operating income of $2.5 million, which included non-cash charges of $1.5 million for depreciation and amortization and $265,000 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 six months ended June 30, 2016, state income tax expense of $50,000 was recorded compared to $0 in the six months ended June 30, 2015. Canadian income tax expense of $184,000 and $663,000 was recorded in the first half of 2016 and 2015, respectively.

Liquidity and Capital Resources

	June 30, 2016	December 31, 2015
	(In thousands)	
Cash and cash equivalents	$105,701	$ 94,094
Short-term investments	7,736	7,225
Working capital	120,304	111,480

Our cash and cash equivalents and short-term investment balances increased to $113.4 million at June 30, 2016 from $101.3 million at December 31, 2015. Our working capital increased to $120.3 million at June 30, 2016 from $111.5 million at December 31, 2015.

During the first half of 2016, we generated $16.7 million in cash from operating activities. Our net income of $6.3 million benefitted from non-cash stock-based compensation expense of $2.9 million, depreciation and amortization expense of $2.8 million, and unrealized foreign currency losses of $115,000. Additional sources of cash included an increase in deferred revenues of $4.1 million related to the receipt of an additional exclusivity payment from AbbVie partially offset by the ratable recognition into revenue of previously deferred exclusivity payments, a decrease in inventory balances of $1.9 million largely associated with higher sales of our OraQuick® HCV and HIV products, and a decrease in accounts receivable of $893,000 resulting from the collection of outstanding balances due at the end of 2015. Uses of cash in operating activities during the period included a $1.5 million decrease in accrued expenses and other liabilities associated with payment of our 2015 management incentive bonuses and a $782,000 decrease in accounts payable associated with payments for year-end inventory purchases and the relocation of our Canadian corporate offices.

Net cash used in investing activities was $2.7 million for the six months ended June 30, 2016, which reflects $15.3 million used to purchase short-term investments and $2.7 million to acquire property and equipment, partially offset by $15.3 million in proceeds from the maturities of short-term investments.

Net cash used in financing activities was $3.1 million for the six months ended June 30, 2016, which resulted from the use of $2.7 million to repurchase shares under our previously authorized stock repurchase plan and $651,000 used for the repurchase of common stock to satisfy withholding taxes related to the vesting of restricted shares, partially offset by $209,000 in proceeds received from the exercise of stock options.

Our current cash and cash equivalents balance is 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 litigation, the magnitude of capital expenditures, changes in existing and potential relationships with business partners, the timing and cost of obtaining regulatory approvals, 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, 2015 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, 2015. As of June 30, 2016, 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, 2015 filed with the SEC. During the first six months of 2016, 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 June 30, 2016, 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 5.4% of our total revenues for the six months ended June 30, 2016. 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 $60.2 million CDN ($46.6 million USD), which are included in the Company's consolidated balance sheet as of June 30, 2016. A 10% unfavorable change in the Canadian-to-U.S. dollar exchange rate would have decreased our comprehensive income by $4.6 million in the six months ended June 30, 2016.

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 June 30, 2016. Based on that evaluation, the Company's management, including such officers, concluded that the Company's disclosure controls and procedures were effective as of June 30, 2016 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 SEC.

(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 June 30, 2016 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 alleges 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 alleges that Ancestry has breached the terms of agreements under which Ancestry previously purchased DNAG products. The complaint also includes an action to quiet title to the Ancestry Device and related patent applications. DNAG is requesting the court to grant injunctive relief and damages. Ancestry has filed counterclaims seeking a declaration of non-infringement, invalidity, and to quiet title to its patent applications. The case is currently in the discovery stage. DNAG amended its complaint to add Lanham Act claims against Ancestry, alleging that Ancestry falsely labeled the Ancestry Device as being "Made in the USA."

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. A final decision from the USPTO is expected in April 2017. On June 3, 2016, Ancestry filed a second Petition for IPR of some, but not all, claims of U.S. Patent No. 8,221,381 B2. The USPTO has not yet decided whether to institute the second IPR.

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"). We believe the Spectrum Device is the same as the Ancestry device mentioned above and that Spectrum is the manufacturer of the Ancestry Device for Ancestry. The complaint alleges 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 alleges that the Delaware District Court lacks jurisdiction over Spectrum. The Court is now considering a fully-briefed 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 alleges 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 is requesting 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 an Petition for IPR of U.S. Patent No. 9,207,164, which was filed by Ancestry in July 2016. The USPTO has not yet decided whether to institute the IPR.

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, 2015.

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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)
April 1, 2016 - April 30, 2016	—	$ —	—	$ 11,984,720
May 1, 2016 - May 31, 2016	18,101(1)	6.84	N/A	11,984,720
June 1, 2016 - June 30, 2016	—	—	—	11,984,720
	18,101		—	

(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: August 8, 2016	Ronald H. Spair Chief Operating Officer and Chief Financial Officer *(Principal Financial Officer)*
	/s/ Mark L. Kuna
Date: August 8 2016	Mark L. Kuna Senior Vice President, Finance and Controller *(Principal Accounting Officer)*

EXHIBIT INDEX

Exhibit Number	Exhibit
10.1	First Amendment to Master Program Services and Product Co-Promotion Agreement, dated as of June 30, 2016 between OraSure Technologies, Inc. and AbbVie Bahamas Ltd., is incorporated by reference to Exhibit 99.2 to the Company's Current Report on Form 8-K filed July 1, 2016.
10.2	Terms of Employment for Michael Reed, Senior Vice President, Research and Development and Chief Science Officer for OraSure Technologies, Inc.*
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

OraSure Technologies, Inc.

Exhibit 10.2

March 14, 2016

Michael Reed
7395 SW 133rd Terrace
Miami, FL 33156

Dear Mike,

It is a pleasure to confirm our offer of employment and your verbal acceptance as Senior Vice President, R&D and Chief Science Officer (SVP, R&D and CSO) on behalf of OraSure Technologies, Inc. with a starting date of April 18, 2016. Your orientation to OraSure will occur on April 18, 2016 at 9:00 am with a representative of the Human Resource department.

The terms and conditions of your employment are contained in this letter and the attachments called "Compensation Package and "Relocation Package." This is subject to Board of Directors approval.

Your employment is contingent upon receipt of proof of eligibility to work in the United States (Form I-9), your successful completion of a pre-employment drug test, and completion of the attached Employee Confidentiality Agreement. Please complete the signed offer letter and return it to the Human Resources Department. You will be asked to complete the I-9 form on your first day of employment. You must also bring the signed Confidentiality Agreement on your first day. Additionally, please contact Ayesha Herrera at 610-882-1820 ext. 1637, to schedule your pre-employment drug test.

As an OraSure employee, you can enroll in an extensive employee benefit package. You will be eligible for health, dental, and life insurance the first day of hire. You will be eligible to participate in the OraSure's Savings Plan 401(k) on the first of the month following three months of employment. Materials have been sent to you under separate cover.

This letter and attachments represent the entire job offer and is not a contract of employment. Your employment with OraSure is "at will" and neither this letter nor any other oral or written representation may be considered a contract for any specific period of time. No changes, additions, or modifications to this letter or attachments shall be binding unless they are in writing and signed by the parties to this letter.

We sincerely are excited that you will be joining our "OraSure team." We look forward to receiving your written confirmation within seven days from the date of this letter. To formally accept the offer, please sign in the place provided below and send it to Human Resources.

Once again, congratulations!

Sincerely,

/s/ Henry B. Cohen

Henry B. Cohen
Senior Vice President
Human Resources

Accepted by: */s/ Michael Reed   3/16/16*
Signature and Date

Name: Michael Reed

220 East First Street, Bethlehem, PA 18015-1360
Phone: 610.882.1820
www.orasure.com

OraSure Technologies, Inc.

Compensation Package
Effective April 18, 2016

Name:	Michael Reed
Job Title:	Senior Vice President, Research and Development and Chief Science Officer
Supervisor:	Doug Michels
Job Grade:	Executive Committee
Status:	Full-time, Regular
Initial Base Salary:	$11,730.77 biweekly, which is equivalent to an annual salary of $305,000.00.
2016 MIP Bonus:	Payable in February, 2017 based on both company performance versus metrics and individual performance on goals and objectives. No proration of payment. Target payout is 35% and "meets requirements" rating of individual performance.
Initial LTIP Award:	The initial incoming equity grant will be made shortly after you join the company. It will be for a value transfer of $274,500 (90% of your base salary). It will be awarded as follows: A) 50% in time-vested restricted stock with a 3 year vesting period, and B) 50% in performance-vested restricted stock units with 3 year vesting. Grants will be made shortly after you join the company. Performance will be measured on the same basis as awards granted in OraSure on 2/1/16.
Subsequent LTIP Awards:	Eligible for LTIP awards for the 2016 performance year and annually thereafter. Awards are discretionary and performance based. Target award is 75% of base salary. Awards are typically made in February. Your 2016 award would typically be paid in February 2017 and consist of 50% time-vested restricted stock, and 50% performance-based restricted stock units. These awards will not be prorated.
Initial Salary Review:	Effective 01/01/17 – no proration. Salary adjustments are typically implemented in mid-February with retroactivity to January 1st.
Paid Time Off:	2016 – 20 days (160 hours) PTO 2017 – 25 days (200 hours) PTO
Employment:	If your employment is terminated by the company for reasons other than a code of conduct violation, we will provide a severance payment equal to twelve months of base salary.
Legal Expenses:	In the event that Danaher Corporation seeks to enforce certain non-compete provisions in the "Agreement Regarding Competition and Protection of Proprietary Issues signed by Employee", OraSure will provide legal counsel at Company expense and is further detailed in the enclosed side agreement with Employee.

OraSure is a dynamic company whose policies, procedures, and programs may change to address its business needs. Therefore, OraSure reserves the right to amend, suspend, or terminate any pay program, benefit program, or incentive program; in whole or in part, at any time and for any reason, without the consent of or prior notification to any eligible employee.

220 East First Street, Bethlehem, PA 18015-1360
Phone: 610.882.1820
www.orasure.com

OraSure Technologies, Inc.

March 14, 2016

Mr. Michael R. Reed
7395 Southwest 133rd Terrace
Miami, FL 33156

Re: Reimbursement Agreement

Dear Mike:

I am writing to follow up our discussions concerning your employment with OraSure Technologies, Inc. ("OraSure" or the "Company") and your Agreement Regarding Competition and Protection of Proprietary Interests (the "Agreement") with your current employer, Danaher Corporation ("Danaher"). Neither you nor OraSure believe that your employment as Senior Vice President, Research and Development and Chief Science Officer with OraSure would violate any term of the Agreement and OraSure expects you to honor any and all valid agreements that you may have with any former employer. However, in the event that Danaher asserts that your employment with OraSure violates your non-competition obligations under Sections 6(a), 6(b), 6(c) or 6(g) of the Agreement, OraSure agrees that it will reimburse your reasonable attorneys' fees in responding to such allegations, provided that: 1) you comply with OraSure's direction concerning the scope and nature of your job responsibilities; and 2) you remain an employee in good standing with OraSure. OraSure's obligation to reimburse you under the terms of this letter shall cease upon the termination of your employment with OraSure where such termination is a voluntary action by you or a termination by the Company as a result of your violation of OraSure's Code of Business Conduct and Ethics. Nothing in this letter will change the at-will nature of your employment with OraSure nor does this letter constitute an employment agreement.

If the foregoing is acceptable, please sign and date this letter in the space provided below.

Sincerely,

/s/ Henry B. Cohen
Henry B. Cohen
Senior Vice President, Human Resources

Agreed and Understood

/s/ Michael R. Reed 3/16/16
Michael R. Reed

220 East First Street, Bethlehem, PA 18015-1360
Phone: 610.882.1820
www.orasure.com

OraSure Technologies, Inc.

Relocation Package
Effective April 18, 2016

Name:	Michael Reed
Job Title:	Senior Vice President, R&D and Chief Science Officer
Supervisor:	Doug Michels, President & CEO
From/To:	Miami, FL to Bethlehem, PA
Home Finding:	2 trips; up to 4 days each; hotel, meals, travel not exceeding a total amount of $7,000.00.
Temporary Housing:	Up to 6 months at a $4,000.00 monthly allowance – receipts required, not to exceed a total of $24,000.00. Will cease upon the close of sale of your primary residence in Florida.
Movement of Household Goods:	Packing, shipment, unpacking of normal household goods and effects not to exceed a total of $25,000.00. (Includes provision for shipping two cars).
Storage of Household Goods:	Up to 6 months at $600.00, not to exceed total of $3,600.00.
Home Sale Expenses:	1. Real Estate Commission, not to exceed 5% of sale price, or $50,000.00, whichever is less. 2. Other transactional expenses – attorney, transfer taxes, other taxes, not to exceed $8,000.00.
Home Purchase Expenses:	Attorney fees, transfer and realty taxes on transaction, etc. – not to exceed $8,000.00.
Travel Allowance:	To and from Miami, Florida - $1,500/month for up to 6 months, not to exceed $9,000.00.
Final Move:	For self and family, one way travel from Miami, FL to PA – not to exceed $2,000.00
Miscellaneous Allowance:	You will receive reimbursement of up to $10,000.00 to cover other expenses related to your relocation, but not specified in this letter. These expenses will require receipts as documentation.
Tax Gross-up:	At your incremental federal and state rates.

It is anticipated that there will be overages and under spending on a line item basis. Allowances may be shifted between areas, subject to Human Resources and Finance approval and subject to staying within the $146,600.00 spending limit (excluding tax gross-up). You will be expected to execute the attached repayment agreement for any relocation expense incurred by the company on your behalf should you voluntarily leave the company before completing two years of employment.

220 East First Street, Bethlehem, PA 18015-1360
Phone: 610.882.1820
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OraSure Technologies, Inc.

RELOCATION
REPAYMENT AGREEMENT

This Agreement, dated as of the day of March 14, 2016, by and between OraSure Technologies, Inc., a Delaware corporation with its principal place of business at 220 E. First Street, Bethlehem, PA 18015 (the “Company”) and Michael Reed (the “Employee”).

1) After the commencement of Employee’s employment with Company, or a subsidiary or affiliate thereof on April 18, 2016 (the “Employment Commencement Date”) if Employee: (i) voluntarily resigns his/her employment from Company or a subsidiary or affiliate; or (ii) Employee fails or refuses to report to work on the Employment Commencement Date, or if Company or such subsidiary or affiliate terminates Employee for “Cause”, within 2 years of the Employment Commencement Date, then Employee shall repay to Company the Expenses previously reimbursed and or paid to Employee for relocation. Expenses may include, but are not limited to the following:

   a. Commission on sale of current residence;
   b. Administrative fees in accordance with home sale, including recording fees, title search, legal fees;
   c. Household Goods transfer from current location to new residence;
   d. Home purchase costs including inspection, mortgage broker, title attorney, closing attorney, title insurance, survey;
   e. Temporary living for 120 days;
   f. Tax Gross-up, if applicable;
   g. Miscellaneous relocation allowance;
   h. Any other expenses related to the Employee’s relocation.

2) For the purposes of this Agreement, termination for “Cause” shall mean (i) Employee’s failure to perform and carry out his/her duties and responsibilities, within his/her reasonable control or responsibility, other than as a result of Employee’s incapacity due to physical or mental disability, as determined in a manner consistent with the short-term disability policies of Company, (ii) any act by Employee of dishonestly or moral turpitude relating to Company, any subsidiary or affiliate, or (iii) any breach by Employee of any non-compete, non-solicitation, confidentiality or restrictive covenants agreement(s) with Company or any subsidiary or affiliate thereof.

3) In the event Employee must repay the Expenses in accordance with Section 2 above, Company will advise Employee of the amount owed upon such termination. Company is hereby authorized to collect the Expenses by deducting from any sums Company is otherwise obligated to pay Employee (including Employee’s final paycheck) to the extent permitted by law. Employee agrees to repay Company any balance remaining after any such deductions are made within thirty (30) days after termination of employment. In the event Employee fails to repay the Expenses after such demand, and it is necessary for

Company to take legal action to collect such amount, Employee agrees to pay Company for all costs incurred by Company to collect such amounts, including reasonable attorneys' fees and court costs.

4) This Agreement shall be construed and interpreted according to the laws of the Commonwealth of Pennsylvania. This Agreement does not, in any way, change or modify Employee's "at-will" employment status.

Please sign and return a copy of this Agreement to:

OraSure Technologies, Inc.
220 E. First Street
Bethlehem, PA 18015
Attn: Human Resources

No payment for Expenses will be issued until receipt of this signed Agreement.

Employee	**OraSure Technologies, Inc.**
Michael Reed Please Print	
/s/ Michael Reed Signature	by: */s/ Henry B. Cohen* Authorized Representative
3/16/16 Date	3/14/16 Date

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: August 8, 2016

/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: August 8, 2016

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

Exhibit 32.1

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 June 30, 2016 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

August 8, 2016

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 June 30, 2016 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

August 8, 2016