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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 September 30, 2015.

OR

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

For the transition period from _____ to _____.

Commission File Number 001-16537

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

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

(610) 882-1820
(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 November 3, 2015: 56,482,384 shares.

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PART I. FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

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

	SEPTEMBER 30, 2015	DECEMBER 31, 2014
ASSETS		
CURRENT ASSETS:		
Cash	$ 100,677	$ 92,867
Short-term investments	7,512	5,000
Accounts receivable, net of allowance for doubtful accounts of $608 and $533	17,089	16,138
Inventories	14,985	15,763
Prepaid expenses	1,400	1,140
Other current assets	159	306
Total current assets	141,822	131,214
PROPERTY AND EQUIPMENT, net	17,800	17,934
INTANGIBLE ASSETS, net	13,661	17,505
GOODWILL	18,974	21,734
OTHER ASSETS	1,589	1,246
	$ 193,846	$ 189,633
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 6,964	$ 7,148
Deferred revenue	13,302	8,043
Deferred income taxes	122	139
Accrued expenses	9,307	11,132
Total current liabilities	29,695	26,462
OTHER LIABILITIES	1,142	1,234
DEFERRED INCOME TAXES	3,010	3,236
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, 56,482 and 56,187 shares issued and outstanding	—	—
Additional paid-in capital	348,677	344,894
Accumulated other comprehensive loss	(13,884)	(7,848)
Accumulated deficit	(174,794)	(178,345)
Total stockholders' equity	159,999	158,701
	$ 193,846	$ 189,633

See accompanying notes to the consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
NET REVENUES:				
Product	$25,714	$24,447	$75,792	$73,610
Other	4,147	3,398	11,545	4,173
	29,861	27,845	87,337	77,783
COST OF PRODUCTS SOLD	9,192	9,140	28,974	29,135
Gross profit	20,669	18,705	58,363	48,648
OPERATING EXPENSES:				
Research and development	2,525	2,990	8,961	8,242
Sales and marketing	9,677	9,216	26,465	30,828
General and administrative	6,931	5,617	18,971	17,317
Gain on contract termination settlement	—	—	—	(5,500)
	19,133	17,823	54,397	50,887
Operating income (loss)	1,536	882	3,966	(2,239)
OTHER INCOME	81	268	395	244
Income (loss) before income taxes	1,617	1,150	4,361	(1,995)
INCOME TAX EXPENSE (BENEFIT)	147	10	810	(33)
NET INCOME (LOSS)	$ 1,470	$ 1,140	$ 3,551	$ (1,962)
EARNINGS (LOSS) PER SHARE:				
BASIC	$ 0.03	$ 0.02	$ 0.06	$ (0.04)
DILUTED	$ 0.03	$ 0.02	$ 0.06	$ (0.04)
SHARES USED IN COMPUTING EARNINGS (LOSS) PER SHARE:				
BASIC	56,482	56,018	56,427	55,897
DILUTED	56,692	56,666	56,900	55,897

See accompanying notes to the consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
NET INCOME (LOSS)	$ 1,470	$ 1,140	$ 3,551	$(1,962)
OTHER COMPREHENSIVE LOSS				
Currency translation adjustments	(2,858)	(2,295)	(6,036)	(2,451)
Other comprehensive loss	(2,858)	(2,295)	(6,036)	(2,451)
COMPREHENSIVE LOSS	$(1,388)	$(1,155)	$(2,485)	$(4,413)

See accompanying notes to the consolidated financial statements.

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

	Nine Months Ended September 30,	
	2015	2014
OPERATING ACTIVITIES:		
Net income (loss)	$ 3,551	$ (1,962)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Stock-based compensation	4,543	4,284
Depreciation and amortization	4,259	4,732
Unrealized foreign currency loss (gain)	450	(73)
Deferred income taxes	198	(33)
Changes in assets and liabilities		
Accounts receivable	(1,572)	(2,111)
Inventories	633	(3,444)
Prepaid expenses and other assets	(614)	576
Accounts payable	(72)	(284)
Deferred revenue	5,269	10,433
Accrued expenses and other liabilities	(1,540)	(3,734)
Net cash provided by operating activities	15,105	8,384
INVESTING ACTIVITIES:		
Purchases of short-term investments	(19,411)	(9,407)
Proceeds from maturities of short-term investments	16,450	4,432
Purchases of property and equipment	(1,885)	(2,353)
Net cash used in investing activities	(4,846)	(7,328)
FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	124	546
Repurchase of common stock	(883)	(639)
Net cash used in financing activities	(759)	(93)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	(1,690)	(299)
NET INCREASE IN CASH	7,810	664
CASH, BEGINNING OF PERIOD	92,867	93,191
CASH, END OF PERIOD	$100,677	$93,855
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for:		
Income taxes	$ 230	$ 42

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 oral fluid collection devices used to collect, stabilize and store samples of genetic material for molecular testing in the consumer genetic, clinical genetic, academic research, pharmacogenomics, personalized medicine, and animal genetics 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 subsidiaries, 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, 2014. Results of operations for the three and nine months ended September 30, 2015 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 loss.

Our available-for-sale securities as of September 30, 2015 and December 31, 2014 consisted of guaranteed investment certificates with amortized cost and fair values of $7,512 and $5,000, respectively.

Fair Value of Financial Instruments. As of September 30, 2015 and December 31, 2014, the carrying values of cash, short-term investments, 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).

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 September 30, 2015 and December 31, 2014 was $1,142 and $1,234, 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 September 30, 2015 and December 31, 2014.

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:

	September 30, 2015	December 31, 2014
Raw materials	$ 7,549	$ 8,539
Work in process	539	898
Finished goods	6,897	6,326
	$ 14,985	$ 15,763

Prepaid Expenses and Other Noncurrent Assets. In June 2015, we amended a license related to our OraQuick® products in order to provide for a buy-out of our royalty obligations under that license. Pursuant to this amendment, we made a one-time payment of $1,100 to the licensor in full satisfaction of all current and future royalty obligations due under the license. We recorded this amount as prepaid royalties, and it is being charged to expense in relation to sales of our OraQuick® HIV products through June 30, 2017.

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 or otherwise disposed of, the related property amounts are relieved from the accounts, and any gain or loss is recorded in the consolidated statement of operations. Accumulated depreciation of property and equipment as of September 30, 2015 and December 31, 2014 was $33,252 and $31,416, respectively.

Intangible Assets. Intangible assets consist of the following:

	Amortization Period (Years)	September 30, 2015 Gross	Accumulated Amortization	Net
Customer list	10	$ 9,410	$ (3,741)	$ 5,669
Patents and product rights	3-10	10,449	(8,294)	2,155
Acquired technology	7	7,309	(4,088)	3,221
Tradename	15	3,607	(991)	2,616
		$30,775	$ (17,114)	$13,661

	Amortization Period (Years)	December 31, 2014 Gross	Accumulated Amortization	Net
Customer list	10	$10,779	$ (3,508)	$ 7,271
Patents and product rights	3-10	10,449	(7,957)	2,492
Acquired technology	7	8,372	(3,833)	4,539
Tradename	15	4,132	(929)	3,203
		$33,732	$ (16,227)	$17,505

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 value 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 their 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 amount. 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 September 30, 2015, we believe no indicators of impairment exist.

The change in goodwill from $21,734 as of December 31, 2014 to $18,974 as of September 30, 2015 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 our OraQuick® In-Home HIV test, 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. Some of these allowances are estimates established by management, based on currently available information, and are adjusted to reflect known changes in the factors that impact those estimates. These allowances are recorded as a reduction of gross revenue when recognized in our statements of operations.

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. The product is used to test individuals at-risk for the hepatitis C virus (“HCV”). We are responsible for manufacturing and selling the product into all markets covered by this agreement.

Pursuant to the Co-Promotion Agreement, we have granted exclusive co-promotion rights for the OraQuick® HCV test in certain markets to AbbVie and we have 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 have also jointly agreed with AbbVie to co-promote our OraQuick® HCV test in certain market segments.

Under the terms of this agreement, which runs through December 31, 2019, we are eligible to receive up to $75,000 in aggregate payments. We are recognizing these payments ratably on a monthly basis over the term of the agreement. During the third quarter of 2015, $3,397 in exclusivity payments were recognized. In addition, if certain performance-based milestones are achieved, we may be eligible to receive additional milestone payments. These payments would be based upon the aggregate number of new patients enrolled in the patient care database, in a given calendar year, after exceeding a baseline threshold, and could range from $3,500 to $55,500 annually over the term of the agreement. The first performance-based milestone period ends on December 31, 2015, but it is unlikely that a milestone will be achieved during this period. The agreement also contains certain termination, indemnification and other provisions, typical of agreements of this type. Amounts related to this agreement are recorded as other revenue in our statements of operations.

On June 12, 2015, we were awarded a contract for up to $10,400 in total funding from the U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response’s Biomedical Advanced Research and Development Authority (BARDA) related to our OraQuick® Ebola Rapid Antigen test. The three-year, multi-phased contract 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 our OraQuick® Ebola Rapid Antigen test. Amounts related to this contract are recorded as other revenue in our statement of operations as the activities are being performed. During the third quarter of 2015, $750 was recognized in connection with this contract.

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 operations. 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 September 30, 2015 and December 31, 2014, the reserve for sales returns and allowances was $277 and $437, 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 September 30, 2015 and December 31, 2014 includes customer prepayments of $953 and $613, respectively. Deferred revenue as of September 30, 2015 and December 31, 2014 also includes $12,349 and $7,430, respectively, from AbbVie, which represents the excess of the payments received from AbbVie over the amounts earned and recognized ratably in revenue.

Customer and Vendor Concentrations. One of our customers accounted for approximately 11% of our accounts receivable balance as of September 30, 2015. We had no significant concentrations in accounts receivable as of December 31, 2014. Another customer accounted for approximately 11% and 12% of our net revenues for the three months ended September 30, 2015 and September 30, 2014, respectively. This same customer accounted for approximately 12% of our net revenues for the nine months ended September 30, 2015. We had no significant concentrations in net revenues for the nine months ended September 30, 2014.

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 (Loss) Per Share. Basic earnings (loss) per share is computed by dividing net income (loss) by the weighted-average number of shares of common stock outstanding during the period. Diluted earnings (loss) per share is computed in a manner similar to basic earnings (loss) 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 (loss) per share are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Net income (loss)	$ 1,470	$ 1,140	$ 3,551	$ (1,962)
Weighted average shares of common stock outstanding:				
Basic	56,482	56,018	56,427	55,897
Dilutive effect of stock options and restricted stock	210	648	473	—
Diluted	56,692	56,666	56,900	55,897
Earnings (loss) per share:				
Basic	$ 0.03	$ 0.02	$ 0.06	$ (0.04)
Diluted	$ 0.03	$ 0.02	$ 0.06	$ (0.04)

For the three-month periods ended September 30, 2015 and 2014, outstanding common stock options and unvested restricted stock, representing 6,231 and 2,647 shares, respectively, were excluded from the computation of diluted earnings per share as their inclusion would have been anti-dilutive. For the nine months ended September 30, 2015 and 2014, outstanding common stock options and unvested restricted stock, representing 4,648 and 3,313 shares, respectively, were similarly excluded from the computation of diluted earnings (loss) 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 income in the period in which the change occurs.

Accumulated Other Comprehensive Loss. We classify items of other comprehensive income (loss) by their nature and disclose the accumulated balance of other comprehensive 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 $6,036 and $2,451 currency translation adjustments recorded in the first nine months of 2015 and 2014, 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 issues ASU 2015-11, *Simplifying the Measurement of Inventory*, which requires an entity that uses the first in first out method for inventory to report inventory cost at the lower of cost or net realizable value versus the current measurement principle of lower cost or market. The ASU requires prospective adoption for inventory measurements for fiscal years beginning after December 15, 2016. Early adoption is permitted. The Company is evaluating the effect that ASU 2015-11 may have on its consolidated financial statements and related disclosures.

3. 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, we issue new shares rather than purchase shares on the open market.

Total compensation cost related to stock options for the nine months ended September 30, 2015 and 2014 was $2,557 and $2,286, respectively. Net cash proceeds from the exercise of stock options were $124 and $546 for the nine months ended September 30, 2015 and 2014, 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 $1,986 and $1,998 related to restricted shares was recognized during the nine months ended September 30, 2015 and 2014, respectively. In connection with the vesting of restricted shares and exercise of stock options during the nine months ended September 30, 2015 and 2014, we purchased and immediately retired 132 and 106 shares with aggregate values of $883 and $639, respectively, in satisfaction of minimum tax withholding and exercise obligations.

4. Accrued Expenses

	September 30, 2015	December 31, 2014
Payroll and related benefits	$ 5,493	$ 6,620
Professional fees	1,076	480
Royalties	618	2,285
Other	2,120	1,747
	$ 9,307	$ 11,132

5. Income Taxes

During the three and nine months ended September 30, 2015, we recorded foreign tax expense of $147 and $810, respectively. Foreign taxes during the three and nine months ended September 30, 2015 includes $168 of deferred tax benefits and $198 of deferred tax expense, respectively. Foreign taxes for the three and nine months ended September 30, 2015 also include $315 and $612, respectively, of current tax expense associated with amounts payable for provincial taxes. During the three and nine months ended September 30, 2014, we recorded foreign deferred tax expense of $10 and foreign deferred tax benefits of $33, respectively.

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 September 30, 2015 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 September 30, 2015 and December 31, 2014 since the facts and circumstances necessitating the allowance have not changed. As a result, no U.S. federal or state income tax benefit was recorded for the three and nine-month periods ended September 30, 2015 and 2014.

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, and animal and livestock genetic testing. DNAG products are also sold into the academic research market, which consists of research laboratories, universities and hospitals.

We organized our operating segments according to the nature of the products included in those segments. The accounting policies of the segments are the same as those described in the summary of significant accounting policies (see Note 2). We evaluate performance of our operating segments based on revenue and operating income (loss). We do not allocate interest income, interest expense, other income, other expenses or income taxes to our operating segments. Reportable segments have no inter-segment revenues.

The following table summarizes operating segment information for the three and nine months ended September 30, 2015 and 2014, and asset information as of September 30, 2015 and December 31, 2014:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Net revenues:				
OSUR	$22,532	$20,978	$65,189	$60,260
DNAG	7,329	6,867	22,148	17,523
Total	$29,861	$27,845	$87,337	$77,783
Operating income (loss):				
OSUR	$ 725	$ (987)	$ (111)	$ (5,177)
DNAG	811	1,869	4,077	2,938
Total	$ 1,536	$ 882	$ 3,966	$ (2,239)
Depreciation and amortization:				
OSUR	$ 764	$ 820	$ 2,224	$ 2,386
DNAG	646	804	2,035	2,346
Total	$ 1,410	$ 1,624	$ 4,259	$ 4,732
Capital expenditures:				
OSUR	$ 536	$ 298	$ 1,102	$ 1,868
DNAG	204	67	783	485
Total	$ 740	$ 365	$ 1,885	$ 2,353

	September 30, 2015	December 31, 2014
Total assets:		
OSUR	$ 141,506	$ 136,542
DNAG	52,340	53,091
Total	$ 193,846	$ 189,633

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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
United States	$24,207	$22,469	$69,695	$58,987
Europe	2,738	3,252	10,051	10,935
Other regions	2,916	2,124	7,591	7,861
	$29,861	$27,845	$87,337	$77,783

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

	September 30, 2015	December 31, 2014
United States	$ 15,866	$ 16,570
Canada	1,923	1,353
Other regions	11	11
	$ 17,800	$ 17,934

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; ability to achieve financial and performance objectives under the HCV co-promotion agreement with AbbVie; 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, 2014, 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 oral fluid collection devices used to collect, stabilize and store samples of genetic material for molecular testing in the consumer genetic, clinical genetic, academic research, pharmacogenomics, personalized medicine, and animal genetics 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, and commercial and industrial entities, retail pharmacies and mass merchandisers, and to consumers over the internet.

Recent Developments

Rapid Ebola Test

In July 2015, the Company received a U.S. Food and Drug Administration (“FDA”) Emergency Use Authorization for its OraQuick® Ebola Rapid Antigen test. This authorization allows the use of the Company’s Ebola test for the duration of the U.S. Secretary of the Department of Health and Human Services (“HHS”) August 5, 2014 declaration regarding the emergency use of in vitro diagnostic tests for the detection of the Ebola virus.

In September 2015, the Biomedical Advanced Research Development Authority(“BARDA”) within HHS exercised an option to provide $7.2 million in additional funding for our OraQuick® Ebola test. This funding will be used primarily for clinical and regulatory activities required to request FDA 510(k) clearance for this product. This option is part of the aggregate $10.4 million funding contract we announced in June 2015. The three-year, multi-phased contract included an initial commitment of $1.8 million and options for up to an additional $8.6 million to fund certain clinical and regulatory activities. Funding received under this contract is recorded as other revenue in our consolidated statement of operations as the activities are being performed.

In addition, during the third quarter of 2015 the Centers for Disease Control and Prevention (“CDC”) agreed to purchase approximately $1.5 million of our OraQuick® Rapid Ebola test. This purchase is expected to be fulfilled by the end of 2015. The CDC is purchasing this product for field testing in West Africa. This is the second such purchase of this product for field testing by the CDC.

Current Consolidated Financial Results

During the nine months ended September 30, 2015, our consolidated net revenues were $87.3 million, compared to $77.8 million for the nine months ended September 30, 2014. Net product revenues during the nine months ended September 30, 2015 increased 3% when compared to the first nine months of 2014, primarily due to higher sales of our molecular collection systems, OraQuick® HCV and Intercept® products. Other revenues for the first nine months of 2015 were $11.5 million, of which $10.1 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 $1.4 million represents revenue recognized in connection with the Ebola-related funding from BARDA.

Our consolidated net income for the nine months ended September 30, 2015 was $3.6 million, or $0.06 per share on a fully-diluted basis, compared to a consolidated net loss of $2.0 million, or $0.04 per share, for the nine months ended September 30, 2014.

Cash provided by operating activities for the nine months ended September 30, 2015 was $15.1 million, compared to $8.4 million provided by operating activities during the nine months ended September 30, 2014. As of September 30, 2015, we had $108.2 million in cash and short-term investments compared to $97.9 million at December 31, 2014.

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, 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 primarily from products sold into the commercial market, which consists of customers engaged in consumer genetics, clinical genetic testing, pharmacogenomics, personalized medicine, 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 September 30, 2015 compared to September 30, 2014

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 September 30, 2015 and 2014.

	Three Months Ended September 30,				
	Dollars			Percentage of Total Net Revenues	
	2015	2014	% Change	2015	2014
OSUR	$18,385	$17,580	5%	61%	63%
DNAG	7,329	6,867	7	25	25
Net product revenues	25,714	24,447	5	86	88
Other	4,147	3,398	22	14	12
Net revenues	$29,861	$27,845	7%	100%	100%

Consolidated net product revenues increased 5% to $25.7 million in the third quarter of 2015 from $24.4 million in the comparable period of 2014. Higher sales of our OraQuick® HCV, Intercept®, molecular collection systems, OraQuick® HIV In-Home and cryosurgical systems products were partially offset by lower sales of our professional OraQuick® HIV and insurance risk assessment products. Other revenues in the third quarter of 2015 were $4.1 million and include $3.4 million in exclusivity payments received under our HCV co-promotion agreement with AbbVie and $750,000 recognized in connection with Ebola-related funding from BARDA. Other revenues in the third quarter of 2014 were $3.4 million and represent the recognition of exclusivity payments from AbbVie.

Consolidated net revenues derived from products sold to customers outside the U.S. were $5.6 million and $5.4 million, or 19% of total net revenues, in the third quarters of 2015 and 2014, 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.

	Three Months Ended September 30,				
	Dollars			Percentage of Total Net Revenues	
Market	2015	2014	% Change	2015	2014
Infectious disease testing	$11,297	$11,183	1%	50%	53%
Substance abuse testing	2,955	2,149	38	13	10
Cryosurgical systems	3,458	3,241	7	16	16
Insurance risk assessment	675	1,007	(33)	3	5
Net product revenues	18,385	17,580	5	82	84
Other	4,147	3,398	22	18	16
Net revenues	$22,532	$20,978	7%	100%	100%

Infectious Disease Testing Market

Sales to the infectious disease testing market increased slightly to $11.3 million in the third quarter of 2015 compared to $11.2 million in the third quarter of 2014. Increased sales of our OraQuick® HCV and OraQuick® In-Home HIV tests were partially offset by lower sales of our professional OraQuick® HIV product. Third quarter 2015 revenues also included $482,000 in sales of our OraQuick® Ebola Rapid Antigen test to the CDC for field testing in Africa. There were no sales of our rapid Ebola test in the comparable period of 2014.

The table below shows a breakdown of our total net OraQuick® HIV and HCV revenues (dollars in thousands) during the third quarters of 2015 and 2014.

	Three Months Ended September 30,		
Market	2015	2014	% Change
Domestic HIV	$ 5,548	$ 7,231	(23)%
International HIV	450	491	(8)
Domestic OTC HIV	1,642	1,368	20
Net HIV revenues	7,640	9,090	(16)
Domestic HCV	1,914	1,301	47
International HCV	957	470	104
Net HCV revenues	2,871	1,771	62
Net OraQuick® revenues	$10,511	$10,861	(3)%

Domestic OraQuick® HIV sales decreased 23% to $5.5 million for the three months ended September 30, 2015 from $7.2 million for the three months ended September 30, 2014. This decrease was primarily the result of the migration of some customers to 4th generation automated HIV immunoassays performed in a laboratory or at the point-of-care, as recommended under testing guidelines issued by the CDC, or to competitive 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 third quarter of 2015 decreased 8% to $450,000 from $491,000. This decrease reflects lower sales into Africa as a result of the variability of project-based business in that region, as well as the absence in 2015 of a large order received from Europe in 2014 which did not recur in the current period. These decreases were partially offset by higher sales in Asia.

Sales of our OraQuick® In-Home HIV test increased 20% to $1.6 million in the third quarter of 2015 from $1.4 million in the third quarter of 2014 largely due to the timing of orders placed by our retail trade customers.

Domestic OraQuick® HCV sales increased 47% to $1.9 million in the third quarter of 2015 from $1.3 million in the third quarter of 2014, primarily due to the continued expansion of our HCV business through the addition of new customers and higher sales to current customers who have expanded their HCV testing programs. International OraQuick® HCV sales increased 104% to $957,000 in the third quarter of 2015 from $470,000 in the third quarter of 2014, largely due to the timing of purchases by a multi-national humanitarian organization. Sales to this organization can be variable, are influenced by its worldwide field activities, and therefore are difficult to predict. Also contributing to the increase in international revenues was an expansion of our business in Asia.

We believe our OraQuick® HCV product represents an opportunity for future sales growth given the recent FDA approvals of several new drug therapies for treating HCV. 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 could adversely affect 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 and donor funding, the impact of competition and other factors. As such, there is no assurance that international revenues will continue at the same levels in future periods.

Substance Abuse Testing Market

Sales to the substance abuse testing market increased 38% to $3.0 million in the third quarter of 2015 from $2.1 million in the third quarter of 2014, primarily as a result of higher sales of our Intercept® drug testing system.

Domestic Intercept® sales for the third quarter of 2015 increased to $2.3 million compared to $1.6 million for the third quarter of 2014 largely due to the recovery of customers previously lost to competition, improved domestic employment conditions, and the addition of customers who recognize the advantages of oral fluid testing in identifying recent drug use.

Cryosurgical Systems Market

Sales of our cryosurgical systems products (which includes both the physicians' office and OTC markets) increased 7% to $3.5 million in the third quarter of 2015, compared to $3.2 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 third quarters of 2015 and 2014.

	Three Months Ended September 30,		
Market	2015	2014	% Change
Domestic professional	$ 1,600	$ 1,590	1%
International professional	258	43	*
Domestic OTC	137	—	*
International OTC	1,463	1,608	(9)
Net cryosurgical systems revenues	$ 3,458	$ 3,241	7%

* Calculation is not considered meaningful.

Sales of our Histofreezer® product to physicians' offices in the United States remained largely unchanged at $1.6 million for both the third quarter of 2015 and 2014. International sales of Histofreezer® increased to $258,000 in the third quarter of 2015, compared to $43,000 in the same period of the prior year, primarily due to the re-introduction of our product into the Asian marketplace. There were no sales in Asia in the third quarter of 2014 due to the lack of inventory as a result of our transition to a new manufacturer of our international Histofreezer® product. Sales into Europe also increased during the current period due to the timing of orders placed by our customers.

In the fourth quarter of 2014, we launched a private labeled version of our wart removal product in the U.S. retail market through a large pharmacy chain. Sales related to this product in the third quarter of 2015 were $137,000.

Sales of our international OTC cryosurgical products during the third quarter of 2015 decreased 9% to $1.5 million compared to $1.6 million in the third quarter of 2014, largely due to distributor ordering patterns.

Insurance Risk Assessment Market

Sales to the insurance risk assessment market decreased 33% to $675,000 in the third quarter of 2015 from $1.0 million in the third quarter of 2014, as a result of reduced demand in the domestic life insurance market, as well as the adoption by some underwriters of a "Simplified Issue" policy. Where such a policy is used, applicants are required to respond to a questionnaire about their behaviors rather than undergoing lab-based testing.

Other revenues

Other revenues in the third quarter of 2015 were $4.1 million and include $3.4 million in exclusivity payments received under our HCV co-promotion agreement with AbbVie and $750,000 recognized in connection with Ebola-related funding from BARDA. Other revenues in the third quarter of 2014 were $3.4 million and represent the recognition of exclusivity payments from AbbVie.

DNAG Segment

Molecular Collection Systems

Net molecular collection systems revenues, which primarily represent sales of our Oragene® product line in the genomics market segment, increased 7% to $7.3 million in the third quarter of 2015 from $6.9 million in the third quarter of 2014. Sales in the commercial market grew 20% in the third quarter of 2015 compared to the third quarter of 2014, primarily as a result of higher sales to existing U.S. based customers. Sales in the academic market decreased 11% in the third quarter of 2015 compared to the third quarter of 2014, largely due to the fulfillment of an order in 2014 for a larger academic research project that did not repeat in 2015.

CONSOLIDATED OPERATING RESULTS

Consolidated gross margin was 69% for the third quarter of 2015 compared to 67% for the third quarter of 2014. Gross margin for the third quarter of 2015 increased primarily due to lower royalty expenses and the increase in other revenues, partially offset by a less favorable product mix.

Consolidated operating income for the third quarter of 2015 was $1.5 million, a $654,000 increase from the $882,000 of operating income reported in the third quarter of 2014. The current quarter operating income benefited from higher revenues, lower royalty expense, and lower research and development costs, partially offset by an increase in sales and marketing and general and administrative expenses.

OPERATING INCOME (LOSS) BY SEGMENT

OSUR Segment

OSUR's gross margin was 69% in the third quarter of 2015 compared to 65% in the third quarter of 2014. OSUR's gross margin in the third quarter of 2015 was positively impacted by lower royalty expenses and the increase in other revenues recognized in the third quarter of 2015.

Research and development expenses decreased 15% to $2.0 million in the third quarter of 2015 from $2.3 million in the third quarter of 2014 due to lower lab supply costs. Sales and marketing expenses increased 6% to $7.7 million in the third quarter of 2015 from $7.3 million in the third quarter of 2014. This increase was primarily the result of higher detailing costs associated with our OraQuick® HCV co-promotion agreement with AbbVie partially offset by lower staffing costs. General and administrative expenses increased 1% to $5.0 million in the third quarter of 2015 from $4.9 million in the third quarter of 2014 due to higher legal costs, partially offset by lower consulting expenses.

All of the above contributed to OSUR's third quarter 2015 operating income of $725,000, which included non-cash charges of $764,000 for depreciation and amortization and $1.4 million for stock-based compensation.

DNAG Segment

DNAG's gross margin was 71% in the third quarter of 2015 compared to 75% in the third quarter of 2014. This decline in margin was attributable to a higher volume of lower margin sales experienced in the third quarter of 2015 when compared to the third quarter of 2014.

Research and development expenses decreased to $542,000 in the third quarter of 2015 from $650,000 in the third quarter of 2014 due to the favorable impact in exchange rates between the Canadian dollar and the U.S. dollar, which approximated $108,000. Sales and marketing expenses also remained unchanged at $1.9 million in both the third quarters of 2015 and 2014 due to higher commission and staffing costs, resulting from increased headcount, offset by a favorable exchange rate impact of approximately $315,000. General and administrative expenses increased to $1.9 million in the third quarter of 2015 compared to $724,000 in the third quarter of 2014, largely due to higher legal costs, partially offset by $122,000 related to the change in foreign currency exchange rates.

All of the above contributed to DNAG's third quarter 2015 operating income of $811,000, which included non-cash charges of $646,000 for depreciation and amortization and $144,000 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. As a result, no U.S. income tax expense or benefit was recorded for OSUR's pre-tax income in the third quarter of 2015 or 2014, respectively. Canadian income tax expense of $147,000 and $10,000 was recorded in the third quarters of 2015 and 2014, respectively.

Nine months ended September 30, 2015 compared to September 30, 2014

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 nine months ended September 30, 2015 and 2014.

	Nine Months Ended September 30,				
	Dollars			Percentage of Total Net Revenues	
	2015	2014	% Change	2015	2014
OSUR	$53,644	$56,087	(4)%	62%	72%
DNAG	22,148	17,523	26	25	23
Net product revenues	75,792	73,610	3	87	95
Other	11,545	4,173	*	13	5
Net revenues	$87,337	$77,783	12%	100%	100%

* Calculation is not considered meaningful.

Consolidated net product revenues increased 3% to $75.8 million in the first nine months of 2015 from $73.6 million in the comparable period of 2014. Higher sales of our molecular collection systems, OraQuick® HCV and Intercept® products were partially offset by lower sales of our professional OraQuick® HIV and cryosurgical systems products. Other revenues were $11.5 million in the first nine months of 2015, of which $10.0 million represents exclusivity payments received under our HCV co-promotion agreement with AbbVie and $1.5 million represents Ebola-related funding from BARDA. Other revenues were $4.2 million in the first nine months of 2014, all of which represents exclusivity payments from AbbVie.

Consolidated net revenues derived from products sold to customers outside the U.S. were $17.6 million and $18.8 million, or 20% and 24% of total net revenues, during the nine months ended September 30, 2015 and 2014, 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.

	Nine Months Ended September 30,				
	Dollars			Percentage of Total Net Revenues	
Market	2015	2014	% Change	2015	2014
Infectious disease testing	$34,585	$34,914	(1)%	53%	58%
Substance abuse testing	7,584	6,187	23	12	10
Cryosurgical systems	8,956	12,128	(26)	13	20
Insurance risk assessment	2,519	2,858	(12)	4	5
Net product revenues	53,644	56,087	(4)	82	93
Other	11,545	4,173	*	18	7
Net revenues	$65,189	$60,260	8%	100%	100%

* Calculation is not considered meaningful.

Infectious Disease Testing Market

Sales to the infectious disease testing market decreased 1% to $34.6 million in the first nine months of 2015 from $34.9 million in the first nine months of 2014 primarily due to lower domestic sales of our professional OraQuick® HIV test, partially offset by higher sales of our OraQuick® HCV product in both the domestic and international markets, higher international sales of our OraQuick® HIV product and $1.2 million of initial sales of our OraQuick® Ebola Rapid Antigen Test to the CDC for field testing in Africa.

The table below shows a breakdown of our total net OraQuick® HIV and HCV revenues (dollars in thousands) during the nine months ended September 30, 2015 and 2014.

	Nine Months Ended September 30,		
Market	2015	2014	% Change
Domestic HIV	$18,147	$21,568	(16)%
International HIV	1,995	1,897	5
Domestic OTC HIV	4,923	4,991	(1)
Net HIV revenues	25,065	28,456	(12)
Domestic HCV	4,803	3,183	51
International HCV	2,577	2,341	10
Net HCV revenues	7,380	5,524	34
Net OraQuick® revenues	$32,445	$33,980	(5)%

Domestic OraQuick® HIV sales decreased 16% to $18.1 million for the nine months ended September 30, 2015 from $21.6 million for the nine months ended September 30, 2014. This decrease was primarily the result of the migration of some customers to 4th generation automated HIV immunoassays performed in a laboratory or at the point-of-care, as recommended under testing guidelines issued by the CDC, or to competitive 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 price and product competition. International sales of our OraQuick® HIV test during the first nine months of 2015 increased 5% to $2.0 million from $1.9 million primarily due to higher sales in Asia. This increase was partially offset by a decline in sales in Europe due to the absence in 2015 of a large order received in 2014 which did not recur in the current period.

Sales of our OraQuick® In-Home HIV test remained unchanged at $4.9 million in the first nine months of both 2015 and 2014.

Domestic OraQuick® HCV sales increased 51% to $4.8 million in the first nine months of 2015 from $3.2 million in the first nine months of 2014, primarily due to the addition of new HCV customers and higher sales to current customers who have expanded their HCV testing programs. International OraQuick® HCV sales increased 10% to $2.6 million in the first nine months of 2015 from $2.3 million in the first nine months of 2014, largely due to the timing of purchases by a multi-national humanitarian organization. Sales to this organization can be variable, are influenced by its worldwide field activities, and therefore are difficult to predict. Also contributing to the increase in international revenues was an expansion of our business in Asia.

We believe our OraQuick® HCV product represents an opportunity for future sales growth given the recent FDA approvals of several new drug therapies for treating HCV. 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 could adversely affect 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 our HIV and HCV products can be sporadic in nature and are often predicated upon the availability of governmental and donor funding, the impact of competition and other factors. As such, there is no assurance that international sales will continue at the same levels in future periods.

Substance Abuse Testing Market

Sales to the substance abuse testing market increased 23% to $7.6 million in the first nine months of 2015 from $6.2 million in the first nine months 2014, primarily as a result of higher sales of our Intercept® drug testing system.

Domestic Intercept® sales for the first nine months of 2015 increased 29% to $5.8 million compared to $4.5 million for the first nine months of 2014 largely due to the recovery of customers previously lost to competition, improved domestic employment conditions, and the addition of customers who recognize the advantages of oral fluid testing in identifying recent drug use.

Cryosurgical Systems Market

Sales of our cryosurgical systems products (which includes both the physicians' office and OTC markets) decreased 26% to $8.9 million in the first nine months of 2015, compared to $12.1 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 nine months ended September 30, 2015 and 2014.

	Nine Months Ended September 30,		
Market	2015	2014	% Change
Domestic professional	$ 3,268	$ 4,601	(29)%
International professional	757	581	30
Domestic over-the-counter	300	—	*
International over-the-counter	4,631	6,946	(33)
Net cryosurgical systems revenues	$ 8,956	$ 12,128	(26)%

* Calculation is not considered meaningful.

Sales of our Histofreezer® product to physicians' offices in the United States decreased 29% to $3.3 million in the first nine months of 2015 from $4.6 million in the first nine months of 2014 largely as a result of distributor consolidation and competition from new private-label brands. International sales of Histofreezer® increased to $757,000 in the first nine months of 2015, compared to $581,000 in the same period of the prior year, primarily due to the re-introduction of our product into the Asian marketplace. There were minimal sales in Asia in the first nine months of 2014 due to the lack of inventory as a result of our transition to a new manufacturer of our international Histofreezer® product.

In the fourth quarter of 2014, we launched a private labeled version of our wart removal product in the U.S. retail market through a large pharmacy chain. Sales related to this product in the first nine months of 2015 were $300,000.

Sales of our international OTC cryosurgical products during the first nine months of 2015 decreased 33% to $4.6 million compared to $6.9 million in the first nine months of 2014, largely due to lower sales to both our European and Latin American distributors. Sales to our European distributor decreased to $3.5 million in the first nine months of 2015, compared to $4.1 million during the first nine months of 2014, primarily due to customer ordering patterns. Sales to our Latin American distributor decreased to $1.0 million in the first nine months of 2015 from $2.7 million in the first nine months of 2014, due to challenges in the local markets, including declining economic conditions in Argentina and a restructuring of our distributor's business operations in Mexico as well as customer ordering patterns.

Insurance Risk Assessment Market

Sales to the insurance risk assessment market decreased 12% to $2.5 million in the first nine months of 2015 from $2.9 million in the same period of 2014, as a result of reduced demand in the domestic life insurance market, as well as the adoption by some underwriters of a "Simplified Issue" policy. Where such a policy is issued, applicants are required to respond to a questionnaire about their behaviors rather than undergoing lab-based tests.

Other revenues

Other revenues were $11.5 million in the first nine months of 2015, of which $10.0 million represent exclusivity payments received under our HCV co-promotion agreement with AbbVie, and $1.5 million represents Ebola-related funding from BARDA. Other revenues in the first nine months of 2014 were $4.2 million and represent the recognition of exclusivity payments from AbbVie.

DNAG Segment

Molecular Collection Systems

Net molecular collection systems revenues, which primarily represent sales of our Oragene® product line, increased 26% to $22.1 million in the first nine months of 2015 from $17.5 million in the first nine months of 2014. Sales in the commercial market grew 43% in the first nine months of 2015 compared to the first nine months of 2014, which was primarily due to increased orders from existing U.S. customers and incremental revenues from new customers. Sales in the academic market increased to $7.8 million in the first nine months of 2015 from $7.6 million in the first nine months of 2014 as we continued efforts to market our product globally and to a broader base of customers.

CONSOLIDATED OPERATING RESULTS

Consolidated gross margin was 67% for the first nine months of 2015 compared to 63% for the first nine months of 2014. Gross margin in 2015 increased primarily due to the $7.4 million increase in other revenues associated with the AbbVie exclusivity payments and the BARDA funding for our Ebola test. These other revenues contributed 500 basis points to gross margin in the first nine months of 2015 and 200 basis points in the first nine months of 2014. Also contributing to the improvement in margin during the current nine month period was a decrease in royalty expense.

Consolidated operating income for the first nine months of 2015 was $4.0 million, a $6.2 million improvement from the $2.2 million operating loss reported in the first nine months of 2014. The improvement in operating income was primarily the result of the $7.4 million increase in other revenues, the reduction in royalty expenses, and lower advertising and promotional costs associated with our OraQuick® In-Home HIV test. Partially offsetting these positive contributions was the absence of a $5.5 million termination payment received under the terms of our drug assay collaboration with Roche, which was recorded as an expense reduction in the first nine months of 2014.

OPERATING INCOME (LOSS) BY SEGMENT

OSUR Segment

OSUR’s gross margin was 65% in the first nine months of 2015 compared to 60% in the first nine months of 2014. OSUR’s gross margin in 2015 was positively impacted by the $7.4 million increase in other revenues recognized in the current period. These other revenues increased gross margin by approximately 750 and 300 basis points in the first nine months of 2015 and 2014, respectively. Gross margin was also positively impacted by a reduction in royalty expense in 2015.

Research and development expenses increased 11% to $7.0 million in the first nine months of 2015 from $6.3 million in the first nine months of 2014 largely due to study and program costs related to the fully-automated high-throughput drugs-of-abuse assays we are jointly developing with Thermo Fisher. Sales and marketing expenses decreased 18% to $20.7 million in the first nine months of 2015 from $25.3 million in the first nine months of 2014. This decrease was primarily the result of lower advertising and promotional costs for our OraQuick® In-Home HIV test, which totaled $7.7 million in the first ninth months of 2014 compared to $1.3 million in the first nine months of 2015, partially offset by an increase in sales and marketing costs associated with our OraQuick® HCV co-promotion agreement with AbbVie. General and administrative expenses remained unchanged at $15.0 million in the first nine months of 2015 and 2014.

All of the above contributed to OSUR’s operating loss of $111,000 for the first nine months of 2015, which included non-cash charges of $2.2 million for depreciation and amortization and $4.1 million for stock-based compensation.

DNAG Segment

DNAG’s gross margin was 71% in the first nine months of 2015 compared to 73% in the first nine months of 2014. This decrease was attributable to increased volume of lower margin sales in the first nine months of 2015 when compared to the same period of 2014.

Research and development expenses remained unchanged at $1.9 million in the first nine months of 2015 and 2014 due to increased spending on new product initiatives offset by the favorable impact of exchange rates between the Canadian and U.S. dollars, which approximated $252,000. Sales and marketing expenses increased 4% to $5.8 million in the first nine months of 2015 from $5.6 million in the first nine months of 2014 due to higher commission and staffing costs, resulting from increased headcount, partially offset by a favorable exchange rate impact of $725,000. General and administrative expenses increased 67% to $3.9 million in the first nine months of 2015 compared to $2.3 million in the first nine months of 2014, largely due to higher legal costs partially offset by a favorable foreign exchange rate impact of $306,000.

All of the above contributed to DNAG's operating income of $4.1 million for the first nine months of 2015, which included non-cash charges of $2.0 million for depreciation and amortization and $433,000 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. As a result, no U.S. income tax expense or benefit was recorded for OSUR's pre-tax income in the first nine months of 2015 or 2014, respectively. Canadian income tax expense of $810,000 was recorded for the nine months ended September 30, 2015. A Canadian income tax benefit of $33,000 was recorded for the nine months ended September 30, 2014 as a result of certain Canadian research and development and investment tax credits and DNAG's loss before income taxes. The Canadian income tax benefit was considered realizable based upon the scheduled reversal of deferred tax liabilities recorded in connection with the acquisition of DNAG.

Liquidity and Capital Resources

	September 30, 2015	December 31, 2014
	(In thousands)	
Cash	$ 100,677	$ 92,867
Short-term investments	7,512	5,000
Working capital	112,127	104,752

Our cash and short-term investment balances increased to $108.2 million at September 30, 2015 from $97.9 million at December 31, 2014. Our working capital increased to $112.1 million at September 30, 2015 from $104.8 million at December 31, 2014.

During the first nine months of 2015, we generated $15.1 million in cash from our operating activities. Our net income of $3.6 million was increased by non-cash stock-based compensation expense of $4.5 million, depreciation and amortization expense of $4.3 million, deferred income taxes of $198,000, and unrealized foreign currency losses of $450,000. An increase in deferred revenue of $5.3 million also contributed to the cash generated in the first nine months of 2015. The increased deferred revenue is related to the receipt of payments from AbbVie reduced by the amounts ratably recognized in revenue during the period. Also contributing to cash provided by operations is a $633,000 decrease in inventory balances largely associated with our OraQuick® HCV product. Uses of cash in operating activities during the period included a $1.6 million increase in accounts receivable resulting from a higher level of product orders placed near the end of the current quarter; a $1.5 million decrease in accrued expenses and other liabilities associated with payment of our 2014 management incentive bonuses, royalty obligations, and certain year-end accruals; a $614,000 increase in prepaid expenses and other assets largely associated with the buy-out of royalty obligations under one of our license agreements; and a $72,000 decrease in accounts payable.

Net cash used in investing activities was $4.8 million for the nine months ended September 30, 2015, which reflects $19.4 million used to purchase short-term investments and $1.9 million to acquire property and equipment, offset by $16.5 million in proceeds from the maturities of short-term investments.

Net cash used in financing activities was $759,000 for the nine months ended September 30, 2015, which resulted from $883,000 used for the repurchase of common stock to satisfy withholding taxes related to the vesting of restricted shares, partially offset by $124,000 in proceeds received from the exercise of stock options.

Our current cash balance is expected to be sufficient to fund our current operating and capital needs through at least the next twelve months. Our cash requirements, however, may vary materially from those now planned due to many factors, including, but not limited to, the scope and timing of future strategic acquisitions, the progress of our research and development programs, the scope and results of clinical testing, the cost of any future litigation, the magnitude of capital expenditures, changes in existing and potential relationships with business partners, the timing and cost of obtaining regulatory approvals, the 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, 2014 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, 2014. As of September 30, 2015, there were no significant changes to this information, including the absence of any off-balance sheet arrangements, other than a new lease agreement and certain purchase obligations related to new office space for our Canadian subsidiary. The following sets forth our approximate aggregate obligations at September 30, 2015 for future payments required under this new lease and the new outstanding non-cancelable purchase commitments (in thousands):

		Payments due by December 31,					
Contractual Obligations	**Total**	**2015**	**2016**	**2017**	**2018**	**2019**	**Thereafter**
Operating leases	$2,431	$ —	$335	$335	$335	$335	$ 1,091
Purchase obligations	1,956	1,895	21	21	19	—	—
Total contractual obligations	$4,387	$1,895	$356	$356	$354	$335	$ 1,091

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, 2014 filed with the SEC. During the first nine months of 2015, 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 September 30, 2015, 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% of our total revenues for the nine months ended September 30, 2015. We do have foreign currency exchange risk related to our operating subsidiary in Canada. While the majority of their revenues are recorded in U.S. dollars almost all of their 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 of $52.4 million CDN ($45.1 million USD), which are included in the Company's consolidated balance sheet as of December 31, 2014. A 10% unfavorable change in the Canadian-to-U.S. dollar exchange rate would increase our comprehensive loss by $4.5 million.

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 September 30, 2015. Based on that evaluation, the Company's management, including such officers, concluded that the Company's disclosure controls and procedures were effective as of September 30, 2015 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 September 30, 2015 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 contains claims for conversion and trespass to chattel and 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. On October 20, 2015, Ancestry filed with the United States Patent and Trademark Office ("USPTO") a Petition for *Inter Partes* Review of some, but not all, claims of U.S. Patent No. 8,221,381 B2. We expect the PTO to decide whether to initiate review of the DNAG patent in April 2016.

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.

Item 1A. RISK FACTORS

Other than the risk factors discussed below, 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, 2014.

Failure To Comply With Privacy, Security and Breach Notification Regulations May Increase Our Costs.

The Company believes it is neither a covered entity nor a business associate of a covered entity and is not responsible for complying with the Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA"). However, the Company has in place certain administrative, technical and physical safeguards to protect the privacy and security of consumers' personal information and endeavors to comply with all applicable state and federal laws with respect to the protection of consumers' personal information. The Company is required to comply with varying state privacy, security and breach reporting laws. In addition, for data transfers of consumers' personal information from other countries relating to citizens of those countries, the Company will endeavor to comply with the laws of those other countries. If we do not comply with existing or new laws and regulations related to properly transferring data containing consumers' personal information, we could be subject to monetary fines, civil penalties or criminal sanctions. In addition to other federal and state laws that protect the privacy and security of consumers' personal information, we may be subject to enforcement and interpretations by various governmental authorities and courts resulting in complex compliance issues. For example, we could incur damages under state laws pursuant to an action brought by a private party for the wrongful use or disclosure of consumers' personal information.

We Rely on Information Technology in Our Operations and Any Material Failure, Inadequacy, Interruption or Security Breach of that Technology Could Harm Our Ability to Efficiently Operate Our Business.

We rely heavily on enterprise resource planning and other complex information technology systems across our operations and on the internet, including for management of inventory, purchase orders, invoices, shipping, interactions with our third-party logistics provider, revenue and expense accounting, online business, consumer call support, and various other processes and transactions. Our ability to effectively manage our business, coordinate the production, distribution and sale of our products, respond to customer inquiries, and ensure the timely and accurate recording and disclosure of financial information depends significantly on the reliability and capacity of these systems and the internet. In addition, we rely on information technology systems for the development and implementation of a patient care database that we are providing as part of our services under the HCV co-promotion agreement with AbbVie. This database contains patient specific healthcare information and must be maintained and operated in accordance with stringent privacy and security requirements.

The failure of any of the foregoing systems to operate effectively, problems with transitioning to upgraded or replacement systems, a breach in security of these systems through a cyber-attack or otherwise, or disruptions in the operation of the internet, could cause delays in product sales, reduced efficiency of our operations and violation of privacy laws and regulations. Significant expenditures could be required to remediate any such problem. Security breaches of employee information or other confidential or proprietary data could also adversely impact our reputation, and could result in litigation against us or the imposition of liability and penalties. In addition, third parties that use or have access to sensitive information about our customers could experience security breaches that could adversely impact our reputation and customer relationships and could, in certain circumstances, expose us to liability and penalties for violations of privacy laws and regulations.

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

None

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: November 6, 2015

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

/s/ Mark L. Kuna

Date: November 6, 2015

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

EXHIBIT INDEX

Exhibit Number	Exhibit
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

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: November 6, 2015

/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: November 6, 2015

/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 September 30, 2015 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

November 6, 2015

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 September 30, 2015 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

November 6, 2015