Table of Contents

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 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 August 5, 2015: 56,481,805 shares.

Table of Contents

PART I. FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

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

	JUNE 30, 2015	DECEMBER 31, 2014
ASSETS		
CURRENT ASSETS:		
Cash	$ 83,403	$ 92,867
Short-term investments	8,005	5,000
Accounts receivable, net of allowance for doubtful accounts of $598 and $533	16,364	16,138
Inventories	15,654	15,763
Prepaid expenses	1,598	1,140
Other current assets	239	306
Total current assets	125,263	131,214
PROPERTY AND EQUIPMENT, net	17,888	17,934
INTANGIBLE ASSETS, net	15,105	17,505
GOODWILL	20,222	21,734
OTHER ASSETS	1,599	1,246
	$ 180,077	$ 189,633
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 4,729	$ 7,148
Deferred revenue	1,780	8,043
Deferred income taxes	130	139
Accrued expenses	8,964	11,132
Total current liabilities	15,603	26,462
OTHER LIABILITIES	1,258	1,234
DEFERRED INCOME TAXES	3,364	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	347,143	344,894
Accumulated other comprehensive loss	(11,026)	(7,848)
Accumulated deficit	(176,265)	(178,345)
Total stockholders' equity	159,852	158,701
	$ 180,077	$ 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 June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
NET REVENUES:				
Product	$ 26,313	$ 25,626	$ 50,078	$ 49,163
Other	4,075	775	7,398	775
	30,388	26,401	57,476	49,938
COST OF PRODUCTS SOLD	9,692	10,385	19,782	19,995
Gross profit	20,696	16,016	37,694	29,943
OPERATING EXPENSES:				
Research and development	2,996	2,771	6,436	5,252
Sales and marketing	8,904	10,272	16,788	21,612
General and administrative	6,075	5,976	12,040	11,700
Gain on contract termination settlement	—	(5,500)	—	(5,500)
	17,975	13,519	35,264	33,064
Operating income (loss)	2,721	2,497	2,430	(3,121)
OTHER INCOME (EXPENSE)	(95)	(142)	314	(24)
Income (loss) before income taxes	2,626	2,355	2,744	(3,145)
INCOME TAX EXPENSE (BENEFIT)	658	(174)	663	(43)
NET INCOME (LOSS)	$ 1,968	$ 2,529	$ 2,081	$ (3,102)
EARNINGS (LOSS) PER SHARE:				
BASIC	$ 0.03	$ 0.05	$ 0.04	$ (0.06)
DILUTED	$ 0.03	$ 0.04	$ 0.04	$ (0.06)
SHARES USED IN COMPUTING EARNINGS (LOSS) PER SHARE:				
BASIC	56,453	55,907	56,398	55,846
DILUTED	56,687	57,243	56,678	55,846

See accompanying notes to the consolidated financial statements.

Table of Contents

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
NET INCOME (LOSS)	$ 1,968	$ 2,529	$ 2,081	$ (3,102)
OTHER COMPREHENSIVE INCOME (LOSS)				
Currency translation adjustments	633	1,622	(3,178)	(156)
Other comprehensive income (loss)	633	1,622	(3,178)	(156)
COMPREHENSIVE INCOME (LOSS)	$ 2,601	$ 4,151	$ (1,097)	$ (3,258)

See accompanying notes to the consolidated financial statements.

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

	Six Months Ended June 30,	
	2015	2014
OPERATING ACTIVITIES:		
Net income (loss)	$ 2,081	$ (3,102)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Stock-based compensation	3,008	2,869
Depreciation and amortization	2,849	3,108
Unrealized foreign currency loss	266	139
Deferred income taxes	366	(43)
Changes in assets and liabilities		
Accounts receivable	(524)	(1,196)
Inventories	35	(1,789)
Prepaid expenses and other assets	(42)	(5,981)
Accounts payable	(2,453)	(179)
Deferred revenue	(6,256)	(418)
Accrued expenses and other liabilities	(2,751)	(3,805)
Net cash used in operating activities	(3,421)	(10,397)
INVESTING ACTIVITIES:		
Purchases of short-term investments	(11,960)	(4,430)
Proceeds from maturities of short-term investments	8,999	—
Purchases of property and equipment	(1,145)	(1,988)
Net cash used in investing activities	(4,106)	(6,418)
FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	124	202
Repurchase of common stock	(883)	(639)
Net cash used in financing activities	(759)	(437)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	(1,178)	(107)
NET DECREASE IN CASH	(9,464)	(17,359)
CASH, BEGINNING OF PERIOD	92,867	93,191
CASH, END OF PERIOD	$ 83,403	$ 75,832
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for:		
Income taxes	$ 81	$ 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 testing, 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 six months ended June 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 June 30, 2015 and December 31, 2014 consisted of guaranteed investment certificates with amortized cost and fair values of $8,005 and $5,000, respectively.

Fair Value of Financial Instruments. As of June 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 June 30, 2015 and December 31, 2014 was $1,258 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 June 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:

	June 30, 2015	December 31, 2014
Raw materials	$ 8,267	$ 8,539
Work in process	434	898
Finished goods	6,953	6,326
	$ 15,654	$ 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 are required to make 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 expensed 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 June 30, 2015 and December 31, 2014 was $32,792 and $31,416, respectively.

Intangible Assets. Intangible assets consist of the following:

	Amortization Period (Years)	June 30, 2015 Gross	Accumulated Amortization	Net
Customer list	10	$10,029	$ (3,743)	$ 6,286
Patents and product rights	3-10	10,449	(8,182)	2,267
Acquired technology	7	7,790	(4,090)	3,700
Tradename	15	3,844	(992)	2,852
		$32,112	$ (17,007)	$15,105

	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, 2014 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 June 30, 2015, we believe no indicators of impairment exist.

The change in goodwill from $21,734 as of December 31, 2014 to $20,222 as of June 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. All 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.

Royalty income from the grant of license rights is recognized during the period in which the revenue is earned and the amount is determinable from the licensee and is recorded as other revenue 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.

In exchange for these exclusive rights and other services, we are eligible to receive up to $75,000 in aggregate payments over the term of the agreement, which runs through December 31, 2019. We are recognizing these payments ratably on a monthly basis over the term of the agreement. During the second quarter of 2015, $3,400 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. Amounts related to this contract are recorded as other revenue in our statement of operations as the activities are being performed. During the second quarter of 2015, $714 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 June 30, 2015 and December 31, 2014, the reserve for sales returns and allowances was $280 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 June 30, 2015 and December 31, 2014 includes customer prepayments of $1,034 and $613, respectively. Deferred revenue as of June 30, 2015 and December 31, 2014 also includes $746 and $7,430 from AbbVie, respectively, which represents the $15,000 payment received in July 2014 under the terms of our HCV co-promotion agreement with AbbVie, less amounts recognized ratably in revenue.

Customer and Vendor Concentrations. We had no significant concentrations in accounts receivable as of June 30, 2015 or December 31, 2014. AbbVie accounted for approximately 11% and 12% of our net revenues for the three and six months ended June 30, 2015, respectively. We had no significant concentrations in net revenues for the three and six months ended June 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 June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Net income (loss)	$ 1,968	$ 2,529	$ 2,081	$ (3,102)
Weighted average shares of common stock outstanding:				
Basic	56,453	55,907	56,398	55,846
Dilutive effect of stock options and restricted stock	234	1,336	280	—
Diluted	56,687	57,243	56,678	55,846
Earnings (loss) per share:				
Basic	$ 0.03	$ 0.05	$ 0.04	$ (0.06)
Diluted	$ 0.03	$ 0.04	$ 0.04	$ (0.06)

For the three-month periods ended June 30, 2015 and 2014, outstanding common stock options and unvested restricted stock, representing 5,010 and 3,594 shares, respectively, were excluded from the computation of diluted earnings per share as their inclusion would have been anti-dilutive. For the six months ended June 30, 2015 and 2014, outstanding common stock options and unvested restricted stock, representing 3,856 and 3,646 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 $3,178 and $156 currency translation adjustments recorded in the first six 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.

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 six months ended June 30, 2015 and 2014 was $1,690 and $1,499, respectively. Net cash proceeds from the exercise of stock options were $124 and $202 for the six months ended June 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 $1,318 and $1,370 related to restricted shares was recognized during the six months ended June 30, 2015 and 2014, respectively. In connection with the vesting of restricted shares and exercise of stock options during the six months ended June 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

	June 30, 2015	December 31, 2014
Payroll and related benefits	$ 4,176	$ 6,620
Royalties	1,831	2,285
Professional fees	752	480
Other	2,205	1,747
	$ 8,964	$ 11,132

5. Income Taxes

During the three and six months ended June 30, 2015, we recorded foreign tax expense of $658 and $663, respectively. Foreign taxes during the three and six months ended June 30, 2015 includes $366 and $371 of deferred income tax expense, respectively. Foreign taxes for the current periods also include $292 of current tax expense associated with amounts payable for provincial taxes. During the three and six months ended June 30, 2014, we recorded foreign deferred tax benefits of $174 and $43, 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 June 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. net deferred tax asset. Management believes the full valuation allowance is still appropriate as of June 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 six-month periods ended June 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 royalties from the grant of license rights, 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 six months ended June 30, 2015 and 2014 and asset information as of June 30, 2015 and December 31, 2014:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Net revenues:				
OSUR	$ 22,286	$ 21,505	$ 42,657	$ 39,283
DNAG	8,102	4,896	14,819	10,655
Total	$ 30,388	$ 26,401	$ 57,476	$ 49,938
Operating income (loss):				
OSUR	$ 685	$ 2,203	$ (836)	$ (4,190)
DNAG	2,036	294	3,266	1,069
Total	$ 2,721	$ 2,497	$ 2,430	$ (3,121)
Depreciation and amortization:				
OSUR	$ 734	$ 790	$ 1,460	$ 1,566
DNAG	706	779	1,389	1,542
Total	$ 1,440	$ 1,569	$ 2,849	$ 3,108
Capital expenditures:				
OSUR	$ 490	$ 1,131	$ 566	$ 1,570
DNAG	218	210	579	418
Total	$ 708	$ 1,341	$ 1,145	$ 1,988

	June 30, 2015	December 31, 2014
Total assets:		
OSUR	$ 126,360	$ 136,542
DNAG	53,717	53,091
Total	$ 180,077	$ 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 June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
United States	$ 25,071	$ 19,113	$ 45,488	$ 36,518
Europe	2,939	3,681	7,313	7,682
Other regions	2,378	3,607	4,675	5,738
	$ 30,388	$ 26,401	$ 57,476	$ 49,938

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

	June 30, 2015	December 31, 2014
United States	$ 16,033	$ 16,570
Canada	1,848	1,353
Other regions	7	11
	$ 17,888	$ 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 testing, 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. In addition, our OTC HIV and cryosurgical products are available at retail pharmacies and mass merchandisers, and our OTC HIV product is also sold to consumers over the internet.

Recent Developments

Rapid Ebola Test

Earlier in 2015, we completed the design of a prototype rapid Ebola test on our OraQuick® platform that suggests analytical performance similar to laboratory PCR tests when evaluated on stored samples from patients infected with Ebola. During the first half of 2015, we also recognized revenues from the initial sales of this product to the Centers for Disease Control and Prevention (“CDC”) for investigational use in Africa. Data generated in clinical and non-clinical studies conducted earlier this year was used in an application to obtain Emergency Use Authorization (“EUA”) from the U.S. Food and Drug Administration (“FDA”).

In June 2015, we were awarded a contract for up to $10.4 million in total funding from the U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response’s Biomedical Advanced Research and Development Authority (“BARDA”) related to our OraQuick® Ebola Rapid Antigen Test. The three-year, multi-phased contract includes 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 late July 2015, the FDA issued an EUA for our OraQuick® Ebola Rapid Antigen Test for use with fingerstick and venous whole blood. Although the EUA does not constitute a clearance or approval by the FDA, our test can now be used by laboratories and facilities adequately equipped, trained, and capable of testing (including treatment centers and public health clinics) for the duration of the U.S. Secretary of the Department of Health and Human Services’ August 5, 2014 declaration that circumstances exist to justify the emergency use of *in vitro* diagnostic tests for the detection of Ebola virus, unless the EUA is terminated or revoked sooner.

We have also continued to focus our efforts on securing sustainable product purchase commitments from both government and non-government sources.

Current Consolidated Financial Results

During the six months ended June 30, 2015, our consolidated net revenues were $57.5 million compared to $49.9 million for the six months ended June 30, 2014. Net product revenues during the six months ended June 30, 2015 increased 2% when compared to the first six months of 2014, primarily due to higher sales of our molecular

collection systems, OraQuick® HCV and Intercept® products. Other revenues for the first six months of 2015 were $7.4 million, of which $6.7 million represents the ratable recognition of payments for exclusive co-promotion rights and certain services provided under our HCV co-promotion agreement with AbbVie, and $714,000 represents revenue recognized in connection with the Ebola-related funding from BARDA, as described above.

Our consolidated net income for the six months ended June 30, 2015 was $2.1 million, or $0.04 per share on a fully-diluted basis, compared to a consolidated net loss of $3.1 million, or $0.06 per share, for the six months ended June 30, 2014.

Cash used in operating activities for the six months ended June 30, 2015 was $3.4 million, compared to $10.4 million used during the six months ended June 30, 2014. As of June 30, 2015, we had $91.4 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 June 30, 2015 compared to June 30, 2014

CONSOLIDATED NET REVENUES

The table below shows the amounts of total net revenues (dollars in thousands) generated by each of our business segments for the three months ended June 30, 2015 and 2014.

	Three Months Ended June 30,				
	Dollars		%	Percentage of Total Net Revenues	
	2015	2014	Change	2015	2014
OSUR	$18,211	$20,730	(12)%	60%	78%
DNAG	8,102	4,896	65	27	19
Net product revenues	26,313	25,626	3	87	97
Other	4,075	775	NM*	13	3
Net revenues	$30,388	$26,401	15%	100%	100%

* Calculation is not considered meaningful.

Consolidated net product revenues increased 3% to $26.3 million in the second quarter of 2015 from $25.6 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 cryosurgical systems and professional OraQuick®

HIV products. Other revenues were $4.1 million in the second quarter of 2015, compared to $775,000 in the comparable period of 2014. Other revenues in 2015 included $3.4 million from exclusivity payments received under our HCV co-promotion agreement with AbbVie and $714,000 recognized in connection with the Ebola-related funding from BARDA.

Consolidated net revenues derived from products sold to customers outside the U.S. were $5.3 million and $7.3 million, or 17% and 28% of total net revenues, in the second 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 June 30,				
	Dollars			Percentage of Total Net Revenues	
Market	2015	2014	% Change	2015	2014
Infectious disease testing	$11,792	$12,668	(7)%	54%	59%
Substance abuse testing	2,527	2,208	14	11	10
Cryosurgical systems	2,953	4,920	(40)	13	23
Insurance risk assessment	939	934	1	4	4
Net product revenues	18,211	20,730	(12)	82	96
Other	4,075	775	NM*	18	4
Net revenues	$22,286	$21,505	4%	100%	100%

* Calculation is not considered meaningful.

Infectious Disease Testing Market

Sales to the infectious disease testing market decreased 7% to $11.8 million in the second quarter of 2015 from $12.7 million in the second quarter of 2014 primarily due to lower sales of our professional OraQuick® HIV product and lower international sales of our OraQuick® HCV test. These decreases were partially offset by higher sales of our OraQuick® HCV product in domestic markets and $396,000 in sales of our OraQuick® Ebola Rapid Antigen Test to the CDC for investigational use in Africa.

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

Market	Three Months Ended June 30, 2015	2014	% Change
Domestic HIV	$ 6,593	$ 7,720	(15)%
International HIV	596	848	(30)
Domestic OTC HIV	1,719	1,669	3
Net HIV revenues	8,908	10,237	(13)
Domestic HCV	1,693	1,221	39
International HCV	646	974	(34)
Net HCV revenues	2,339	2,195	7
Net OraQuick® revenues	$11,247	$12,432	(10)%

Domestic OraQuick® HIV sales decreased 15% to $6.6 million for the three months ended June 30, 2015 from $7.7 million for the three months ended June 30, 2014. This decrease was primarily the result of the migration of some customers to 4th generation automated HIV immunoassays performed in a laboratory, as recommended under testing guidelines issued by the CDC. Partially offsetting this decrease were additional revenues related to orders that did not occur in the first quarter of 2014 due to an underlying delay in the release of funding by the federal government. We anticipate that future sales of our professional HIV product will continue to be negatively affected as a result of the CDC's new testing guidelines, changes in government funding, and continued price competition. International sales of our OraQuick® HIV test during the second quarter of 2015 decreased 30% to $596,000 from $848,000. This decrease reflects the inclusion of bulk purchases associated with a significant African testing program in the second quarter of 2014, which did not repeat in the current quarter but are expected to occur again in a future period.

Sales of our OraQuick® In-Home HIV test remained relatively flat at $1.7 million in both the second quarters of 2015 and 2014.

Domestic OraQuick® HCV sales increased 39% to $1.7 million in the second quarter of 2015 from $1.2 million in the second quarter 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 decreased 34% to $646,000 in the second quarter of 2015 from $974,000 in the second quarter of 2014, largely due to lower purchases by a multi-national humanitarian organization. Sales to this organization can be variable, are influenced by its worldwide field activities, and are thus difficult to predict.

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. We also expect that sales of our HCV product will be positively impacted as we continue to implement awareness and testing programs under our agreement with AbbVie. However, demand for our HCV product, particularly in the public health marketplace, is 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 sales will continue at the same levels in future periods.

Substance Abuse Testing Market

Sales to the substance abuse testing market increased 14% to $2.5 million in the second quarter of 2015 from $2.2 million in the second quarter of 2014, primarily as a result of higher sales of our Intercept® drug testing system.

Domestic Intercept® sales for the second quarter of 2015 increased to $2.0 million compared to $1.6 million for the second 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) decreased 40% to $3.0 million in the second quarter of 2015, compared to $4.9 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 second quarters of 2015 and 2014.

	Three Months Ended June 30,		
Market	2015	2014	% Change
Domestic professional	$1,008	$1,469	(31)%
International professional	142	229	(38)
Domestic OTC	108	—	100
International OTC	1,695	3,222	(47)
Net cryosurgical systems revenues	$2,953	$4,920	(40)%

Sales of our Histofreezer® product to physicians' offices in the United States decreased 31% to $1.0 million in the second quarter of 2015 from $1.5 million in the second quarter of 2014 largely as a result of distributor consolidation and competition from new private-label brands. International sales of Histofreezer® decreased 38% to $142,000 in the second quarter of 2015, compared to $229,000 in the same period of the prior year, primarily due to pricing pressure from a similar, lower-priced competing product promoted by our former contract manufacturer. This competing product has adversely affected, and is expected to continue to adversely affect, revenues generated from our cryosurgical systems business. In order to remain competitive with this new product offering, we have decreased the per unit sales price of our Histofreezer® product in certain international markets.

In the fourth quarter of 2014, we launched our wart removal product in the U.S. retail market through private labeling with a large pharmacy chain. Sales related to this product in the second quarter of 2015 were $108,000.

Sales of our international OTC cryosurgical products during the second quarter of 2015 decreased 47% to $1.7 million compared to $3.2 million in the second quarter of 2014, largely due to lower sales to both our European and Latin American distributors. Current quarter sales to our European distributor decreased to $1.4 million, compared to $1.7 million during the second quarter of 2015, primarily due to customer ordering patterns. Sales to our Latin American distributor decreased to $266,000 in the second quarter of 2015 from $1.5 million in the second quarter of 2014, due to challenges faced in the local markets, including declining economic conditions in Argentina and a restructuring of our distributor's business operations in Mexico.

Insurance Risk Assessment Market

Sales to the insurance risk assessment market remained flat in the second quarter of 2015 at $939,000 compared to $934,000 in the second quarter of 2014.

Other revenues

Other revenues were $4.1 million in the second quarter of 2015, compared to $775,000 in the comparable period of 2014. Other revenues in 2015 included $3.4 million from exclusivity payments received under our HCV co-promotion agreement with AbbVie and $714,000 recognized in connection with the Ebola-related funding from BARDA.

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 65% to $8.1 million in the second quarter of 2015 from $4.9 million in the second quarter of 2014. Sales in the commercial market grew 82%, as a result of increased sales from existing U.S. based customers and an initial order from one of the largest breast cancer screening providers in the market. Sales in the academic market increased 44% largely due to higher sales across a multitude of DNAG's academic customers in all geographies including North America, Europe, and Asia and primarily driven by the timing of orders placed by those customers.

CONSOLIDATED OPERATING RESULTS

Consolidated gross margin was 68% for the second quarter of 2015 compared to 61% for the second quarter of 2014. Gross margin for the second quarter of 2015 increased primarily due to the $4.1 million of other revenues associated with the AbbVie co-promotion agreement and the BARDA funding. These other revenues contributed 500 basis points to gross margin in the current quarter of 2015 and 100 basis points in the second quarter of 2014. Margins for the quarter were also positively impacted by a reduction in royalty expense and a more favorable product mix, partially offset by an increase in scrap and spoilage costs.

Consolidated operating income for the second quarter of 2015 was $2.7 million, a $224,000 increase from the $2.5 million of operating income reported in the second quarter of 2014. The second quarter 2014 operating income included a $5.5 million payment received under the terms of the termination of our drug assay collaboration with Roche. The current quarter operating income benefited from increased revenues, lower HIV OTC marketing costs, and lower royalty expense.

OPERATING INCOME (LOSS) BY SEGMENT

OSUR Segment

OSUR's gross margin was 66% in the second quarter of 2015 compared to 58% in the second quarter of 2014. OSUR's gross margin in the second quarter of 2015 was positively impacted by the $4.1 million in other revenues recognized in the current quarter. These other revenues increased gross margin by approximately 700 and 200 basis points in the second quarters of 2015 and 2014, respectively. Gross margin was also positively impacted by a reduction in royalty expense, partially offset by an increase in scrap and spoilage costs during the second quarter of 2015.

Research and development expenses remained relatively flat at $2.2 million in the second quarter of 2015 compared to $2.1 million in the second quarter of 2014. Sales and marketing expenses decreased 18% to $6.9 million in the second quarter of 2015 from $8.4 million in the second quarter of 2014. This decrease was primarily the result of lower advertising and promotional costs for our OraQuick® In-Home HIV test, which totaled $3.0 million in the second quarter of 2014, compared to $484,000 in the second quarter 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 decreased 2% to $5.1 million in the second quarter of 2015 from $5.2 million in the second quarter of 2014 due to lower staffing-related costs, partially offset by higher legal fees.

All of the above contributed to OSUR's second quarter 2015 operating income of $685,000, which included non-cash charges of $733,000 for depreciation and amortization and $1.4 million for stock-based compensation.

DNAG Segment

DNAG's gross margin was 73% in the second quarter of 2015 compared to 72% in the second quarter of 2014. This improvement was attributable to a higher volume of high margin sales experienced in the second quarter of 2015 when compared to the second quarter of 2014.

Research and development expenses increased 30% to $809,000 in the second quarter of 2015 from $623,000 in the second quarter of 2014 due to higher spending on new product initiatives and increased staffing costs. Sales and marketing expenses increased 10% to $2.1 million in the second quarter of 2015 from $1.9 million in the second quarter of 2014 due to higher commission expense and increased staffing costs as a result of increased headcount. General and administrative expenses increased 30% to $989,000 in the second quarter of 2015 compared to $761,000 in the second quarter of 2014, largely due to higher legal fees.

All of the above contributed to DNAG's second quarter 2015 operating income of $2.0 million, which included non-cash charges of $706,000 for depreciation and amortization and $153,000 for stock-based compensation.

CONSOLIDATED INCOME TAXES

We continue to believe the full valuation allowance established in 2008 against OSUR's total U.S. net 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 second quarter of 2015 or 2014, respectively. Canadian income tax expense of $658,000 was recorded in the second quarter of 2015. A Canadian income tax benefit of $174,000 was recorded in the second quarter of 2014 associated with certain Canadian research and development and investment tax credits and DNAG's loss before income taxes. The Canadian income tax benefit is considered realizable based upon the scheduled reversal of deferred tax liabilities recorded in connection with the acquisition of DNAG.

Six months ended June 30, 2015 compared to June 30, 2014

CONSOLIDATED NET REVENUES

The table below shows the amounts of total net revenues (dollars in thousands) generated by each of our business segments for the six months ended June 30, 2015 and 2014.

	Six Months Ended June 30,				
	Dollars		%	Percentage of Total Net Revenues	
	2015	2014	Change	2015	2014
OSUR	$35,259	$38,508	(8)%	61%	77%
DNAG	14,819	10,655	39	26	21
Net product revenues	50,078	49,163	2	87	98
Other	7,398	775	NM*	13	2
Net revenues	$57,476	$49,938	15%	100%	100%

* Calculation is not considered meaningful.

Consolidated net product revenues increased 2% to $50.1 million in the first half of 2015 from $49.2 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 cryosurgical systems, professional OraQuick® HIV, and OraQuick® In-Home HIV products. Other revenues were $7.4 million in the first half of 2015, of which $6.7 million represent the recognition of revenues from exclusivity payments received under our HCV co-promotion agreement with AbbVie, compared to $775,000 in comparable period of 2014. Other revenues also include $714,000 recognized in connection with the Ebola-related funding from BARDA.

Consolidated net revenues derived from products sold to customers outside the U.S. were $12.0 million and $13.4 million, or 21% and 27% of total net revenues, during the six months ended June 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.

	Six Months Ended June 30,				
	Dollars			Percentage of Total Net Revenues	
Market	2015	2014	%	2015	2014
Infectious disease testing	$23,288	$23,732	(2)%	55%	60%
Substance abuse testing	4,629	4,038	15	11	10
Cryosurgical systems	5,498	8,887	(38)	13	23
Insurance risk assessment	1,844	1,851	—	4	5
Net product revenues	35,259	38,508	(8)%	83	98%
Other	7,398	775	NM*	17	2
Net revenues	$42,657	$39,283	9%	100%	100%

* Calculation is not considered meaningful.

Infectious Disease Testing Market

Sales to the infectious disease testing market decreased 2% to $23.3 million in the first half of 2015 from $23.7 million in the first half of 2014 primarily due to lower domestic sales of our professional OraQuick® HIV and OraQuick® In-Home HIV products and lower international sales of our OraQuick® HCV product. These decreases were partially offset by higher sales of our OraQuick® HCV product in the domestic market and $760,000 in initial sales of our OraQuick® Ebola Rapid Antigen Test to the CDC for investigational use in Africa.

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

Market	Six Months Ended June 30, 2015	2014	% Change
Domestic HIV	$12,601	$14,339	(12)%
International HIV	1,544	1,405	10
Domestic OTC HIV	3,280	3,622	(9)
Net HIV revenues	17,425	19,366	(10)
Domestic HCV	2,889	1,884	53
International HCV	1,619	1,870	(13)
Net HCV revenues	4,508	3,754	20
Net OraQuick® revenues	$21,933	$23,120	(5)%

Domestic OraQuick® HIV sales decreased 12% to $12.6 million for the six months ended June 30, 2015 from $14.3 million for the six months ended June 30, 2014. This decrease was primarily the result of the migration of some customers to 4th generation automated HIV immunoassays performed in a laboratory, as recommended under testing guidelines issued by the CDC. We anticipate that future sales of our professional HIV product will continue to be negatively affected as a result of the CDC's new testing guidelines, changes in government funding, and continued price competition. International sales of our OraQuick® HIV test during the first half of 2015 increased 10% to $1.5 million from $1.4 million primarily due to higher sales in Asia. This increase was partially offset by a decline in sales in Europe.

Sales of our OraQuick® In-Home HIV test decreased 9% to $3.3 million in the first half of 2015 from $3.6 million in the first half of 2014. The decline in sales is primarily the result of our decision in the second half of 2014 to transition away from broad-based consumer advertising and focus our marketing and promotional efforts at the retail outlet level.

Domestic OraQuick® HCV sales increased 53% to $2.9 million in the first half of 2015 from $1.9 million in the first half 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 decreased 13% to $1.6 million in the first half of 2015 from $1.9 million in the first half of 2014, largely due to lower purchases by a multi-national humanitarian organization. Sales to this organization can be variable, are influenced by its worldwide field activities, and are thus difficult to predict. This decrease was partially offset by higher sales 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. We also expect that sales of our HCV product will be positively impacted as we continue to implement awareness and testing programs under our agreement with AbbVie. However, demand for our HCV product, particularly in the public health marketplace, is 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 sales will continue at the same levels in future periods.

Substance Abuse Testing Market

Sales to the substance abuse testing market increased 15% to $4.6 million in the first six months of 2015 from $4.0 million in the first six months 2014, primarily as a result of higher sales of our Intercept® drug testing system.

Domestic Intercept® sales for the first half of 2015 increased to $3.5 million compared to $2.9 million for the first half 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 38% to $5.5 million in the first half of 2015, compared to $8.9 million in the same period of the prior year.

The table below shows a breakdown of our total net cryosurgical systems revenues (dollars in thousands) generated in each market during the six months ended June 30, 2015 and 2014.

	Six Months Ended June 30,		
Market	2015	2014	% Change
Domestic professional	$1,668	$3,011	(45)%
International professional	498	538	(7)
Domestic over-the-counter	163	—	100
International over-the-counter	3,169	5,338	(41)
Net cryosurgical systems revenues	$5,498	$8,887	(38)%

Sales of our Histofreezer® product to physicians' offices in the United States decreased 45% to $1.7 million in the first six months of 2015 from $3.0 million in the first six months of 2014 largely as a result of distributor consolidation and competition from new private-label brands. International sales of Histofreezer® decreased to $498,000 in the first half of 2015, compared to $538,000 in the same period of the prior year, primarily due to pricing pressure from a similar, lower-priced competing product promoted by our former contract manufacturer. This competing product has adversely affected, and is expected to continue to adversely affect, revenues generated from our cryosurgical systems business. In order to remain competitive with this new product offering, we have decreased the per unit sales price of our Histofreezer® product in certain international markets.

In the fourth quarter of 2014, we launched our wart removal product in the U.S. retail market through private labeling with a large pharmacy chain. Sales related to this product in the first half of 2015 were $163,000.

Sales of our international OTC cryosurgical products during the first six months of 2015 decreased 41% to $3.2 million compared to $5.3 million in the first six months of 2014, largely due to lower sales to both our European and Latin American distributors. Sales to our European distributor decreased to $2.7 million in the first half of 2015, compared to $3.0 million during the first half of 2014, primarily due to customer ordering patterns. Sales to our Latin American distributor decreased to $398,000 in the first half of 2015 from $2.2 million in the first half 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.

Insurance Risk Assessment Market

Sales to the insurance risk assessment market remained flat in the first six months of 2015 at $1.8 million compared to $1.9 million in the first six months of 2014.

Other revenues

Other revenues were $7.4 million in the first half of 2015, compared to $775,000 in the comparable period of 2014. Other revenues in 2015 included $6.7 million from exclusivity payments received under our HCV co-promotion agreement with AbbVie and $714,000 in connection with Ebola-related funding from BARDA.

DNAG Segment

Molecular Collection Systems

Net molecular collection systems revenues, which primarily represent sales of our Oragene® product line, increased 39% to $14.8 million in the first half of 2015 from $10.7 million in the first half of 2014. Sales in the commercial market grew 57%, which was primarily due to increased orders from existing U.S. customers, as well as incremental revenues from new customers. Sales in the academic market increased slightly to $5.0 million the first half of 2015 from $4.4 million in the first half of 2014.

CONSOLIDATED OPERATING RESULTS

Consolidated gross margin was 66% for the first half of 2015 compared to 60% for the first half of 2014. Gross margin in 2015 increased primarily due to the $7.4 million of other revenues associated with the AbbVie co-promotion agreement and the BARDA funding. These other revenues contributed 500 basis points to gross margin in the current period and 100 basis points in the first half of 2014.

Consolidated operating income for the first half of 2015 was $2.4 million, a $5.5 million improvement from the $3.1 million operating loss reported in the first half of 2014. The improvement in operating income was primarily the result of the $7.4 million of other revenues recorded in the first half of 2015 coupled with the reduction in royalty expenses and advertising and promotional costs associated with our OraQuick® In-Home HIV test, partially offset by 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 half of 2014.

OPERATING INCOME (LOSS) BY SEGMENT

OSUR Segment

OSUR’s gross margin was 64% in the first half of 2015 compared to 57% in the first half of 2014. OSUR’s gross margin in the first half of 2015 was positively impacted by the $7.4 million in other revenues recognized in the current period. These other revenues increased gross margins by approximately 800 and 100 basis points in the first six months of 2015 and 2014, respectively. Gross margin was also positively impacted by a reduction in royalty expense partially offset by an increase in scrap and spoilage cost during the first half of 2015.

Research and development expenses increased 26% to $5.0 million in the first half of 2015 from $4.0 million in the first half 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 28% to $13.0 million in the first half of 2015 from $17.9 million in the first half of 2014. This decrease was primarily the result of lower advertising and promotional costs for our OraQuick® In-Home HIV test, which totaled $7.6 million in the first half of 2014, compared to $917,000 in the first half 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 relatively flat at $10.0 million in the first half of 2015 compared to $10.1 million in the first half of 2014.

All of the above contributed to OSUR’s operating loss of $836,000 for the first half of 2015, which included non-cash charges of $1.5 million for depreciation and amortization and $2.7 million for stock-based compensation.

DNAG Segment

DNAG's gross margin was 71% in the first half of 2015 compared to 72% in the first half of 2014. This decrease was attributable to increased volume of lower margin sales experienced in the first half of 2015 when compared to the first half of 2014.

Research and development expenses increased 12% to $1.4 million in the first half of 2015 from $1.3 million in the first half of 2014 due to increased spending on new product initiatives. Sales and marketing expenses increased 4% to $3.8 million in the first half of 2015 from $3.7 million in the first half of 2014 due to higher commission expense and increased staffing costs as a result of increased headcount. General and administrative expenses increased 23% to $2.0 million in the first half of 2015 compared to $1.6 million in the first half of 2014, largely due to higher legal costs.

All of the above contributed to DNAG's operating income of $3.3 million for the first half of 2015, which included non-cash charges of $1.4 million for depreciation and amortization and $290,000 for stock-based compensation.

CONSOLIDATED INCOME TAXES

We continue to believe the full valuation allowance established in 2008 against OSUR's total U.S. net 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 half of 2015 or 2014, respectively. Canadian income tax expense of $663,000 was recorded for the six months ended June 30, 2015. A Canadian income tax benefit of $43,000 was recorded for the six months ended June 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 is considered realizable based upon the scheduled reversal of deferred tax liabilities recorded in connection with the acquisition of DNAG.

Liquidity and Capital Resources

	June 30, 2015	December 31, 2014
	(In thousands)	
Cash	$ 83,403	$ 92,867
Short-term investments	8,005	5,000
Working capital	109,660	104,752

Our cash and short-term investment balances decreased to $91.4 million at June 30, 2015 from $97.9 million at December 31, 2014. Our working capital increased to $109.7 million at June 30, 2015 from $104.8 million at December 31, 2014.

During the first half of 2015, we used $3.4 million in cash to finance our operating activities. Our net income of $2.1 million was increased by non-cash stock-based compensation expense of $3.0 million, depreciation and amortization expense of $2.8 million, deferred income taxes of $366,000, and unrealized foreign currency losses of $266,000. Uses of cash in operating activities during the period included a $6.3 million decrease in deferred revenues, largely due to the ratable recognition of AbbVie-related deferred revenue during the period; a $2.5 million decrease in accounts payable associated with year-end inventory purchases and expense payments related to the AbbVie agreement; a $2.8 million decrease in accrued expenses and other liabilities associated with payment of our 2014 management incentive bonuses, royalty obligations, and certain year-end accruals; and a $524,000 increase in accounts receivable resulting from the increase in orders placed near the end of the current quarter.

Net cash used in investing activities was $4.1 million for the six months ended June 30, 2015, which reflects $12.0 million used to purchase short-term investments and $1.1 million to acquire property and equipment, partially offset by $9.0 million in proceeds from the maturities of short-term investments.

Net cash used in financing activities was $759,000 for the six months ended June 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 June 30, 2015, there were no significant changes to this information, including the absence of any off-balance sheet arrangements.

Critical Accounting Policies and Estimates

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

A more detailed review of our critical accounting policies is contained in our Annual Report on Form 10-K for the year ended December 31, 2014 filed with the SEC. During the first six 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 June 30, 2015, we did not have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. We have operations in Canada and Europe, which are subject to foreign currency fluctuations. As currency rates change, translation of revenues and expenses for these operations from foreign currencies to U.S. dollars affects year-to-year comparability of operating results. Sales denominated in a foreign currency comprised 5.8% of our total revenues for the six months ended June 30, 2015. We expect our international business will continue to grow and our exposure to fluctuations in foreign currency exchange rates may increase.

Item 4. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures. The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) as of June 30, 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 June 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 June 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.

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

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.

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

Period	Total number of shares purchased (1)	Average price paid per Share	Total number of shares purchased as part of publicly announced plans or programs	Maximum number (or approximate dollar value) of shares that may yet be repurchased under the plans or programs (2, 3)
April 1, 2015 - April 30, 2015	—	$ —	—	$ 19,570,287
May 1, 2015 - May 31, 2015	20,111	5.53	—	19,570,287
June 1, 2015 - June 30, 2015	—	—	—	19,570,287

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

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

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

Item 3. DEFAULTS UPON SENIOR SECURITIES

None

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable

ITEM 5. OTHER INFORMATION

None

Item 6. EXHIBITS

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

SIGNATURES

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

ORASURE TECHNOLOGIES, INC.

/s/ Ronald H. Spair

Date: August 7, 2015

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

/s/ Mark L. Kuna

Date: August 7, 2015

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

EXHIBIT INDEX

Exhibit Number	Exhibit
10.1	Description of the OraSure Technologies, Inc. 2015 Management Incentive Plan is incorporated by reference to Item 5.02 to the Company's Current Report on Form 8-K filed May 14, 2015.*
10.2	Description of Amended Long-Term Incentive Policy is incorporated by reference to Item 5.02 to the Company's Current Report on Form 8-K filed May 14, 2015.*
31.1	Certification of Douglas A. Michels required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Ronald H. Spair required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
32.1	Certification of Douglas A. Michels required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Ronald H. Spair required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Management contract or compensatory plan or arrangement.

Exhibit 31.1

Certification

I, Douglas A. Michels, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 7, 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: August 7, 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 June 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

August 7, 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 June 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

August 7, 2015