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

# FORM 10-Q

**(Mark One)**

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

**For the quarterly period ended September 30, 2014.**

**OR**

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

**For the transition period from _____ to _____.**

**Commission File Number 001-16537**

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

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

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

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

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

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

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

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

Number of shares of Common Stock, par value $.000001 per share, outstanding as of November 4, 2014: 56,056,813 shares.

**Item 1. FINANCIAL STATEMENTS**

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

| | SEPTEMBER 30, 2014 | DECEMBER 31, 2013 |
|---|---|---|
| **ASSETS** | | |
| CURRENT ASSETS: | | |
| Cash | $ 93,855 | $ 93,191 |
| Short-term investments | 5,000 | — |
| Accounts receivable, net of allowance for doubtful accounts of $288 and $299 | 14,920 | 12,957 |
| Inventories | 14,843 | 11,444 |
| Prepaid expenses | 1,089 | 1,712 |
| Deferred income taxes | 67 | 71 |
| Other current assets | 273 | 200 |
| Total current assets | 130,047 | 119,575 |
| PROPERTY AND EQUIPMENT, net | 17,958 | 17,933 |
| INTANGIBLE ASSETS, net | 18,831 | 22,226 |
| GOODWILL | 22,562 | 23,782 |
| OTHER ASSETS | 1,102 | 729 |
| | $ 190,500 | $ 184,245 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| CURRENT LIABILITIES: | | |
| Accounts payable | $ 4,510 | $ 4,834 |
| Deferred revenue | 11,540 | 1,119 |
| Accrued expenses | 9,203 | 13,032 |
| Total current liabilities | 25,253 | 18,985 |
| OTHER LIABILITIES | 1,090 | 677 |
| DEFERRED INCOME TAXES | 3,233 | 3,437 |
| 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, 56,052 and 55,632 shares issued and outstanding | — | — |
| Additional paid-in capital | 342,865 | 338,674 |
| Accumulated other comprehensive loss | (6,248) | (3,797) |
| Accumulated deficit | (175,693) | (173,731) |
| Total stockholders' equity | 160,924 | 161,146 |
| | $ 190,500 | $ 184,245 |

See accompanying notes to the consolidated financial statements.

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2014 | 2013 | 2014 | 2013 |
| NET REVENUES: | | | | |
| Product | $ 24,447 | $ 24,524 | $ 73,610 | $ 69,549 |
| Licensing and product development | 3,398 | 147 | 4,173 | 623 |
| | 27,845 | 24,671 | 77,783 | 70,172 |
| COST OF PRODUCTS SOLD | 9,140 | 9,738 | 29,135 | 28,711 |
| Gross profit | 18,705 | 14,933 | 48,648 | 41,461 |
| OPERATING EXPENSES: | | | | |
| Research and development | 2,990 | 2,670 | 8,242 | 8,720 |
| Sales and marketing | 9,216 | 8,981 | 30,828 | 35,224 |
| General and administrative | 5,617 | 5,342 | 17,317 | 15,742 |
| Gain on contract termination settlement | — | — | (5,500) | — |
| | 17,823 | 16,993 | 50,887 | 59,686 |
| Operating income (loss) | 882 | (2,060) | (2,239) | (18,225) |
| OTHER INCOME | 268 | 41 | 244 | 36 |
| Income (loss) before income taxes | 1,150 | (2,019) | (1,995) | (18,189) |
| INCOME TAX EXPENSE (BENEFIT) | 10 | (127) | (33) | (786) |
| NET INCOME (LOSS) | $ 1,140 | $ (1,892) | $ (1,962) | $ (17,403) |
| EARNINGS (LOSS) PER SHARE: | | | | |
| BASIC | $ 0.02 | $ (0.03) | $ (0.04) | $ (0.31) |
| DILUTED | $ 0.02 | $ (0.03) | $ (0.04) | $ (0.31) |
| SHARES USED IN COMPUTING EARNINGS (LOSS) PER SHARE: | | | | |
| BASIC | 56,018 | 55,592 | 55,897 | 55,534 |
| DILUTED | 56,666 | 55,592 | 55,897 | 55,534 |

See accompanying notes to the consolidated financial statements.

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2014 | 2013 | 2014 | 2013 |
| NET INCOME (LOSS) | $ 1,140 | $ (1,892) | $ (1,962) | $ (17,403) |
| OTHER COMPREHENSIVE INCOME (LOSS) | | | | |
| Currency translation adjustments | (2,295) | 876 | (2,451) | (1,709) |
| Other comprehensive income (loss) | (2,295) | 876 | (2,451) | (1,709) |
| COMPREHENSIVE LOSS | $ (1,155) | $ (1,016) | $ (4,413) | $ (19,112) |

See accompanying notes to the consolidated financial statements.

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

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2014 | 2013 |
| OPERATING ACTIVITIES: | | |
| Net loss | $ (1,962) | $ (17,403) |
| Adjustments to reconcile net loss to net cash provided by (used in) operating activities: | | |
| Stock-based compensation | 4,284 | 4,187 |
| Depreciation and amortization | 4,732 | 4,846 |
| Unrealized foreign currency loss | (73) | — |
| Deferred income taxes | (33) | (786) |
| Changes in assets and liabilities | | |
| Accounts receivable | (2,111) | 3,127 |
| Inventories | (3,444) | 745 |
| Prepaid expenses and other assets | 576 | (554) |
| Accounts payable | (284) | 497 |
| Deferred revenue | 10,433 | (1,098) |
| Accrued expenses and other liabilities | (3,734) | 3,297 |
| Net cash provided by (used in) operating activities | 8,384 | (3,142) |
| INVESTING ACTIVITIES: | | |
| Purchases of short term investments | (9,407) | — |
| Proceeds from maturities of short term investments | 4,432 | — |
| Purchases of property and equipment | (2,353) | (1,696) |
| Net cash used in investing activities | (7,328) | (1,696) |
| FINANCING ACTIVITIES: | | |
| Proceeds from exercise of stock options | 546 | 317 |
| Repurchase of common stock | (639) | (817) |
| Net cash used in financing activities | (93) | (500) |
| EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH | (299) | 40 |
| NET INCREASE (DECREASE) IN CASH | 664 | (5,298) |
| CASH, BEGINNING OF PERIOD | 93,191 | 87,888 |
| CASH, END OF PERIOD | $ 93,855 | $ 82,590 |
| SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION: | | |
| Cash paid for: | | |
| Income taxes | $ 42 | $ 28 |

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 oral fluid diagnostic products and specimen collection devices using our proprietary oral fluid 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 and tests that are processed in a laboratory. We sell the first and only 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. 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.

## 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, 2013. Results of operations for the three and nine months ended September 30, 2014 are not necessarily indicative of the results of operations expected for the full year.

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

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

Our available-for-sale securities as of September 30, 2014 consisted of guaranteed investment certificates with amortized cost and fair value of $5,000. As of December 31, 2013, we had no available-for-sale securities.

*Fair Value of Financial Instruments*. As of September 30, 2014, the carrying values of cash, short-term investments, accounts receivable, accounts payable and accrued expenses approximate their respective fair values based on their short-term nature.

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

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

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

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

We offer a nonqualified deferred compensation plan for certain eligible employees and members of our Board of Directors. The assets of the plan are held in the name of the Company at a third-party financial institution. Separate accounts are maintained for each participant to reflect the amounts deferred by the participant and all earnings and losses on those deferred amounts. The assets of the plan are held in mutual funds and Company stock. The fair value of the plan assets as of September 30, 2014 and December 31, 2013 was $1,090 and $677, 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 were classified and measured as Level 1 instruments as of September 30, 2014.

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

| | September 30, 2014 | December 31, 2013 |
|---|---|---|
| Raw materials | $ 6,772 | $ 6,700 |
| Work in process | 937 | 833 |
| Finished goods | 7,134 | 3,911 |
| | $ 14,843 | $ 11,444 |

*Property and Equipment*. Property and equipment are stated at cost. Additions or improvements are capitalized, while repairs and maintenance are charged to expense. Depreciation and amortization are provided using the straight-line method over the estimated useful lives of the related assets. Buildings are depreciated over twenty to forty years, while computer equipment, machinery and equipment, and furniture and fixtures are depreciated over two to ten years. Building improvements are amortized over their estimated useful lives. When assets are sold or otherwise disposed of, the related property amounts are relieved from the accounts, and any gain or loss is recorded in the consolidated statement of operations. Accumulated depreciation of property and equipment as of September 30, 2014 and December 31, 2013 was $30,603 and $28,390, respectively.

Intangible Assets. Intangible assets consist of the following:

| | Amortization Period (Years) | September 30, 2014 Gross | Accumulated Amortization | Net |
|---|---|---|---|---|
| Customer list | 10 | $11,190 | $ (3,370) | $ 7,820 |
| Patents and product rights | 3-10 | 10,449 | (7,844) | 2,605 |
| Acquired technology | 7 | 8,692 | (3,682) | 5,010 |
| Tradename | 15 | 4,289 | (893) | 3,396 |
| | | $34,620 | $ (15,789) | $18,831 |

| | Amortization Period(Years) | December 31, 2013 Gross | Accumulated Amortization | Net |
|---|---|---|---|---|
| Customer list | 10 | $11,795 | $ (2,701) | $ 9,094 |
| Patents and product rights | 3-10 | 10,449 | (7,466) | 2,983 |
| Acquired technology | 7 | 9,162 | (2,952) | 6,210 |
| Tradename | 15 | 4,521 | (715) | 3,806 |
| Non-compete agreements | 1-3 | 787 | (654) | 133 |
| | | $36,714 | $ (14,488) | $22,226 |

*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 September 30, 2014, we believe no indicators of impairment exist.

The change in goodwill from $23,782 as of December 31, 2013 to $22,562 as of September 30, 2014 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.

We began selling our OraQuick® In-Home HIV test in the third quarter of 2012. From launch through November 2013, our revenue recognition practices with respect to the OraQuick® In-Home HIV test were different than those customarily used in the consumer package goods industry. Under U.S. generally accepted accounting principles, product revenue cannot be recognized unless the amount of future returns can be reasonably estimated. Because our OraQuick® In-Home HIV test was a new product for which we did not have a historical record of returns, we did not believe we could reasonably determine a return rate. As a result, initially we did not recognize revenue when we shipped to the retail trade. For these product shipments, we invoiced the retailer or distributor, recorded deferred revenue at gross invoice sales price, and classified the cost basis of the product held by the retailer or distributor as a component of inventory. We then recognized revenue upon the consummation of a sale to the consumer either in a store or over the internet. With the passage of time, however, we concluded that we have sufficient data and visibility into our distribution channel to develop a reasonable estimate of the level of expected returns. As such, commencing in December 2013, we recognized previously deferred revenue and its related cost of goods sold, and began to recognize revenue for this product upon shipment to the retailers or distributors. Accordingly, revenues in the first nine months of 2014 were recorded based upon shipments into the distribution channel, while revenues in the first nine months of 2013 were recorded based upon the consummation of a sale to the consumer.

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 licensing and product development 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 Rapid Test in the United States. The product will be used to test individuals at-risk for the hepatitis C virus (“HCV”). We will be responsible for manufacturing and selling the product into all markets.

Under the terms of our agreement, we have granted exclusive promotion rights to AbbVie for the OraQuick® HCV Rapid test in certain markets and we have agreed to develop, implement, administer and maintain a patient care database for the exclusive use of AbbVie. This patient care database will be used to compile patient information regarding new individuals who have tested positive for HCV using our OraQuick® HCV Rapid test. We have also jointly agreed with AbbVie to co-promote our OraQuick® HCV Rapid test in certain market segments, namely: healthcare providers such as primary care physicians, gastroenterologists, hepatologists and infectious disease specialists; employers and employee groups experiencing a high HCV prevalence rate, such as the long-haul trucking industry; and national retail pharmacies and retail clinics that perform routine healthcare screening services.

In exchange for these exclusive rights and other services, we will receive up to $75,000 in payments over the term of the agreement which expires on December 31, 2019. We will recognize revenues from these periodic payments ratably, over the life of the agreement. In addition, if certain performance-based milestones are achieved, we could 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 life of the agreement. The first performance-based milestone period ends on December 31, 2015. The agreement also contains certain termination, indemnification and other provisions, typical of agreements of this type. Payments received under this agreement will be recorded as licensing and product development revenue in our statements of operations.

*Customer Sales Returns and Allowances*. We do not grant return rights to our customers for any product, except for our OraQuick® In-Home HIV test. Accordingly, we have recorded an estimate of expected returns as a reduction of gross OraQuick® In-Home HIV product revenues in our consolidated statements of operations. This estimate reflects our historical sales experience to retailers and consumers, as well as other retail factors, and is reviewed regularly to ensure that it reflects potential product returns. As of September 30, 2014 and December 31, 2013, the reserve for sales returns and allowances was $398 and $279, 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.

*Termination Settlement.* On November 21, 2013, we terminated our assay development collaboration with Roche Diagnostics ("Roche"). Pursuant to a termination agreement, Roche paid us $8,300 which was recorded as a reduction of operating expense in our consolidated statement of operations for the quarter ended December 31, 2013. Roche agreed to provide certain transitional product support services to us and to continue to supply certain of the assays developed under the collaboration on a transitional basis for up to five years following the termination. We had the right to stop the supply of assays prior to the end of this five-year period and to receive an additional payment from Roche of up to $5,500 depending on how early in that five-year period the supply obligation was ended. During the second quarter of 2014, we issued our final purchase order for fully-automated assays previously developed under the terminated collaboration and as such, have recorded $5,500 as a reduction of operating expense in our consolidated statement of operations.

*Deferred Revenue*. We record deferred revenue when funds are received prior to the recognition of the associated revenue. Deferred revenue at September 30, 2014 and December 31, 2013 includes customer prepayments of $713 and $1,119, respectively. Deferred revenue also includes $10,827 which represents the $15,000 payment received in July 2014 under the terms of our HCV collaboration with AbbVie, less amounts recognized ratably in revenue.

*Customer and Vendor Concentrations*. We had no significant concentrations (greater than 10%) in accounts receivable as of September 30, 2014. One of our customers, AbbVie, accounted for approximately 12% of our net revenues for the three months ended September 30, 2014. We had no significant concentrations (greater than 10%) in net revenues for the nine months ended September 30, 2014 and the three or nine months ended September 30, 2013.

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

*Earnings (Loss) Per Share*. Basic earnings (loss) per share is computed by dividing net income (loss) by the weighted-average number of shares of common stock outstanding during the period. Diluted earnings (loss) per share is computed in a manner similar to basic earnings (loss) per share except that the weighted average number of shares outstanding is increased to include incremental shares from the assumed vesting or exercise of dilutive securities, such as common stock options and unvested restricted stock, unless the impact is antidilutive. The number of incremental shares is calculated by assuming that outstanding stock options were exercised and unvested restricted shares were vested, and the proceeds from such exercises or vesting were used to acquire shares of common stock at the average market price during the reporting period.

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2014 | 2013 | 2014 | 2013 |
| Net income (loss) | $ 1,140 | $ (1,892) | $ (1,962) | $ (17,403) |
| Weighted average shares of common stock outstanding: | | | | |
| Basic | 56,018 | 55,592 | 55,897 | 55,534 |
| Dilutive effect of stock options and restricted stock | 648 | — | — | — |
| Diluted | 56,666 | 55,592 | 55,897 | 55,534 |
| Earnings (loss) per share: | | | | |
| Basic | $ 0.02 | $ (0.03) | $ (0.04) | $ (0.31) |
| Diluted | $ 0.02 | $ (0.03) | $ (0.04) | $ (0.31) |

For the three-month periods ended September 30, 2014 and 2013, outstanding common stock options and unvested restricted stock, representing 2,647 and 5,499 shares, respectively, were excluded from the computation of diluted earnings (loss) per share, as their inclusion would have been anti-dilutive. For the nine months ended September 30, 2014 and 2013, outstanding common stock options and unvested restricted stock, representing 3,313 and 5,324 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 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 $2,451 and $1,709 currency translation adjustments recorded in the first nine months of 2014 and 2013, 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, 2016, with no early adoption permitted. We will evaluate 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 to issue new restricted stock, we normally issue new shares rather than purchase shares on the open market.

Total compensation cost related to stock options for the nine months ended September 30, 2014 and 2013 was $2,286 and $2,028, respectively. Net cash proceeds from the exercise of stock options were $546 and $317 for the nine months ended September 30, 2014 and 2013, 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 $1,998 and $2,159 related to restricted shares was recognized during the nine months ended September 30, 2014 and 2013, respectively. In connection with the vesting of restricted shares, during the nine months ended September 30, 2014 and 2013, 106 and 122 shares, respectively, with aggregate values of $639 and $817, respectively, were withheld and retired in satisfaction of minimum tax withholding obligations.

### 4. Accrued Expenses

| | September 30, 2014 | December 31, 2013 |
|---|---|---|
| Payroll and related benefits | $ 5,093 | $ 5,827 |
| Royalties | 1,703 | 4,374 |
| Professional fees | 484 | 749 |
| Other | 1,923 | 2,082 |
| | $ 9,203 | $ 13,032 |

### 5. Income Taxes

During the three months ended September 30, 2014, we recorded foreign deferred tax expense of $10. During the nine months ended September 30, 2014, we recorded foreign deferred tax benefits of $33. During the three and nine months ended September 30, 2013, we recorded foreign deferred tax benefits of $127 and $786, respectively. The foreign deferred tax benefits are associated with certain Canadian research and development and investment tax credits. The income tax benefits associated with DNAG are considered realizable based upon the estimated scheduled reversal of the deferred tax liabilities recorded in connection with the acquisition of DNAG.

Deferred income taxes reflect the tax effects of temporary differences between the basis of assets and liabilities recognized for financial reporting and tax purposes, and net operating loss and tax credit carryforwards. The significant components of our total deferred tax liability as of September 30, 2014 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, and management believes the full valuation allowance is still appropriate as of September 30, 2014 and December 31, 2013 since the facts and circumstances necessitating the allowance have not changed. As a result, no U.S. federal or state income tax benefit was recorded for the three and nine month periods ended September 30, 2014 and 2013.

## 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 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 oral fluid diagnostic products and specimen collection devices and the manufacture and sale of medical devices used for the removal of benign skin lesions by cryosurgery; and our molecular collection systems or "DNAG" business, which 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, and commercial and industrial entities. Revenues from OSUR's OTC products result from sales to retail pharmacies and mass merchandisers, and to consumers over the internet. OSUR also derives revenues from licensing and product development activities. DNAG revenues result primarily from products sold into the commercial market which consists of companies and other entities 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 segment information for the three and nine months ended September 30, 2014 and 2013:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2014 | 2013 | 2014 | 2013 |
| Net revenues: | | | | |
| OSUR | $ 20,978 | $ 19,707 | $ 60,260 | $ 56,622 |
| DNAG | 6,867 | 4,964 | 17,523 | 13,550 |
| Total | $ 27,845 | $ 24,671 | $ 77,783 | $ 70,172 |
| Operating income (loss): | | | | |
| OSUR | $ (987) | $ (2,516) | $ (5,177) | $ (18,012) |
| DNAG | 1,869 | 456 | 2,938 | (213) |
| Total | $ 882 | $ (2,060) | $ (2,239) | $ (18,225) |
| Depreciation and amortization: | | | | |
| OSUR | $ 820 | $ 815 | $ 2,386 | $ 2,389 |
| DNAG | 804 | 810 | 2,346 | 2,457 |
| Total | $ 1,624 | $ 1,625 | $ 4,732 | $ 4,846 |
| Capital expenditures: | | | | |
| OSUR | $ 298 | $ 369 | $ 1,868 | $ 1,096 |
| DNAG | 67 | 235 | 485 | 600 |
| Total | $ 365 | $ 604 | $ 2,353 | $ 1,696 |

| | September 30, 2014 | December 31, 2013 |
|---|---|---|
| Total assets: | | |
| OSUR | $ 137,418 | $ 130,848 |
| DNAG | 53,082 | 53,397 |
| Total | $ 190,500 | $ 184,245 |

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

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2014 | 2013 | 2014 | 2013 |
| United States | $ 22,469 | $ 19,052 | $ 58,987 | $ 54,052 |
| Europe | 3,252 | 2,540 | 10,935 | 7,823 |
| Other regions | 2,124 | 3,079 | 7,861 | 8,297 |
| | $ 27,845 | $ 24,671 | $ 77,783 | $ 70,172 |

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

| | September 30, 2014 | December 31, 2013 |
|---|---|---|
| United States | $ 16,802 | $ 16,925 |
| Canada | 1,139 | 975 |
| Other regions | 17 | 33 |
| | $ 17,958 | $ 17,933 |

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

*Statements below regarding future events or performance are "forward-looking statements" within the meaning of the Federal securities laws. These may include statements about our expected revenues, earnings/loss per share, net income (loss), expenses, cash flow or other financial performance or developments, clinical trial or development activities, expected regulatory filings and approvals, planned business transactions, views of future industry, competitive or market conditions, and other factors that could affect our future operations, results of operations or financial position. These statements often include the words "believes," "expects," "anticipates," "intends," "plans," "estimates," "may," "will," "should," "could," or similar expressions. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include, but are not limited to: ability to market and sell products, whether through our internal, direct sales force or third parties; ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements; ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; ability to comply with applicable regulatory requirements; ability to effectively resolve warning letters, audit observations and other findings or comments from the FDA or other regulators; changes in relationships, including disputes or disagreements, with strategic partners or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements; ability to achieve financial and performance objectives under the HCV collaboration 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, including the OraQuick® In-Home HIV test; 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, 2013, 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.*

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 oral fluid diagnostic products and specimen collection devices using our proprietary oral fluid 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 and tests that are processed in a laboratory. We sell the OraQuick® In-Home HIV test, the first and only rapid point-of-care HIV test approved for use in the domestic consumer retail 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 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 and other public health organizations, research and academic institutions, distributors, government agencies, physicians' offices, and commercial and industrial entities. Our over-the-counter ("OTC") HIV and cryosurgery products are available at retail pharmacies and mass merchandisers, and our OTC HIV product is also sold to consumers over the internet.

**Recent Developments**

HCV Co-Promotion Initiatives

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 Rapid Test in the United States. The product will be used to test individuals at-risk for the hepatitis C virus ("HCV"). We will be responsible for manufacturing and selling the product into all markets covered by the agreement.

During the third quarter, we initiated three co-promotion initiatives pursuant to our co-promotion agreement. The first initiative focuses on primary care and specialty physicians. In August 2014, AbbVie began detailing our OraQuick® HCV test to physicians and we commenced a comprehensive product training program for these customers. As a result of these efforts, hundreds of physician offices have indicated an interest in our product. We expect that sales of our OraQuick® HCV test to physician offices will begin to increase later in 2014 and throughout 2015.

The second initiative targets employers or employer groups with employees that are at high risk for HCV. Our initial focus has been on commercial long-haul truck drivers and we have been working closely with the Healthy Trucking Association of America ("HTAA") and an organization known as Rolling Strong. We are promoting the use of our test in physician offices, health clinics and retail pharmacies where truckers receive their health care, driving schools where newly-hired drivers are required to take and pass a physical exam, and at health events sponsored by HTAA and Rolling Strong where truckers can take advantage of a variety of health and wellness services.

Lastly, we have identified national retail pharmacies and retail clinics as a major market segment. We and AbbVie have initiated discussions with several major retail pharmacies about increasing awareness and making our OraQuick® HCV test and AbbVie's patient support program available through retail outlets.

Launch of I2 Collection Device

We have completed development of a new version of our Intercept® oral specimen collection device, which is called the "I2" collection device. In July 2014, we commercially launched the new I2 device into the U.S. criminal justice and forensic toxicology markets and into certain international markets. We eventually intend to market the I2 device with the fully-automated high throughput oral fluid drug assays being developed pursuant to our collaboration with Thermo Fisher. We expect to commercially launch the I2 device with a NIDA-5 panel of the Thermo Fisher assays into the U.S. criminal justice and forensic toxicology markets beginning in the fourth quarter of 2014.

**Current Consolidated Financial Results**

During the nine months ended September 30, 2014, our consolidated net revenues were $77.8 million compared to $70.2 million in the nine months ended September 30, 2013. Net product revenues during the nine months ended September 30, 2014 increased 6% when compared to the first nine months of 2013, primarily due to higher sales of our Oragene®, OraQuick® HCV, and cryosurgical systems products. Licensing and product development revenues for the first nine months of 2014 were $4.2 million compared to $623,000 in the first nine months of 2013. Licensing and product development revenues in 2014 represent the recognition of payments from AbbVie for exclusive promotion rights and certain services we provided under our HCV collaboration. Licensing and product development revenues for the first nine months of 2013 represent royalties related to sales of Merck's OTC cryosurgical wart removal product pursuant to a license and settlement agreement that expired in August 2013.

Our consolidated net loss for the nine months ended September 30, 2014 was $2.0 million, or $0.04 per share, compared to a net loss of $17.4 million, or $0.31 per share, for the nine months ended September 30, 2013. Results for the nine months ended September 30, 2014 included a $5.5 million payment received pursuant to the termination of our oral fluid drug assay collaboration with Roche Diagnostics.

Cash provided by operating activities for the nine months ended September 30, 2014 was $8.4 million, compared to $3.1 million used during the nine months ended September 30, 2013. As of September 30, 2014, we had $98.9 million in cash and short-term investments compared to $93.2 million at December 31, 2013.

**Economic Outlook**

Many of our customers rely on public funding provided by federal, state and local governments. This funding has been and may continue to be reduced or deferred as a result of current economic conditions. These circumstances may adversely impact our customers and suppliers, which, in turn, could adversely affect their ability to purchase our products or supply us with necessary equipment, raw materials or components. In addition, these circumstances could adversely affect our access to liquidity that may be needed to conduct or expand our business, conduct future acquisitions or make other discretionary investments. Legislative, budgetary or regulatory changes may also be adopted which could adversely affect our ability to sell our current products or successfully develop and commercialize new products.

**Business Segments**

We operate our business within two reportable segments: our "OSUR" business, which consists of the development, manufacture and sale of oral fluid diagnostic products, specimen collection devices, and medical devices used for the removal of benign skin lesions by cryosurgery; 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, and commercial and industrial entities. Revenues from OSUR's OTC products result from sales to retail pharmacies and mass merchandisers and to consumers over the internet. DNAG revenues result primarily from products sold into the commercial market, which consists of companies and other entities engaged in consumer genetics, clinical genetic testing, pharmacogenomics, personalized medicine, and animal genetic testing, as well as products sold into the academic research market which consists of research laboratories, universities and hospitals.

**Results of Operations**

**Three months ended September 30, 2014 compared to September 30, 2013**

**CONSOLIDATED NET REVENUES**

The table below shows the amount of total net product revenues (dollars in thousands) generated by each of our business segments and net revenues from licensing and product development activities for the three months ended September 30, 2014 and 2013.

| | Three Months Ended September 30, | | | | |
|---|---|---|---|---|---|
| | Dollars | | | Percentage of Total Net Revenues | |
| | 2014 | 2013 | % Change | 2014 | 2013 |
| OSUR | $17,580 | $19,560 | (10)% | 63% | 79% |
| DNAG | 6,867 | 4,964 | 38 | 25 | 20 |
| Net product revenues | 24,447 | 24,524 | (0) | 88 | 99 |
| Licensing and product development | 3,398 | 147 | NM* | 12 | 1 |
| Net revenues | $27,845 | $24,671 | 13% | 100% | 100% |

* Calculation is not considered meaningful.

Consolidated net product revenues in the third quarters of 2014 and 2013 remained flat at $24.5 million. Higher sales of our molecular collection systems and OraQuick® HCV products were offset by lower sales of our OraQuick® professional HIV, cryosurgical systems, and OraQuick® In-Home HIV products. Licensing and product development revenues were $3.4 million in the third quarter of 2014 and represent the recognition of payments from AbbVie for exclusive promotion rights and certain services provided under our HCV collaboration agreement. Third quarter 2013 licensing and product development revenues of $147,000 represent royalties received on sales of Merck's OTC cryosurgical wart removal product, pursuant to a license and settlement agreement that expired in August 2013.

Consolidated net revenues derived from products sold to customers outside the U.S. were $5.4 million and $5.6 million, or 19% and 23% of total net revenues, in the third quarters of 2014 and 2013, 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 the amount of total net revenues (dollars in thousands) generated by our OSUR segment in each of our principal markets and by licensing and product development activities.

| | Three Months Ended September 30, | | | | |
|---|---|---|---|---|---|
| | Dollars | | | Percentage of Total Net Revenues | |
| Market | 2014 | 2013 | % Change | 2014 | 2013 |
| Infectious disease testing | $11,183 | $12,873 | (13)% | 53% | 65 % |
| Substance abuse testing | 2,149 | 2,092 | 3 | 10 | 10 |
| Cryosurgical systems | 3,241 | 3,649 | (11) | 16 | 19 |
| Insurance risk assessment | 1,007 | 946 | 6 | 5 | 5 |
| Net product revenues | 17,580 | 19,560 | (10) | 84 | 99 |
| Licensing and product development | 3,398 | 147 | NM* | 16 | 1 |
| Net revenues | $20,978 | $19,707 | 6% | 100% | 100 % |

* Calculation is not considered meaningful.

### Infectious Disease Testing Market

Sales to the infectious disease testing market decreased 13% to $11.2 million in the third quarter of 2014 from $12.9 million in the third quarter of 2013 primarily due to lower sales of our professional OraQuick® HIV product in both domestic and international markets and lower sales of our OraQuick® In-Home HIV test, partially offset by higher domestic sales of our OraQuick® HCV product.

The table below shows a breakdown of our total net OraQuick® revenues (dollars in thousands) during the third quarters of 2014 and 2013.

| | Three Months Ended September 30, | | |
|---|---|---|---|
| Market | 2014 | 2013 | % Change |
| Domestic HIV | $ 7,231 | $ 8,093 | (11)% |
| International HIV | 491 | 1,157 | (58) |
| Domestic OTC HIV | 1,368 | 1,762 | (22) |
| Net HIV revenues | 9,090 | 11,012 | (17) |
| Domestic HCV | 1,301 | 653 | 99 |
| International HCV | 470 | 924 | (49) |
| Net HCV revenues | 1,771 | 1,577 | 12 |
| Net OraQuick® revenues | $10,861 | $12,589 | (14)% |

Domestic OraQuick® HIV sales decreased 11% to $7.2 million for the three months ended September 30, 2014 from $8.1 million for the three months ended September 30, 2013. This decrease was primarily the result of some customer migration to automated 4th generation HIV immunoassays performed in a laboratory, as recommended under new 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 guidelines and by reductions in government funding. International sales of our OraQuick® HIV test during the third quarter of 2014 decreased 58% to $491,000 from $1.2 million primarily due to the timing of product shipments in support of a significant African testing program.

During the third quarter of 2014, we recorded $1.5 million in gross revenues from sales of our OraQuick® In-Home HIV test. These revenues were partially offset by $177,000 in customer allowances, including cooperative advertising, cash discounts, and other allowances, which were netted against gross revenues in accordance with U.S. generally accepted accounting principles. Thus, net revenues from this product were $1.4 million for the third quarter of 2014 as compared to net revenues of $1.8 million in the second quarter of 2013 ($1.9 million in gross revenues, partially offset by $172,000 of allowances and discounts).

OraQuick® In-Home HIV revenues recorded in the current and prior year periods are not readily comparable due to the December 2013 change in our revenue recognition policy related to this product. Since the product launch in late 2012, revenues had been recognized upon consummation of a purchase by consumers either in a store or over the internet. In December 2013, as a result of our growing experience with this product and improved ability to estimate potential product returns, we began recognizing revenues upon shipment of product to the retailers or distributors. Based on available point-of-sale data, consumer purchases of our OraQuick® In-Home HIV test in the third quarter were flat when compared to the same period of 2013.

Sales of our OraQuick® In-Home HIV test in the third quarters of 2014 and 2013 included approximately $48,000 and $217,000, respectively, of direct sales to public health customers. We anticipate that some public health entities may choose to use a portion of their funding to purchase our OTC product in lieu of professional rapid HIV testing products.

Domestic OraQuick® HCV sales increased 99% to $1.3 million in the third quarter of 2014 from $653,000 in the third quarter of 2013, primarily due to the addition of new HCV customers, including certain clinics operated by the U.S. Department of Veterans Affairs, and higher sales to current customers who have expanded their HCV testing programs. International OraQuick® HCV sales decreased 49% to $470,000 in the third quarter of 2014 from $924,000 in the third quarter of 2013, primarily as a result of lower sales to a multi-national humanitarian organization that purchased a large stocking order in the third quarter of 2013. We expect that purchases by this customer will continue at a reduced rate for the remainder of 2014.

We believe our OraQuick® HCV product represents an opportunity for future sales growth, especially as new therapies for treating HCV come to market. We also expect that sales of our HCV product will be positively impacted as we implement awareness and testing programs in collaboration 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.

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

**Substance Abuse Testing Market**

Sales to the substance abuse testing market increased 3% to $2.2 million in the third quarter of 2014 from $2.1 million in the third quarter of 2013, primarily as a result of higher sales of our Intercept® drug testing system. The table below shows a breakdown of our total net Intercept® revenues (dollars in thousands) generated in each market during the third quarters of 2014 and 2013.

| | Three Months Ended September 30, | | |
|---|---|---|---|
| Market | 2014 | 2013 | % Change |
| Domestic | $ 1,606 | $ 1,495 | 7% |
| International | 3 | 29 | (90) |
| Net Intercept® revenues | $ 1,609 | $ 1,524 | 6% |

Domestic Intercept® sales for the third quarter of 2014 increased to $1.6 million compared to $1.5 million for the third quarter of 2013 largely due to the recovery of customers that were previously lost to competition. A new version of our Intercept® collection device, known as the I2 collection device, was commercially launched into the U.S. criminal justice and forensic toxicology markets and into certain international markets.

**Cryosurgical Systems Market**

Sales of our cryosurgical systems products (which includes both the physicians' office and OTC markets) decreased 11% to $3.2 million in the third quarter of 2014, compared to $3.6 million in the same period of the prior year.

The table below shows a breakdown of our total net cryosurgical systems revenues (dollars in thousands) generated in each market during the third quarters of 2014 and 2013.

| | Three Months Ended September 30, | | |
|---|---|---|---|
| Market | 2014 | 2013 | % Change |
| Domestic professional | $ 1,590 | $ 1,803 | (12)% |
| International professional | 43 | 435 | (90) |
| International OTC | 1,608 | 1,411 | 14 |
| Net cryosurgical systems revenues | $ 3,241 | $ 3,649 | (11)% |

Sales of our Histofreezer® product to physicians' offices in the United States decreased 12% to $1.6 million in the third quarter of 2014 from $1.8 million in the third quarter of 2013 largely due to the merger of two of our large distributors who began selling a private label cryosurgical product in direct competition with our Histofreezer® product. International sales of Histofreezer® decreased to $43,000 in the third quarter of 2014 compared to $435,000 in the same period of the prior year, primarily due to delivery problems and inventory shortages associated with the transition to a new manufacturer of our international Histofreezer® product and the introduction of a new competing product. Our long-term supply agreement for the Histofreezer® product with Koninklijke Utermöhlen, N.V., the party from whom we acquired the Histofreezer® business in 1998, terminated in late 2013, and Utermöhlen began promoting a competing product similar to Histofreezer®. In order to remain competitive with this new product, we have decreased the per unit sales price of our Histofreezer® product in certain international markets and we are transitioning the manufacturer of this product to a new supplier. While we expect the delivery problems and inventory shortages to be corrected in the fourth quarter of 2014, we expect the competing product from Utermöhlen will adversely affect revenues generated from our cryosurgical systems business.

Sales of our OTC cryosurgical products during the third quarter of 2014 increased 14% to $1.6 million compared to $1.4 million in the third quarter of 2013, largely due to higher sales to our European distributor, Reckitt Benckiser, partially offset by lower sales to our Latin American distributor, Genomma.

Current quarter sales to Reckitt Benckiser increased to $1.0 million, compared to $606,000 during the third quarter of 2013, primarily due to customer ordering patterns. Sales to Genomma decreased to $531,000 in the third quarter of 2014 from $754,000 in the third quarter of 2013, also due to customer ordering patterns.

**Insurance Risk Assessment Market**

Sales to the insurance risk assessment market increased slightly to $1.0 million in the third quarter of 2014 from $946,000 in the third quarter of 2013, as a result of the timing of orders by one of our large laboratory customers.

**Licensing and Product Development**

Licensing and product development revenues in the third quarter of 2014 were $3.4 million and represent the ratable recognition of revenues received for exclusive promotion rights and certain other services provided under our HCV collaboration agreement with AbbVie. Licensing and product development revenues in the third quarter of 2013 were $147,000 and represent royalties paid on domestic outsales of Merck's OTC cryosurgical wart removal product, pursuant to a license and settlement agreement that expired in August 2013.

*DNAG Segment*

**Molecular Collection Systems**

Net molecular collection systems revenues, which primarily represent sales of our Oragene® product line, increased 38% to $6.9 million in the third quarter of 2014 from $5.0 million in the third quarter of 2013. Sales of Oragene® in the commercial market increased 16%, which was primarily due to higher sales to commercial customers specializing in pharmacogenomic testing. Sales of Oragene® in the academic market increased 84% largely due to orders placed by two new international customers as well as higher sales to one of the Company's larger existing academic customers.

## CONSOLIDATED OPERATING RESULTS

Consolidated gross margin was 67% for the third quarter of 2014 compared to 61% for the third quarter of 2013. Gross margin for the third quarter of 2013 increased primarily due to the $3.4 million of licensing and product development revenues associated with our AbbVie collaboration, as well as a more favorable product mix driven largely by increased DNAG sales to higher margin customers.

Consolidated operating income for the third quarter of 2014 was $882,000, a $3.0 million improvement from the $2.1 million operating loss reported in the third quarter of 2013. The improvement in operating income was primarily the result of the $3.4 million of licensing and product development revenues recorded in the third quarter of 2014.

## OPERATING INCOME (LOSS) BY SEGMENT

*OSUR Segment*

OSUR's gross margin was 65% in the third quarter of 2014 compared to 58% in the third quarter of 2013. OSUR's 2014 margin was positively impacted by the higher licensing and product development revenues.

Research and development expenses increased 15% to $2.3 million in the third quarter of 2014 from $2.0 million in the third quarter of 2013 largely due to higher laboratory supply costs. Sales and marketing expenses remained relatively flat at $7.3 million in the third quarter of 2014 compared to $7.4 million in the third quarter of 2013. The decrease in advertising and promotional costs for our OraQuick® In-Home HIV test which totaled $280,000 in the third quarter of 2014, compared to $1.9 million in third quarter of 2013, was offset by an increase in sales and marketing costs associated with our OraQuick® HCV co-promotion agreement with AbbVie. General and administrative expenses increased 7% to $4.9 million in the third quarter of 2014 from $4.6 million in the third quarter of 2013 due to higher legal expenses and consulting costs.

All of the above contributed to OSUR's third quarter 2014 operating loss of $987,000, which included non-cash charges of $820,000 for depreciation and amortization and $1.3 million for stock-based compensation.

*DNAG Segment*

DNAG's gross margin was 75% in the third quarter of 2014 compared to 70% in the third quarter of 2013. This improvement was directly attributable to an increased volume of higher margin sales experienced in the third quarter of 2014 when compared to the third quarter of 2013.

DNAG operating expenses rose to $3.3 million in the third quarter of 2014 from $3.0 million in the third quarter of 2013. Research and development expenses remained relatively flat at $650,000 in the third quarter of 2014 compared to $631,000 in the third quarter of 2013. Sales and marketing expenses increased 16% to $1.9 million in the third quarter of 2014 from $1.6 million in the third quarter of 2013 due to higher staffing costs. General and administrative expenses decreased 7% to $724,000 in the third quarter of 2014 compared to $775,000 in the third quarter of 2013, largely due to a decrease in legal fees partially offset by higher staffing costs.

All of the above contributed to DNAG's third quarter 2014 operating income of $1.9 million, which included non-cash charges of $804,000 for depreciation and amortization and $112,000 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 or loss in the third quarter of 2014 or 2013, respectively. Canadian income tax expense of $10,000 was recorded in the third quarter of 2014. A Canadian income tax benefit of $127,000 was recorded in the third quarter of 2013, which was associated with certain Canadian research and development and investment tax credits and DNAG's loss before income taxes. The Canadian income tax benefits are considered realizable based upon the scheduled reversal of the deferred tax liabilities recorded in connection with the acquisition of DNAG.

**Nine months ended September 30, 2014 compared to September 30, 2013**

## CONSOLIDATED NET REVENUES

The table below shows the amount of total net product revenues (dollars in thousands) generated by each of our business segments and net revenues from licensing and product development activities for the nine months ended September 30, 2014 and 2013.

| | Nine Months Ended September 30, | | | | |
|---|---|---|---|---|---|
| | Dollars | | | Percentage of Total Net Revenues | |
| | 2014 | 2013 | % Change | 2014 | 2013 |
| OSUR | $56,087 | $55,999 | — % | 72% | 80% |
| DNAG | 17,523 | 13,550 | 29 | 23 | 19 |
| Net product revenues | 73,610 | 69,549 | 6 | 95 | 99 |
| Licensing and product development | 4,173 | 623 | 570 | 5 | 1 |
| Net revenues | $77,783 | $70,172 | 11% | 100% | 100% |

Consolidated net product revenues increased 6% to $73.6 million in the first nine months of 2014 from $69.5 million in the comparable period of 2013, primarily as a result of higher sales of our molecular collection systems, OraQuick® HCV, and cryosurgical systems products. These increases were partially offset by lower sales of our professional OraQuick® HIV, substance abuse and insurance risk assessment products. Licensing and product development revenues were $4.2 million in the first nine months of 2014 and represent the recognition of payments from AbbVie for exclusive promotion rights and certain services provided under our HCV collaboration agreement. Licensing and product development revenues were $623,000 in the first nine months of 2013 and represent royalties received on sales of Merck's OTC cryosurgical wart removal product, pursuant to a license and settlement agreement that expired in August 2013.

Consolidated net revenues derived from products sold to customers outside the U.S. were $18.8 million and $16.1 million, or 24% and 23% of total net revenues, during the nine months ended September 30, 2014 and 2013, 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 the amount of total net revenues (dollars in thousands) generated by our OSUR segment in each of our principal markets and by licensing and product development activities.

| | Nine Months Ended September 30, | | | | |
|---|---|---|---|---|---|
| | Dollars | | | Percentage of Total Net Revenues | |
| Market | 2014 | 2013 | % | 2014 | 2013 |
| Infectious disease testing | $34,914 | $35,526 | (2)% | 58% | 63% |
| Substance abuse testing | 6,187 | 6,455 | (4) | 10 | 11 |
| Cryosurgical systems | 12,128 | 10,910 | 11 | 20 | 19 |
| Insurance risk assessment | 2,858 | 3,108 | (8) | 5 | 6 |
| Net product revenues | 56,087 | 55,999 | 0% | 93 | 99% |
| Licensing and product development | 4,173 | 623 | 570 | 7 | 1 |
| Net revenues | $60,260 | $56,622 | 6% | 100% | 100% |

### Infectious Disease Testing Market

Sales to the infectious disease testing market decreased 2% to $34.9 million in the first nine months of 2014 from $35.5 million in the first nine months of 2013, primarily due to lower sales of our OraQuick® HIV professional product and OraQuick® In-Home HIV test, partially offset by higher sales of our OraQuick® HCV product.

The table below shows a breakdown of our total net OraQuick® revenues (dollars in thousands) during the nine months ended September 30, 2014 and 2013.

| | Nine Months Ended September 30, | | |
|---|---|---|---|
| Market | 2014 | 2013 | % Change |
| Domestic HIV | $21,568 | $23,854 | (10)% |
| International HIV | 1,897 | 2,457 | (23) |
| Domestic OTC HIV | 4,991 | 5,196 | (4) |
| Net HIV revenues | 28,456 | 31,507 | (10) |
| Domestic HCV | 3,183 | 1,772 | 80 |
| International HCV | 2,341 | 1,409 | 66 |
| Net HCV revenues | 5,524 | 3,181 | 74 |
| Net OraQuick® revenues | $33,980 | $34,688 | (2)% |

Domestic OraQuick® HIV sales decreased 10% to $21.6 million for the nine months ended September 30, 2014 from $23.9 million for the nine months ended September 30, 2013. This decrease was primarily the result of some customer migration to automated 4th generation HIV immunoassays performed in a laboratory, as recommended under new 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 guidelines and by reductions in government funding. International sales of our OraQuick® HIV test during the first nine months of 2014 decreased 23% to $1.9 million from $2.5 million in the first nine months of 2013 largely due to decreased order volume related to project work in Africa.

During the first nine months of 2014, we recorded $5.6 million in gross revenues from sales of our OraQuick® In-Home HIV test. These revenues were partially offset by $584,000 in customer allowances, including cooperative advertising, cash discounts, and other allowances, which were netted against gross revenues in accordance with U.S. generally accepted accounting principles. Thus, net revenues from this product were $5.0 million for the first nine months of 2014 as compared to net revenues of $5.2 million in the first nine months of 2013 ($5.6 million in gross revenues, partially offset by $415,000 of allowances and discounts).

OraQuick® In-Home HIV revenues recorded in the current and prior year periods are not readily comparable due to the December 2013 change in our revenue recognition policy related to this product. Since the product launch in late 2012, revenues had been recognized upon consummation of a purchase by consumers either in a store or over the internet. In December 2013, as a result of our growing experience with this product and improved ability to estimate potential product returns, we began recognizing revenues upon shipment of product to the retailers or distributors. Based on available point-of-sale data, consumer purchases increased 6% in the first nine months of 2014 as compared to the first nine months of 2013 due to increased awareness about the product.

Sales of our OraQuick® In-Home HIV test in the first nine months of 2014 and 2013 included approximately $299,000 and $600,000, respectively, of direct sales to public health customers. We anticipate that some public health entities may choose to use a portion of their funding to purchase our OTC product in lieu of professional rapid HIV testing products.

Domestic OraQuick® HCV sales increased 80% to $3.2 million in the first nine months of 2014 from $1.8 million in the first nine months of 2013, primarily due to the addition of new HCV customers and higher sales to current customers who have expanded their HCV testing programs. International OraQuick® HCV sales increased 66% to $2.3 million in the first nine months of 2014 from $1.4 million in the first nine months of 2013, primarily as a result of purchases by a multi-national humanitarian organization which first began purchasing product in the third quarter of 2013. We expect that purchases by this customer will be at a reduced rate for the remainder of 2014. Also contributing to the increase in international sales is higher sales into certain Asian markets.

We believe our OraQuick® HCV product represents an opportunity for future sales growth, especially as new therapies for treating HCV come to market. We also expect that sales of our HCV product will be positively impacted as we implement awareness and testing programs 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.

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

**Substance Abuse Testing Market**

Sales to the substance abuse testing market decreased 4% to $6.2 million in the first nine months of 2014 from $6.5 million in the first nine months of 2013, primarily as a result of lower sales of our Intercept® drug testing system. The table below shows a breakdown of our total net Intercept® revenues (dollars in thousands) generated in each market during the nine months ended September 30, 2014 and 2013.

| Market | Nine Months Ended September 30, 2014 | 2013 | % Change |
|---|---|---|---|
| Domestic | $ 4,473 | $ 4,240 | 5% |
| International | 76 | 385 | (80) |
| Net Intercept® revenues | $ 4,549 | $ 4,625 | (2)% |

Domestic Intercept® sales for the first nine months of 2014 increased to $4.5 million compared to $4.2 million for the first nine months of 2013, primarily due to increased interest in oral fluid testing by customers who previously used alternative specimen types for drug testing. In addition, we added several new larger accounts. International Intercept® sales decreased 80% to $76,000 in the first nine months of 2014 from $385,000 in 2013 largely due the discontinuance of purchases by our UK distributor who in 2012 began selling its own competing oral specimen collection device. Sales to this distributor were $286,000 in the first nine months of 2013.

**Cryosurgical Systems Market**

Sales of our cryosurgical systems products (which includes both the physicians' office and OTC markets) increased 11% to $12.1 million in the first nine months of 2014, compared to $10.9 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 nine months ended September 30, 2014 and 2013.

| Market | Nine Months Ended September 30, 2014 | 2013 | % Change |
|---|---|---|---|
| Domestic professional | $ 4,601 | $ 4,192 | 10% |
| International professional | 581 | 1,039 | (44) |
| International OTC | 6,946 | 5,679 | 22 |
| Net cryosurgical systems revenues | $ 12,128 | $ 10,910 | 11% |

Sales of our Histofreezer® product to physicians' offices in the United States increased 10% to $4.6 million in the first nine months of 2014, compared to $4.2 million in the first nine months of 2013. This increase is largely due to market share gained by two of our larger distributors and the introduction of our product into a new market segment. These increases were partially offset by the impact of the merger of our two largest distributors who began selling a private label cryosurgical product in direct competition with our Histofreezer® product, as well as a decrease in sales to our Canadian distributor due to delivery issues associated with our transition to a new Histofreezer® manufacturer.

During the first nine months of 2014, international sales of Histofreezer® decreased to $581,000, compared to $1.0 million in the same period of the prior year. Our long-term supply agreement for the Histofreezer® product with Koninklijke Utermöhlen, N.V., the party from whom we acquired the Histofreezer® business in 1998, terminated in late 2013, and Utermöhlen began promoting a competing product similar to Histofreezer®. In order to remain competitive with this new product, we have decreased the per unit sales price of our Histofreezer® product in certain international markets. In addition, we have experienced delivery problems and inventory shortages as we transitioned to a new manufacturer of our international Histofreezer® product. While we expect the delivery problems and inventory shortage to be corrected in the fourth quarter of 2014 we expect the competing product from Utermöhlen will adversely affect revenues generated from our cryosurgical systems business.

Sales of our OTC cryosurgical products during the first nine months of 2014 increased 22% to $6.9 million compared to $5.7 million in the first nine months of 2013, largely due to higher sales to our European distributor, Reckitt Benckiser.

Sales to Reckitt Benckiser increased to $4.1 million, compared to $2.8 million during the first nine month of 2013, primarily due to the launch of our product into new geographic territories and new market segments. Sales to Genomma, our Latin American distributor, remained flat at $2.7 million in the first nine months of 2014 and 2013.

**Insurance Risk Assessment Market**

Sales to the insurance risk assessment market decreased 8% to $2.9 million in the first nine months of 2014 from $3.1 million in the first nine months of 2013, as a result of continued reduced demand in the domestic life insurance market, as well as the adoption by some underwriters of a “Simplified Issues” policy, pursuant to which testing for risk factors is replaced by having applicants respond to a questionnaire about their behaviors.

**Licensing and Product Development**

Licensing and product development revenues were $4.2 million in the first nine months of 2014 and represent the ratable recognition of revenues received for exclusive promotion rights and certain other services provided under our HCV collaboration with AbbVie. Licensing and product development revenues in 2013 were $623,000 and represent royalties paid on domestic outsales of Merck’s OTC cryosurgical wart removal product, pursuant to a license and settlement agreement which expired in August 2013.

***DNAG Segment***

**Molecular Collection Systems**

Net molecular collection systems revenues, which primarily represent sales of our Oragene® product line, increased 29% to $17.5 million in the first nine months of 2014 from $13.6 million in the first nine months of 2013. Sales of Oragene® in the commercial market increased approximately 25% in the first nine months of 2014 primarily as a result of overall market growth and more specifically, increased use of our Oragene® product in pharmacogenomics testing. Sales of Oragene® in the academic market increased 42% largely due to orders placed by two new international customers as well as higher sales to one of the Company’s larger existing academic customers.

**CONSOLIDATED OPERATING RESULTS**

Consolidated gross margin was 63% for the first nine months of 2014 compared to 59% for the first nine months of 2013. Gross margin for the third quarter of 2014 increased primarily because of the $3.4 million of licensing and product development revenues associated with our AbbVie collaboration, as well as a more favorable product mix driven largely by increased DNAG sales to higher margin customers.

Consolidated operating loss for the first nine months of 2014 was $2.2 million, a $16.0 million improvement from the $18.2 million operating loss reported in the first nine months of 2013. The operating results for the third quarter of 2014 include a $5.5 million payment received under the terms of the termination of our drug assay collaboration with Roche Diagnostics. Also contributing to this improvement in operating loss were higher licensing and product development revenues, higher product revenues and lower HIV OTC sales and marketing costs during the first nine months of 2014.

## OPERATING INCOME (LOSS) BY SEGMENT

***OSUR Segment***

OSUR's gross margin was 60% in the first nine months of 2014 compared to 57% in the first nine months of 2013. OSUR's 2014 margin was positively impacted by the higher licensing and product development revenues recorded during the third quarter of 2014.

Research and development expenses decreased 7% to $6.3 million in the first nine months of 2014 from $6.8 million in the first nine months of 2013 largely due to lower clinical trial and staffing costs. Sales and marketing expenses decreased 16% to $25.3 million in the first nine months of 2014 from $30.1 million in the first nine months of 2013. This decrease was primarily the result of lower advertising and promotional costs for our OraQuick® In-Home HIV test which totaled $7.7 million in the first nine months of 2014, as compared to $14.2 million in the first nine months of 2013. This reduction was the result of our decision to focus our marketing and promotional efforts at the retail outlet level and transition away from broad-based consumer advertising by June 30, 2014. The decrease in advertising and promotional costs were partially offset by higher sales and marketing costs associated with our OraQuick® HCV co-promotion agreement with AbbVie. General and administrative expenses increased 11% to $15.0 million in the first nine months of 2014 from $13.5 million in the first nine months of 2013 due to higher legal, staffing and consulting expenses.

All of the above, along with the $5.5 million favorable payment from Roche, contributed to OSUR's operating loss of $5.2 million for the first nine months of 2014, which included non-cash charges of $2.4 million for depreciation and amortization and $4.0 million for stock-based compensation.

***DNAG Segment***

DNAG's gross margin was 73% in the first nine months of 2014 compared to 67% in the first nine months of 2013. This improvement was directly attributable to an increased volume of higher margin sales experienced in the first nine months of 2014 when compared to the same period in 2013.

DNAG operating expenses rose to $9.8 million in the first nine months of 2014 from $9.3 million in the first nine months of 2013. Research and development expenses remained relatively flat at $1.9 million in the first nine months of 2014 and 2013. Sales and marketing expenses increased 9% to $5.6 million in the first nine months of 2014 from $5.1 million in the first nine months of 2013 largely due to higher staffing and consulting costs. General and administrative expenses remained relatively flat at $2.3 million in 2014 and 2013.

All of the above contributed to DNAG's operating income of $2.9 million for the first nine months of 2014, which included non-cash charges of $2.4 million for depreciation and amortization and $318,000 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 benefit was recorded for OSUR's pre-tax loss in the first nine months of 2014 or 2013. For the nine months ended September 30, 2014 and 2013, we recorded Canadian income tax benefits of $33,000 and $786,000, respectively, associated with certain Canadian research and development and investment tax credits and for the 2013 period, DNAG's loss before income taxes. The Canadian income tax benefits are considered realizable based upon the scheduled reversal of the deferred tax liabilities recorded in connection with the acquisition of DNAG.

**Liquidity and Capital Resources**

| | September 30, 2014 | December 31, 2013 |
|---|---|---|
| | (In thousands) | |
| Cash | $ 93,855 | $ 93,191 |
| Short-term investments | 5,000 | — |
| Working capital | 104,794 | 100,590 |

Our cash and short-term investment balances increased to $98.9 million at September 30, 2014 from $93.2 million at December 31, 2013. Our working capital increased to $104.8 million at September 30, 2014 from $100.6 million at December 31, 2013.

During the first nine months of 2014, we generated $8.4 million in cash from our operating activities. Our net loss of $2.0 million was offset by non-cash stock-based compensation expense of $4.3 million and depreciation and amortization expense of $4.7 million. An increase in deferred revenue of $10.4 million also contributed to the cash generated in the quarter. The deferred revenue increase is related to the receipt of $15.0 million from AbbVie in July 2014 reduced by the amounts ratably recognized in revenue during the period. Also contributing to the increase in cash was a decrease in prepaid expenses and other current assets of $576,000. These increases in cash were partially offset by a $3.7 million decrease in accrued expenses and other liabilities associated with payment of our 2013 management incentive bonuses, royalty obligations, and certain year-end accruals, a $3.4 million increase in inventory associated with our OraQuick® HCV product, a $2.1 million increase in accounts receivable resulting from the timing of orders during the current quarter, and a $284,000 decrease in accounts payable.

We used a total of $7.3 million in investing activities during the first nine months of 2014 to purchase $9.4 million in short-term investments and $2.3 million to acquire property and equipment. These payments were offset by proceeds received from the maturities of short-term investments of $4.4 million.

Net cash used in financing activities was $93,000 for the nine months ended September 30, 2014, which resulted from the use of $639,000 for the repurchase of common stock related to the vesting of restricted shares, partially offset by $546,000 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, 2013 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, 2013. As of September 30, 2014, 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 2013 Annual Report on Form 10-K filed with the SEC. During the first nine months of 2014, there were no material changes in our critical accounting policies.

## Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

As of September 30, 2014, 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 7% of our total revenues for the nine months ended September 30, 2014. 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 September 30, 2014. Based on that evaluation, the Company’s management, including such officers, concluded that the Company’s disclosure controls and procedures were effective as of September 30, 2014 to provide reasonable assurance that material information required to be disclosed by the Company in the reports that we file or submit under the Securities Exchange Act of 1934 was accumulated and communicated to the Company’s management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure and was recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC.

(b) Changes in Internal Control Over Financial Reporting. There was no change in the Company’s internal control over financial reporting that occurred during the three months ended September 30, 2014 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

Employment Termination Claim

In August 2012, DNA Genotek Inc. (“DNAG”) received a Statement of Claim filed by a former employee with the Ontario Superior Court of Justice alleging, among other things, that DNAG had wrongfully terminated this individual and had breached the terms of his employment. DNAG was also alleged to have violated this individual’s rights under the Ontario Human Rights Code. The Statement of Claim sought to recover in excess of $500,000 CDN in damages from DNAG. A Statement of Defense denying the allegations was filed by DNAG in October 2012. In September 2014, the matter was settled in exchange for the payment of an immaterial amount by DNAG to the complainant.

### 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, 2013.

### Item 2. UNREGISTERED SALE OF EQUITY SECURITIES AND USE OF PROCEEDS

None

### Item 6. EXHIBITS

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

**SIGNATURES**

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

ORASURE TECHNOLOGIES, INC.

*/s/ Ronald H. Spair*

Date: November 7, 2014

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

*/s/ Mark L. Kuna*

Date: November 7, 2014

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

## EXHIBIT INDEX

| Exhibit | |
|---|---|
| 31.1 | Certification of Douglas A. Michels required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended. |
| 31.2 | Certification of Ronald H. Spair required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended. |
| 32.1 | Certification of Douglas A. Michels required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 32.2 | Certification of Ronald H. Spair required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101.INS | XBRL Instance Document |
| 101.SCH | XBRL Taxonomy Extension Schema Document |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.LAB | XBRL Taxonomy Extension Labels Linkbase Document |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document |

**Exhibit 31.1**

**Certification**

I, Douglas A. Michels, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 7, 2014

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

**Exhibit 31.2**

**Certification**

I, Ronald H. Spair, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 7, 2014

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

**Exhibit 32.1**

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

In connection with the Quarterly Report of OraSure Technologies, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2014 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Douglas A. Michels, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

*/s/ Douglas A. Michels*

Douglas A. Michels
President and Chief Executive Officer

November 7, 2014

**Exhibit 32.2**

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

In connection with the Quarterly Report of OraSure Technologies, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2014 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ronald H. Spair, Chief Operating Officer and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

*/s/ Ronald H. Spair*

Ronald H. Spair
Chief Operating Officer and
Chief Financial Officer

November 7, 2014