ORASURE TECHNOLOGIES INC
Form 10-Q
May 08, 2014
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**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

# FORM 10-Q

**(Mark One)**

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

**For the quarterly period ended March 31, 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 x 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 x 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 x |
| 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 x

Number of shares of Common Stock, par value $.000001 per share, outstanding as of May 5, 2014: 55,841,785 shares.

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## PART I. FINANCIAL INFORMATION

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**Item 1. FINANCIAL STATEMENTS**

**ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES**

**CONSOLIDATED BALANCE SHEETS**

**(Unaudited)**

**(in thousands, except per share amounts)**

| | MARCH 31, 2014 | DECEMBER 31, 2013 |
|---|---|---|
| **ASSETS** | | |
| CURRENT ASSETS: | | |
| Cash | $ 84,193 | $ 93,191 |
| Accounts receivable, net of allowance for doubtful accounts of $284 and $299 | 13,287 | 12,957 |
| Inventories | 11,994 | 11,444 |
| Prepaid expenses | 2,016 | 1,712 |
| Deferred income taxes | 68 | 71 |
| Other current assets | 197 | 200 |
| Total current assets | 111,755 | 119,575 |
| PROPERTY AND EQUIPMENT, net | 17,826 | 17,933 |
| INTANGIBLE ASSETS, net | 20,659 | 22,226 |
| GOODWILL | 22,860 | 23,782 |
| OTHER ASSETS | 980 | 729 |
| | $ 174,080 | $ 184,245 |
| **LIABILITIES AND STOCKHOLDERS EQUITY** | | |
| CURRENT LIABILITIES: | | |
| Accounts payable | $ 4,114 | $ 4,834 |
| Deferred revenue | 954 | 1,119 |
| Accrued expenses | 9,902 | 13,032 |
| Total current liabilities | 14,970 | 18,985 |
| OTHER LIABILITIES | 961 | 677 |
| DEFERRED INCOME TAXES | 3,435 | 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, 55,842 and 55,632 shares issued and outstanding | | | | |
| Additional paid-in capital | | 339,651 | | 338,674 |
| Accumulated other comprehensive loss | | (5,575) | | (3,797) |
| Accumulated deficit | | (179,362) | | (173,731) |
| Total stockholders equity | | 154,714 | | 161,146 |
| | $ | 174,080 | $ | 184,245 |

See accompanying notes to the consolidated financial statements.

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**ORASURE TECHNOLOGIES, INC. AND SUBIDIARIES**

**CONSOLIDATED STATEMENTS OF OPERATIONS**

**(Unaudited)**

**(in thousands, except per share amounts)**

| | Three Months ended March 31, | |
|---|---|---|
| | 2014 | 2013 |
| NET REVENUES: | | |
| Product | $ 23,537 | $ 20,962 |
| Licensing and product development | | 202 |
| | 23,537 | 21,164 |
| COST OF PRODUCTS SOLD | 9,610 | 9,135 |
| Gross profit | 13,927 | 12,029 |
| OPERATING EXPENSES: | | |
| Research and development | 2,481 | 3,357 |
| Sales and marketing | 11,340 | 13,874 |
| General and administrative | 5,724 | 5,387 |
| | 19,545 | 22,618 |
| Operating loss | (5,618) | (10,589) |
| OTHER INCOME (EXPENSE) | 118 | (47) |
| Loss before income taxes | (5,500) | (10,636) |
| INCOME TAX EXPENSE (BENEFIT) | 131 | (410) |
| NET LOSS | $ (5,631) | $ (10,226) |
| LOSS PER SHARE: | | |
| BASIC | $ (0.10) | $ (0.18) |
| DILUTED | $ (0.10) | $ (0.18) |
| SHARES USED IN COMPUTING LOSS PER SHARE: | | |
| BASIC | 55,762 | 55,449 |
| DILUTED | 55,762 | 55,449 |

See accompanying notes to the consolidated financial statements.

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**ORASURE TECHNOLOGIES, INC. AND SUBIDIARIES**

**CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

**(Unaudited)**

**(in thousands)**

| | Three Months Ended March 31, | |
|---|---|---|
| | 2014 | 2013 |
| NET LOSS | $ (5,631) | $ (10,226) |
| OTHER COMPEHENSIVE LOSS | | |
| Currency translation adjustments | (1,778) | (1,125) |
| Other comprehensive loss | (1,778) | (1,125) |
| COMPREHENSIVE LOSS | $ (7,409) | $ (11,351) |

See accompanying notes to the consolidated financial statements.

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**ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**(Unaudited)**

**(in thousands)**

| | Three Months Ended March 31, | |
|---|---|---|
| | 2014 | 2013 |
| OPERATING ACTIVITIES: | | |
| Net loss | $ (5,631) | $ (10,226) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Stock-based compensation | 1,406 | 1,394 |
| Depreciation and amortization | 1,539 | 1,602 |
| Deferred income taxes | 131 | (410) |
| Changes in assets and liabilities | | |
| Accounts receivable | (402) | 512 |
| Inventories | (586) | (312) |
| Prepaid expenses and other assets | (280) | (1,545) |
| Accounts payable | (683) | 2,263 |
| Deferred revenue | (153) | 37 |
| Accrued expenses and other liabilities | (3,009) | (989) |
| Net cash used in operating activities | (7,668) | (7,674) |
| INVESTING ACTIVITIES: | | |
| Purchases of property and equipment | (647) | (480) |
| Net cash used in investing activities | (647) | (480) |
| FINANCING ACTIVITIES: | | |
| Proceeds from exercise of stock options | 93 | 301 |
| Repurchase of common stock | (521) | (743) |
| Net cash used in financing activities | (428) | (442) |
| EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH | (255) | (16) |
| NET DECREASE IN CASH | (8,998) | (8,612) |
| CASH, BEGINNING OF PERIOD | 93,191 | 87,888 |
| CASH, END OF PERIOD | $ 84,193 | $ 79,276 |
| SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION: | | |
| Cash paid for: | | |

| | | |
|---|---|---|
| Income taxes | $ 40 | $ 27 |

See accompanying notes to the consolidated financial statements.

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**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 sold to retail pharmacies and mass merchandisers as well as 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 m 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 months ended March 31, 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.

*Fair Value of Financial Instruments.* As of March 31, 2014, the carrying values of cash, accounts receivable, accounts payable and accrued expenses approximate their respective fair values based on their short-term nature.

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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 highly compensated employees. The assets of the plan are held in the name of the Company at a third-party financial institution. Separate accounts are maintained for each participant to reflect the amounts deferred by the participant and all earnings and losses on those deferred amounts. The assets of the plan are held in mutual funds and Company stock. The fair value of the plan assets as of March 31, 2014 and December 31, 2013 was $1,111 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.

*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:

| | March 31, 2014 | December 31, 2013 |
|---|---|---|
| Raw materials | $ 6,815 | $ 6,700 |
| Work in process | 890 | 833 |
| Finished goods | 4,289 | 3,911 |
| | $ 11,994 | $ 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 March 31, 2014 and December 31, 2013 was $29,081 and $28,390, respectively.

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Intangible Assets. Intangible assets consist of the following:

| | Amortization Period (Years) | March 31, 2014 Gross | Accumulated Amortization | Net |
|---|---|---|---|---|
| Customer list | 10 | $ 11,338 | $ (2,866) | $ 8,472 |
| Patents and product rights | 3-10 | 10,449 | (7,601) | 2,848 |
| Acquired technology | 7 | 8,807 | (3,132) | 5,675 |
| Tradename | 15 | 4,346 | (759) | 3,587 |
| Non-compete agreements | 1-3 | 615 | (538) | 77 |
| | | $ 35,555 | $ (14,896) | $ 20,659 |

| | 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 values of the applicable reporting units with their aggregate carrying values, 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 annual impairment assessment as of July 31, 2013 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 performed our last quantitative impairment test for goodwill as of July 31, 2012 and determined there was no impairment. That quantitative assessment determined that our DNAG reporting unit had a fair value in excess of its carrying value (including goodwill of $25,179) of approximately 13%. We believe we have made reasonable estimates and assumptions to calculate the fair value of our reporting unit. If actual future results are not consistent with management s estimates and assumptions, we may have to take an impairment charge in the future related to our goodwill. Future impairment tests will continue to be performed annually in the fiscal third quarter, or sooner if a

triggering event occurs. As of March 31, 2014, we believe no indicators of impairment exist.

The change in goodwill from $23,782 as of December 31, 2013 to $22,860 as of March 31, 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

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recorded net of allowances for any discounts or rebates. Other than for our OraQuick® In-Home HIV tests, 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 we initially 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 quarter of 2014 were recorded based upon shipments into the distribution channel while revenues in the first quarter 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 statement 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.

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.

*Customer Sales Returns and Allowances.* We do not grant product return rights to our customers, 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 March 31, 2014 and December 31, 2013, the reserve for sales returns and allowances was $329 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.

*Deferred Revenue.* We record deferred revenue when funds are received prior to the recognition of the associated revenue. Deferred revenue at March 31, 2014 and December 31, 2013 included customer prepayments of $954 and $1,119, respectively.

*Customer and Vendor Concentrations*. One of our customers, Reckitt Benckiser, accounted for approximately 11% of our accounts receivable balance as of March 31, 2014. We had no significant concentrations in accounts receivable as of December 31, 2013. We had no significant concentrations (greater than 10%) in revenues for the three months ended March 31, 2014 or 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.

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*Loss Per Share*. Basic and diluted loss per share is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during the period. Diluted loss per share is generally computed assuming the exercise or vesting of all dilutive securities such as common stock options and unvested restricted stock. Common stock options and unvested restricted stock totaling 6,792 and 5,997 shares were outstanding as of March 31, 2014 and 2013, respectively. As a result of our net losses for the three months ended March 31, 2014 and 2013, these shares were excluded from the computation of diluted loss per share, as their inclusion would have been anti-dilutive.

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

Transaction gains and losses resulting from exchange rate changes on transactions denominated in currencies other than functional currency are included in 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 $1,778 and $1,125 currency translation adjustments recorded in the first three months of 2014 and 2013, respectively, are largely the result of the translation of our Canadian operation s financial statements into U.S. dollars.

**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 three months ended March 31, 2014 and 2013 was $719 and $662, respectively. Net cash proceeds from the exercise of stock options were $93 and $301 for the three months ended March 31, 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.

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The following table summarizes the stock option activity for the three months ended March 31, 2014:

| | Options |
|---|---|
| Outstanding on January 1, 2014 | 5,271 |
| Granted | 1,168 |
| Exercised | (22) |
| Expired | (319) |
| Forfeited | (70) |
| Outstanding on March 31, 2014 | 6,028 |

Compensation cost of $687 and $732 related to restricted shares was recognized during the three months ended March 31, 2014 and 2013, respectively. In connection with the vesting of restricted shares, during the three months ended March 31, 2014 and 2013, 89 and 106 shares, respectively, with aggregate values of $521 and $743, respectively, were withheld and retired in satisfaction of minimum tax withholding obligations.

The following table summarizes restricted stock award activity for the three months ended March 31, 2014:

| | Shares |
|---|---|
| Issued and unvested, January 1, 2014 | 653 |
| Granted | 403 |
| Vested | (276) |
| Forfeited | (16) |
| Issued and unvested, March 31, 2014 | 764 |

## 4. Accrued Expenses

| | March 31, 2014 | December 31, 2013 |
|---|---|---|
| Payroll and related benefits | $ 2,763 | $ 5,827 |
| Royalties | 4,813 | 4,374 |
| Professional fees | 733 | 749 |
| Other | 1,593 | 2,082 |
| | $ 9,902 | $ 13,032 |

## 5. Income Taxes

During the three months ended March 31, 2014, we recorded foreign deferred tax expense of $131. During the three months ended March 31, 2013, we recorded a foreign deferred tax benefit of $410. The foreign deferred tax benefit is

associated with certain Canadian research and development and investment tax credits and DNAG s loss before income taxes in 2013. The 2013 income tax benefit associated with DNAG was 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 March 31, 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 March 31, 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 months ended March 31, 2014 and 2013.

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**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 primarily 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, as well as, products 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.

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The following table summarizes segment information for the three months ended March 31, 2014 and 2013.

| | Three Months Ended March 31, | |
|---|---|---|
| | 2014 | 2013 |
| Net revenues: | | |
| OSUR | $ 17,778 | $ 17,232 |
| DNAG | 5,759 | 3,932 |
| Total | $ 23,537 | $ 21,164 |
| Operating income (loss): | | |
| OSUR | $ (6,394) | $ (10,040) |
| DNAG | 776 | (549) |
| Total | $ (5,618) | $ (10,589) |
| Depreciation and amortization: | | |
| OSUR | $ 776 | $ 777 |
| DNAG | 763 | 825 |
| Total | $ 1,539 | $ 1,602 |
| Capital expenditures: | | |
| OSUR | $ 439 | $ 243 |
| DNAG | 208 | 237 |
| Total | $ 647 | $ 480 |

| | March 31, 2014 | December 31, 2013 |
|---|---|---|
| Total assets: | | |
| OSUR | $ 122,675 | $ 130,848 |
| DNAG | 51,405 | 53,397 |
| Total | $ 174,080 | $ 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 March 31, | |
|---|---|---|
| | 2014 | 2013 |
| United States | $ 17,406 | $ 16,040 |
| Europe | 4,001 | 2,846 |

| | | |
|---|---|---|
| Other regions | 2,130 | 2,278 |
| | $ 23,537 | $ 21,164 |

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

| | March 31, 2014 | December 31, 2013 |
|---|---|---|
| United States | $ 16,729 | $ 16,925 |
| Canada | 1,069 | 975 |
| Other regions | 28 | 33 |
| | $ 17,826 | $ 17,933 |

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## 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 and other audit observations, 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; 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; 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 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.

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**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 sold to retail pharmacies and mass merchandisers and to consumers over the internet.

**Current Consolidated Financial Results**

During the three months ended March 31, 2014, our consolidated net revenues were $23.5 million compared to $21.2 million in the three months ended March 31, 2013. Net product revenues during the three months ended March 31, 2014 increased 12% when compared to the first three months of 2013, primarily due to higher sales of our Oragene®, OraQuick® HCV, cryosurgical systems and OraQuick® In-Home HIV products.

Our consolidated net loss for the three months ended March 31, 2014 was $5.6 million, or $0.10 per share, compared to a net loss of $10.2 million, or $0.18 per share, for the three months ended March 31, 2013.

Cash used in operating activities was $7.7 million in both the three months ended March 31, 2014 and 2013. As of March 31, 2014, we had $84.2 million in cash 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, and 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.

In 2011, President Obama signed into law the Budget Control Act of 2011, which was designed to reduce federal spending over the next 10 years by $2.5 trillion. Under that law, certain automatic cuts to discretionary, national defense and Medicare spending (often referred to as Federal sequestration) have become effective. We cannot predict whether Congress will attempt to suspend or restructure the automatic budget cuts or what other deficit reduction initiatives may be proposed by Congress. Although the full impact of sequestration is difficult to ascertain, the spending cuts implemented under this new law have adversely affected, and are expected to continue to adversely affect, our customers ability to purchase our products. In addition, other legislative or regulatory changes may be adopted which could adversely affect our ability to sell our current products or successfully develop and commercialize new products.

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**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 primarily 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 March 31, 2014 compared to March 31, 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 March 31, 2014 and 2013.

| | Three Months Ended March 31, | | | | |
|---|---|---|---|---|---|
| | Dollars | | | Percentage of Total Net Revenues | |
| | 2014 | 2013 | % Change | 2014 | 2013 |
| OSUR | $ 17,778 | $ 17,030 | 4% | 76% | 80% |
| DNAG | 5,759 | 3,932 | 46 | 24 | 19 |
| Net product revenues | 23,537 | 20,962 | 12 | 100 | 99 |
| Licensing and product development | | 202 | (100) | | 1 |
| Net revenues | $ 23,537 | $ 21,164 | 11% | 100% | 100% |

Consolidated net revenues increased 11% to $23.5 million in the first quarter of 2014 from $21.2 million in the comparable period of 2013, primarily as a result of higher sales of our molecular collection systems, cryosurgical systems, OraQuick® HCV and OraQuick® In-Home HIV products. These increases were partially offset by lower sales of our OraQuick® HIV product in the domestic professional market and our substance abuse testing and insurance risk assessment products, as well as the absence of licensing and product development revenues in the current quarter.

Consolidated net revenues derived from products sold to customers outside the U.S. were $6.1 million and $5.1 million, or 26% and 24% of total net revenues, in the first 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.

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## 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 March 31, | | | | |
|---|---|---|---|---|---|
| | Dollars | | | Percentage of Total Net Revenues | |
| **Market** | **2014** | **2013** | **% Change** | **2014** | **2013** |
| Infectious disease testing | $ 11,064 | $ 10,687 | 4% | 63% | 62% |
| Substance abuse testing | 1,830 | 2,249 | (19) | 10 | 13 |
| Cryosurgical systems | 3,967 | 3,085 | 29 | 22 | 18 |
| Insurance risk assessment | 917 | 1,009 | (9) | 5 | 6 |
| Net product revenues | 17,778 | 17,030 | 4 | 100 | 99 |
| Licensing and product development | | 202 | (100) | | 1 |
| Net revenues | $ 17,778 | $ 17,232 | 3% | 100% | 100% |

**Infectious Disease Testing Market**

Sales to the infectious disease testing market increased 4% to $11.1 million in the first quarter of 2014 from $10.7 million in the first quarter of 2013, primarily due to higher sales of both our OraQuick® HCV and OraQuick® In-Home HIV products.

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

| | Three Months Ended March 31, | | |
|---|---|---|---|
| **Market** | **2014** | **2013** | **% Change** |
| Domestic HIV | $ 6,618 | $ 7,672 | (14)% |
| International HIV | 558 | 554 | 1 |
| Domestic OTC HIV | 1,953 | 1,442 | 35 |
| Net HIV revenues | 9,129 | 9,668 | (6) |
| Domestic HCV | 663 | 428 | 55 |
| International HCV | 896 | 240 | 273 |
| Net HCV revenues | 1,559 | 668 | 133 |
| Net OraQuick® revenues | $ 10,688 | $ 10,336 | 3% |

Domestic OraQuick® HIV sales decreased 14% to $6.6 million for the three months ended March 31, 2014 from $7.7 million for the three months ended March 31, 2013. This decrease was primarily caused by delayed purchasing in certain jurisdictions resulting from an underlying delay in the release of funding by the federal government. We expect this funding delay should be resolved over the next few quarters. Also contributing to the lower domestic OraQuick® HIV sales were changes in customer ordering patterns and reduced testing as a result of the inclement winter weather experienced on the East Coast during the first quarter of 2014. Although we do not forsee any ongoing negative impact from inclement weather, we do anticipate that future sales of our professional HIV product may continue to be challenged by reductions in government funding and a shift to automated laboratory-based blood tests by certain customers.

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During the first quarter of 2014, we recorded $2.2 million in gross revenues from sales of our OraQuick® In-Home HIV test. These revenues were partially offset by $210,000 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 $2.0 million for the first quarter of 2014 as compared to net revenues of $1.4 million in the first quarter of 2013 ($1.5 million in gross revenues, partially offset by $109,000 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, we began recognizing revenues upon shipment of product to the retailers or distributors. Based on available point-of-sale data, consumer purchases increased 22% in the first quarter of 2014 as compared to the first quarter of 2013 due to increased awareness about the product.

Sales of our OraQuick® In-Home HIV test in both the first quarter of 2014 and 2013 included approximately $183,000 and $128,000, respectively, of direct sales to certain 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 55% to $663,000 in the first quarter of 2014 from $428,000 in the first quarter 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 273% to $896,000 in the first quarter of 2014 from $240,000 in the first quarter of 2013, primarily as a result of purchases by a multi-national humanitarian organization which did not occur during the first quarter of 2013. We believe our HCV product represents an opportunity for future sales growth, especially as new therapies for treating HCV come to market. However, demand for our HCV product, particularly in the public health marketplace, has been, and will likely continue to be, 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 19% to $1.8 million in the first quarter of 2014 from $2.2 million in the first quarter 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 first quarters of 2014 and 2013.

| | Three Months Ended March 31, | | |
|---|---|---|---|
| **Market** | **2014** | **2013** | **% Change** |
| Domestic | $ 1,250 | $ 1,404 | (11)% |
| International | 40 | 258 | (84) |

| | | | |
|---|---|---|---|
| Net Intercept® revenues | $ 1,290 | $ 1,662 | (22)% |

Domestic Intercept® sales for the first quarter of 2014 decreased slightly to $1.3 million compared to $1.4 million for the first quarter of 2013. First quarter 2013 revenues included $130,000 of equipment sales which did not repeat

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in the first quarter of 2014. International Intercept® sales decreased 84% to $40,000 in the first quarter of 2014 from $258,000 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 $237,000 in the first quarter of 2013.

**Cryosurgical Systems Market**

Sales of our cryosurgical systems products (which includes both the physicians office and OTC markets) increased 29% to $4.0 million in the first quarter of 2014, compared to $3.1 million in the same period of the prior year.

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

| | Three Months Ended March 31, | | |
|---|---|---|---|
| **Market** | **2014** | **2013** | **% Change** |
| Domestic professional | $ 1,542 | $ 891 | 73% |
| International professional | 310 | 348 | (11) |
| International OTC | 2,115 | 1,846 | 15 |
| Net cryosurgical systems revenues | $ 3,967 | $ 3,085 | 29% |

Sales of our Histofreezer® product to physicians offices in the United States increased 73% to $1.5 million in the first quarter of 2014, compared to $891,000 in the first quarter of 2013. This increase reflects below normal sales in the first quarter of 2013, resulting from higher distributor purchases in the fourth quarter of 2012 in advance of a price increase implemented in January 2013. During the first quarter of 2014, international sales of Histofreezer® decreased slightly to $310,000, compared to $348,000 in the same period of the prior year.

Sales of our OTC cryosurgical products during the first quarter of 2014 increased 15% to $2.1 million compared to $1.8 million in the first quarter of 2013, largely due to higher sales to our European distributor, Reckitt Benckiser. In the first quarter of 2014, sales to Reckitt Benckiser increased to $1.4 million, compared to $1.1 during the first quarter of 2013, primarily due to the launch of our product into new geographic territories and new market segments. Sales to our Latin American distributor, Genomma, decreased slightly to $709,000 in the first quarter of 2014 from $769,000 in the first quarter of 2013 due to customer ordering patterns.

**Insurance Risk Assessment Market**

Sales to the insurance risk assessment market decreased 9% to $917,000 in the first quarter of 2014 from $1.0 million in the first quarter of 2013, as a result of reduced demand in the domestic life insurance market, as well as the adoption by some underwriters of a Simplified Issues policy, pursuant to which lab-based testing is replaced by having applicants respond to a questionnaire about their behaviors.

**Licensing and Product Development**

We had no licensing and product development revenues in the first quarter of 2014. Licensing and product development revenues were $202,000 in the first quarter of 2013 and represented royalties paid on domestic outsales of Merck s OTC cryosurgical wart removal product, pursuant to a license and settlement agreement executed in January 2008. We stopped receiving royalties under this license when certain of our cryosurgical patents expired in

August 2013.

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*DNAG Segment*

**Molecular Collection Systems**

Net molecular collection systems revenues, which primarily represent sales of our Oragene® product line, increased 46% to $5.8 million in the first quarter of 2014 from $3.9 million in the first quarter of 2013. Sales of Oragene® in the commercial market increased approximately 83% in the first quarter of 2014 primarily as a result of higher sales to DNAG s largest commercial customer. Sales of Oragene® in the academic market increased 29% largely due to the timing of orders placed by one of DNAG s UK customers.

**CONSOLIDATED OPERATING RESULTS**

Consolidated gross margin was 59% for the first quarter of 2014 compared to 57% for the first quarter of 2013. Gross margin for the current quarter primarily benefited from improved overhead absorption due to the absence of production issues which negatively impacted overhead absorption in the first quarter of 2013 and a more favorable product mix driven largely by the increased DNAG sales.

Consolidated operating loss for the first quarter of 2014 was $5.6 million, a $5.0 million decrease from the $10.6 million operating loss reported in the first quarter of 2013. This improvement in operating loss resulted primarily from higher revenues and lower sales and marketing costs during the current quarter.

**OPERATING INCOME (LOSS) BY SEGMENT**

*OSUR Segment*

OSUR s gross margin was 55% in the first quarter of 2014 compared to 54% in the first quarter of 2013. OSUR s 2014 margin benefited from improved overhead absorption due to the absence of production issues which negatively impacted overhead absorption in the first quarter of 2013.

Research and development expenses decreased 33% to $1.8 million in the first quarter of 2014 from $2.7 million in the first quarter of 2013 largely due to lower clinical trial, supply, and staffing costs. Sales and marketing expenses decreased 21% to $9.5 million in the first quarter of 2014 from $12.1 million in the first quarter of 2013. This decrease was primarily the result of lower advertising and promotional costs for our OraQuick® In-Home HIV test which totaled $4.6 million in the first quarter of 2014, compared to $6.9 million in first quarter of 2013. This reduction was the result of a decision made in the second half of 2013 to narrow our marketing and promotional efforts to focus on increasing brand awareness among men who have sex with men and African American consumers. General and administrative expenses increased 6% to $4.9 million in the first quarter of 2014 from $4.6 million in the first quarter of 2013 due to an increase in consulting expenses.

All of the above contributed to OSUR s first quarter 2014 operating loss of $6.4 million, which included non-cash charges of $776,000 for depreciation and amortization and $1.3 million for stock-based compensation.

*DNAG Segment*

DNAG s gross margin was 71% in the first quarter of 2014 compared to 67% in the first quarter of 2013. This increase was directly attributable to increased volume of high margin sales experienced in the first quarter of 2014 when compared to the first quarter of 2013.

DNAG operating expenses increased to $3.3 million in the first quarter of 2014 from $3.2 million in the first quarter of 2013. Research and development expenses remained relatively flat at $659,000 in the first quarter of 2014 compared to $622,000 in the first quarter of 2013. Sales and marketing expenses were also flat at $1.8 million in both the first quarters of 2014 and 2013. General and administrative expenses increased 10% to $863,000 in the first quarter of 2014 from $785,000 in the first quarter of 2013 largely due to higher staffing related expenses.

All of the above contributed to DNAG s first quarter 2014 operating income of $776,000, which included non-cash charges of $763,000 for depreciation and amortization and $96,000 for stock-based compensation.

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**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 OraSure s pre-tax loss in the first quarter of 2014 or 2013. For the quarter ended March 31, 2014, we recorded Canadian income tax expense of $131,000. For the quarter ended March 31, 2013, we recorded a Canadian income tax benefit of $410,000 associated with the DNAG loss before income taxes and certain Canadian research and development and investment tax credits.

**Liquidity and Capital Resources**

| | March 31, 2014 | December 31, 2013 |
|---|---|---|
| | (In thousands) | |
| Cash | $ 84,193 | $ 93,191 |
| Working capital | 96,785 | 100,590 |

Our cash balances decreased $9.0 million to $84.2 million at March 31, 2014 from $93.2 million at December 31, 2013. Our working capital also decreased to $97.0 million at March 31, 2014 from $100.6 million at December 31, 2013.

During the first quarter of 2014, we used $7.7 million in cash to finance our operating activities. Our net loss of $5.6 million was partially offset by non-cash stock-based compensation expense of $1.4 million, depreciation and amortization expense of $1.5 million and deferred income tax expense of $131,000. Additional uses of cash in operating activities included a $3.0 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 $683,000 decrease in accounts payable associated with payment for year-end inventory purchases and advertising and marketing services, a $586,000 increase in inventory associated with our infectious disease products, a $402,000 increase in accounts receivable resulting from the increase in orders placed at the end of the current quarter, a $280,000 increase in prepaid expenses and a $153,000 increase in deferred revenues.

We used a total of $647,000 in investing activities during the first three months of 2014 to acquire property and equipment.

Net cash used in financing activities was $428,000 for the three months ended March 31, 2014, which resulted from the use of $521,000 for the repurchase of common stock related to the vesting of restricted shares, partially offset by $93,000 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 timing and amount of promotional costs for our products including our OraQuick® In-Home HIV test, 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 ongoing economic downturn and other

factors.

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**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 March 31, 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 three 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 March 31, 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 9.1% of our total revenues for the three months ended March 31, 2014 (including revenues from DNAG). 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 March 31, 2014. Based on that evaluation, the Company s management, including such officers, concluded that the Company s disclosure controls and procedures were adequate and effective as of March 31, 2014 to ensure that 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 March 31, 2014 that has materially affected, or is reasonably likely to materially affect, the Company s internal control over financial reporting.

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## PART II. OTHER INFORMATION

### 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

During the quarter ended March 31, 2014, pursuant to the OraSure Technologies, Inc. Stock Award Plan, and in connection with the vesting of restricted shares, we retired 88,906 shares of our common stock to satisfy minimum tax withholding obligations at an average price paid per share of $5.86.

### Item 6. EXHIBITS

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

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**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.

Date: May 8, 2014

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

Date: May 8, 2014

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

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## 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 |