

ORASURE TECHNOLOGIES INC  
Form 10-Q  
November 07, 2013  
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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, 2013.**

**OR**

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

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_.**

**Commission File Number 001-16537**

**ORASURE TECHNOLOGIES, INC.**

**(Exact Name of Registrant as Specified in Its Charter)**

**DELAWARE**  
**(State or Other Jurisdiction of**  
**Incorporation or Organization)**

**36-4370966**  
**(IRS Employer**  
**Identification No.)**

**220 East First Street, Bethlehem, Pennsylvania**  
**(Address of Principal Executive Offices)**  
**(610) 882-1820**

**18015**  
**(Zip code)**

**(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

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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, 2013:  
55,601,782 shares.

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**Table of Contents****Item 1. FINANCIAL STATEMENTS****ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS****(Unaudited)***(in thousands, except per share amounts)*

	SEPTEMBER 30, 2011	DECEMBER 31, 2012
<b>ASSETS</b>		
CURRENT ASSETS:		
Cash	\$ 82,590	\$ 87,888
Accounts receivable, net of allowance for doubtful accounts of \$282 and \$285	14,292	17,545
Inventories	12,000	12,758
Prepaid expenses	2,005	1,719
Other current assets	511	493
Total current assets	111,398	120,403
PROPERTY AND EQUIPMENT, net	17,989	18,546
INTANGIBLE ASSETS, net	23,701	27,207
GOODWILL	24,510	25,445
OTHER ASSETS	614	124
	\$ 178,212	\$ 191,725
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
CURRENT LIABILITIES:		
Accounts payable	\$ 3,859	\$ 3,380
Deferred revenue	4,472	5,580
Accrued expenses	10,995	7,960
Total current liabilities	19,326	16,920
OTHER LIABILITIES	539	89
DEFERRED INCOME TAXES	3,456	4,401

## 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, 55,602 and 55,281 shares issued and outstanding

Additional paid-in capital	337,210	333,522
Accumulated other comprehensive loss	(2,375)	(666)
Accumulated deficit	(179,944)	(162,541)

Total stockholders equity	154,891	170,315
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	\$	178,212	\$	191,725
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See accompanying notes to the consolidated financial statements.

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

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2013</b>	<b>2012</b>	<b>2013</b>	<b>2012</b>
<b>NET REVENUES:</b>				
Product	\$ 24,524	\$ 21,729	\$ 69,549	\$ 63,806
Licensing and product development	147	386	623	1,869
	24,671	22,115	70,172	65,675
<b>COST OF PRODUCTS SOLD</b>	<b>9,738</b>	<b>8,227</b>	<b>28,711</b>	<b>23,356</b>
Gross profit	14,933	13,888	41,461	42,319
<b>OPERATING EXPENSES:</b>				
Research and development	2,670	2,994	8,720	9,551
Sales and marketing	8,981	8,602	35,224	25,490
General and administrative	5,342	5,220	15,742	17,398
	16,993	16,816	59,686	52,439
Operating loss	(2,060)	(2,928)	(18,225)	(10,120)
<b>INTEREST EXPENSE</b>		(22)		(171)
<b>OTHER INCOME (EXPENSE)</b>	41	(12)	36	(96)
Loss before income taxes	(2,019)	(2,962)	(18,189)	(10,387)
<b>INCOME TAX BENEFIT</b>	(127)	(527)	(786)	(1,138)
<b>NET LOSS</b>	<b>\$ (1,892)</b>	<b>\$ (2,435)</b>	<b>\$ (17,403)</b>	<b>\$ (9,249)</b>
<b>LOSS PER SHARE:</b>				
<b>BASIC</b>	<b>\$ (0.03)</b>	<b>\$ (0.04)</b>	<b>\$ (0.31)</b>	<b>\$ (0.18)</b>
<b>DILUTED</b>	<b>\$ (0.03)</b>	<b>\$ (0.04)</b>	<b>\$ (0.31)</b>	<b>\$ (0.18)</b>

SHARES USED IN COMPUTING LOSS PER  
SHARE:

BASIC	55,592	54,441	55,534	50,177
DILUTED	55,592	54,441	55,534	50,177

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)*

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2013</b>	<b>2012</b>	<b>2013</b>	<b>2012</b>
NET LOSS	\$ (1,892)	\$ (2,435)	\$ (17,403)	\$ (9,249)
OTHER COMPREHENSIVE INCOME (LOSS)				
Currency translation adjustments	876	1,486	(1,709)	1,732
Other comprehensive income (loss)	876	1,486	(1,709)	1,732
COMPREHENSIVE LOSS	\$ (1,016)	\$ (949)	\$ (19,112)	\$ (7,517)

See accompanying notes to the consolidated financial statements.

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

	<b>Nine Months Ended September 30,</b>	
	<b>2013</b>	<b>2012</b>
<b>OPERATING ACTIVITIES:</b>		
Net loss	\$ (17,403)	\$ (9,249)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	4,187	3,845
Depreciation and amortization	4,846	5,455
Deferred income taxes	(786)	(1,138)
Inventory purchase accounting step-up adjustment		16
Changes in assets and liabilities		
Accounts receivable	3,127	(2,053)
Inventories	745	(3,222)
Prepaid expenses and other assets	(554)	92
Accounts payable	497	953
Deferred revenue	(1,098)	3,459
Accrued expenses and other liabilities	3,297	(2,164)
<b>Net cash used in operating activities</b>	<b>(3,142)</b>	<b>(4,006)</b>
<b>INVESTING ACTIVITIES:</b>		
Purchases of property and equipment	(1,696)	(1,402)
<b>Net cash used in investing activities</b>	<b>(1,696)</b>	<b>(1,402)</b>
<b>FINANCING ACTIVITIES:</b>		
Repayments of long-term debt		(7,292)
Proceeds from the issuance of common stock, net of expenses		70,292
Proceeds from exercise of stock options	317	9,457
Repurchase of common stock	(817)	(1,539)
<b>Net cash (used in) provided by financing activities</b>	<b>(500)</b>	<b>70,918</b>
<b>EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH</b>	<b>40</b>	<b>27</b>
<b>NET (DECREASE) INCREASE IN CASH</b>	<b>(5,298)</b>	<b>65,537</b>

CASH, BEGINNING OF PERIOD	87,888	23,878
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CASH, END OF PERIOD	\$ 82,590	\$ 89,415
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**SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:**

Cash paid for:

Interest	\$	\$ 199
Income taxes	\$ 28	\$ 20

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 manufacture and market 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. In September 2012, we began selling our 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 academic research, clinical genetic testing, 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 cryosurgical products are sold to retail pharmacies and mass merchandisers, and to consumers over the internet.

**2. Summary of Significant Accounting Policies**

Principles of Consolidation and Basis of Presentation. The consolidated financial statements include the accounts of OraSure Technologies, Inc. ( OraSure ) and its wholly-owned subsidiary, DNA Genotek, Inc. ( DNAG ). All intercompany transactions and balances have been eliminated. References herein to we, us, our, or the Company mean OraSure and its consolidated subsidiaries, unless otherwise indicated.

The accompanying consolidated financial statements are unaudited and, in the opinion of management, include all adjustments (consisting only of normal and recurring adjustments) necessary for a fair presentation of our financial position and results of operations for these interim periods. These financial statements should be read in conjunction with the financial statements and notes thereto included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2012. Results of operations for the three and nine months ended September 30, 2013 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 September 30, 2013, 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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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 that 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).

The Company offers a nonqualified Deferred Compensation Plan to 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 September 30, 2013 and December 31, 2012 was \$539 and \$89, 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:

	September 30, 2013	December 31, 2012
Raw materials	\$ 6,668	\$ 6,777
Work in process	471	393
Finished goods	4,861	5,588
	\$ 12,000	\$ 12,758

*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 removed 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, 2013 and December 31, 2012 was \$27,651 and \$25,846, respectively.

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Intangible Assets. Intangible assets consist of the following:

	<b>Amortization Period (Years)</b>	<b>Gross</b>	<b>September 30, 2013</b>		<b>Net</b>
			<b>Accumulated Amortization</b>		
Customer list	10	\$ 12,156	\$ (2,488)	\$	9,668
Patents and product rights	3-10	10,449	(7,331)		3,118
Acquired technology	7	9,442	(2,719)		6,723
Tradenname	15	4,659	(659)		4,000
Non-compete agreements	1-3	811	(619)		192
		\$ 37,517	\$ (13,816)	\$	23,701

	<b>Amortization Period (Years)</b>	<b>Gross</b>	<b>December 31, 2012</b>		<b>Net</b>
			<b>Accumulated Amortization</b>		
Customer list	10	\$ 12,619	\$ (1,673)	\$	10,946
Patents and product rights	3-10	10,449	(6,926)		3,523
Acquired technology	7	9,802	(1,829)		7,973
Tradenname	15	4,837	(443)		4,394
Non-compete agreements	1-3	842	(471)		371
		\$ 38,549	\$ (11,342)	\$	27,207

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 required. 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 most recent annual 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 September 30, 2013, we believe no indicators of impairment exist.

The change in goodwill from \$25,445 as of December 31, 2012 to \$24,510 as of September 30, 2013 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. We do not grant price protection or product return rights to our customers (other than for our OraQuick® In-Home HIV test, which we began to sell in the third quarter of 2012), except for warranty returns. Historically, returns arising from warranty issues have been infrequent and immaterial. Accordingly, we expense warranty returns as incurred.

Our revenue recognition practices with respect to the OraQuick® In-Home HIV test are 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 is a new product for which we do not have a historical record of returns, we do not believe we can reasonably determine a return rate at this time. As a result, we do not recognize revenue when we ship to the retail trade. For these product shipments, we invoice the retailer or distributor, record deferred revenue at gross invoice sales price, and classify the cost basis of the product held by the retailer or distributor as a component of inventory. We then recognize revenue upon the consummation of a sale by the retailer or distributor either in a store or over the internet. With the passage of time, however, we continue to gather information regarding retailer and distributor inventory levels and return practices as they relate to our OraQuick® In-Home HIV test. As such, we expect to change to a more traditional revenue recognition policy, under which revenue is recognized upon shipment to the retailers or distributors, once we believe we have a sufficient amount of this data to develop a reasonable estimate of the level of expected returns.

Our net revenues recorded on sales of the OraQuick® In-Home HIV test represent total gross revenue less customer allowances, including estimates for cooperative advertising, cash discounts and other allowances. These allowances are recorded as a reduction of gross revenue when recognized in our statement of operations. These allowances are established by management as our best estimate based on available information and are adjusted to reflect known changes in the factors that impact those estimates.

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.

*Deferred Revenue.* We record deferred revenue when funds are received prior to the recognition of the associated revenue and when shipments of our OraQuick® In-Home HIV test are made to the retailers or distributors who have product return rights. Deferred revenue as of September 30, 2013 and December 31, 2012 included customer prepayments of \$1,761 and \$1,880, respectively, as well as \$2,711 and \$3,700, respectively, related to the OraQuick® In-Home HIV test, representing the estimated value of product held by those retailers or distributors having product return rights.

*Customer and Vendor Concentrations.* We had no significant concentrations (greater than 10%) in accounts receivable as of September 30, 2013. At December 31, 2012, one of our customers, CVS Distribution, Inc., accounted for approximately 11% of our accounts receivable balances. We had no significant concentrations (greater than 10%) in revenues for the three or nine months ended September 30, 2013 or 2012.

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.

*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 5,890 and 5,437 shares were outstanding as of September 30, 2013 and 2012, respectively. As a result of our net losses for the three and nine months ended September 30, 2013 and 2012, these shares were excluded from the computation of diluted loss per share, as their inclusion would have been anti-dilutive.

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***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.

***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 (\$1,709) and \$1,732 currency translation adjustments recorded in the first nine months of 2013 and 2012, 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 nine months ended September 30, 2013 and 2012 was \$2,028 and \$1,682, respectively. Net cash proceeds from the exercise of stock options were \$317 and \$9,457 for the nine months ended September 30, 2013 and 2012, 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 \$2,159 and \$2,163 related to restricted shares was recognized during the nine months ended September 30, 2013 and 2012, respectively. In connection with the vesting of restricted shares, during the nine months ended September 30, 2013 and 2012, 122 and 139 shares, respectively, with aggregate values of \$817 and \$1,539, respectively, were withheld and retired in satisfaction of minimum tax withholding obligations.

#### *Public Equity Offering*

On July 11, 2012, we completed a public equity offering of 6,100 common shares, at a price of \$12.30 per share, raising \$75,030 before expenses of the offering. In connection with the offering, we paid \$4,502 in underwriting discounts and commissions and incurred \$236 in additional offering expenses.



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	September 30, 2013	December 31, 2012
Payroll and related benefits	\$ 4,823	\$ 4,248
Royalties	3,938	1,948
Professional fees	369	413
Other	1,865	1,351
	\$ 10,995	\$ 7,960

**5. Income Taxes**

During the three months ended September 30, 2013 and 2012, we recorded foreign deferred tax benefits of \$127 and \$527, respectively. During the nine months ended September 30, 2013 and 2012, we recorded foreign deferred tax benefits of \$786 and \$1,138, respectively. These foreign deferred tax benefits are associated with DNAG's loss before income taxes and certain Canadian research and development and investment tax credits. The income tax benefits associated with DNAG were 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, 2013 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, 2013 and December 31, 2012 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 months ended September 30, 2013 and 2012.

**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 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 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.

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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, 2013 and 2012.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
<b>Net revenues:</b>				
OSUR	\$ 19,707	\$ 18,762	\$ 56,622	\$ 55,683
DNAG	4,964	3,353	13,550	9,992
Total	\$ 24,671	\$ 22,115	\$ 70,172	\$ 65,675
<b>Operating income (loss):</b>				
OSUR	\$ (2,516)	\$ (2,156)	\$ (18,012)	\$ (7,442)
DNAG	456	(772)	(213)	(2,678)
Total	\$ (2,060)	\$ (2,928)	\$ (18,225)	\$ (10,120)
<b>Depreciation and amortization:</b>				
OSUR	\$ 815	\$ 798	\$ 2,389	\$ 2,595
DNAG	810	1,043	2,457	2,860
Total	\$ 1,625	\$ 1,841	\$ 4,846	\$ 5,455
<b>Capital expenditures:</b>				
OSUR	\$ 369	\$ 644	\$ 1,096	\$ 1,291
DNAG	235	28	600	111
Total	\$ 604	\$ 672	\$ 1,696	\$ 1,402

	September 30, 2013	December 31, 2012
<b>Total assets:</b>		
OSUR	\$ 124,820	\$ 137,544
DNAG	53,392	54,181
Total	\$ 178,212	\$ 191,725

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

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

	<b>Three Months Ended September 30,</b>		<b>Three Months Ended September 30,</b>	
	<b>2013</b>	<b>2012</b>	<b>2013</b>	<b>2012</b>
United States	\$ 19,052	\$ 17,323	\$ 54,052	\$ 49,855
Europe	2,540	1,847	7,823	7,376
Other regions	3,079	2,945	8,297	8,444
	\$ 24,671	\$ 22,115	\$ 70,172	\$ 65,675



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

	<b>September 30, 2013</b>	<b>December 31, 2012</b>
United States	\$ 17,021	\$ 17,868
Canada	921	589
Other regions	47	89
	\$ 17,989	\$ 18,546

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**Table of Contents****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; 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 or minimum purchase requirements for the Company's products; impact of replacing distributors; inventory levels at distributors and other customers; ability to integrate and realize the full benefits of the Company's acquisition of DNA Genotek; 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 and high unemployment; 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 our 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, 2012, 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.

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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 are a leader in the development, manufacture, marketing and sale of 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. In September 2012, we began selling our OraQuick® In-Home HIV test, the first and only rapid point-of-care HIV test approved for consumer use. We also manufacture and sell kits that are used to collect, stabilize, and store samples of genetic material for molecular testing in the consumer genetics, academic research, clinical genetic testing, pharmacogenomics, personalized medicine, and animal and livestock 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 cryosurgical products are sold primarily to retail pharmacies and mass merchandisers, as well as to consumers over the internet.

### **Current Consolidated Financial Results**

During the nine months ended September 30, 2013, our consolidated net revenues were \$70.2 million compared to \$65.7 million in the nine months ended September 30, 2012. Net product revenues during the nine months ended September 30, 2013 increased 9% when compared to the first nine months of 2012, primarily due to sales of our OraQuick® In-Home HIV test, which was not commercially launched until the end of the third quarter of 2012, higher sales from our molecular collection systems business, and higher international sales of our OraQuick® HCV test. Licensing and product development revenues for the first nine months of 2013 decreased 67% primarily as a result of the absence of a \$1.0 million milestone payment received in the first quarter of 2012 related to the achievement of certain regulatory and commercial objectives pursuant to the terms of our HCV collaboration agreement with Merck & Co., Inc. ( Merck ). No similar payment was received during 2013 because the collaboration agreement with Merck has been terminated.

Our consolidated net loss for the nine months ended September 30, 2013 was \$17.4 million, or \$0.31 per share, compared to a net loss of \$9.2 million, or \$0.18 per share, for the nine months ended September 30, 2012. The first nine months of 2013 included \$14.2 million in promotional and advertising expenses associated with commercialization of our new OraQuick® In-Home HIV test. The first nine months of 2012 included \$4.7 million of similar expenses.

Cash used in operating activities for the nine months ended September 30, 2013 was \$3.1 million, compared to the \$4.0 million used during the nine months ended September 30, 2012. As of September 30, 2013, we had \$82.6 million in cash compared to \$87.9 million at December 31, 2012.

### **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.

On August 2, 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, a select committee of Congress was tasked with identifying and recommending \$1.2 trillion in spending cuts by late November 2011. Because the committee did not agree on spending cuts within that time frame, certain automatic cuts to discretionary, national defense and

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Medicare spending (often referred to as Federal sequestration) became effective on March 1, 2013. Although the full impact is difficult to ascertain, the spending cuts implemented under this new law have adversely affected, and are expected to continue to adversely affect, the ability of certain of our customers to purchase 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 and other 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 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. 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 markets which consists of research laboratories, universities and hospitals.

**Results of Operations****Three months ended September 30, 2013 compared to September 30, 2012****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, 2013 and 2012.

	<b>Three Months Ended September 30,</b>				
	<b>Dollars</b>			<b>Percentage of Total Revenues</b>	
	<b>2013</b>	<b>2012</b>	<b>% Change</b>	<b>2013</b>	<b>2012</b>
OSUR	\$ 19,560	\$ 18,376	6%	79%	83%
DNAG	4,964	3,353	48	20	15
Net product revenues	24,524	21,729	13	99	98
Licensing and product development	147	386	(62)	1	2
Net revenues	\$ 24,671	\$ 22,115	12%	100%	100%

Consolidated net revenues increased 12% to \$24.7 million in the third quarter of 2013 from \$22.1 million in the comparable period of 2012, primarily as a result of higher sales of our infectious disease testing and molecular

collection systems products. These increases were partially offset by lower sales of our cryosurgical systems, substance abuse testing, and insurance risk assessment products. Licensing and product development revenues decreased in the quarter as compared to the prior year period.

Consolidated net revenues derived from products sold to customers outside the U.S. were \$5.6 million and \$4.8 million, or 23% and 22% of total net revenues, in the third quarters of 2013 and 2012, 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.

**Table of Contents****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.

Market	Three Months Ended September 30,			Percentage of Total	
	Dollars			Revenues	
	2013	2012	% Change	2013	2012
Infectious disease testing	\$ 12,873	\$ 10,718	20%	65%	58%
Substance abuse testing	2,092	2,331	(10)	10	12
Cryosurgical systems	3,649	4,199	(13)	19	22
Insurance risk assessment	946	1,128	(16)	5	6
Net product revenues	19,560	18,376	6	99	98
Licensing and product development	147	386	(62)	1	2
Net revenues	\$ 19,707	\$ 18,762	5%	100%	100%

**Infectious Disease Testing Market**

Sales to the infectious disease testing market increased 20% to \$12.9 million in the third quarter of 2013 from \$10.7 million in the third quarter of 2012, primarily due to sales of our OraQuick® In-Home HIV test, which we began shipping to retail outlets at the end of September 2012, and increased sales of our OraQuick® HCV product in international markets.

The table below shows a breakdown of our total net OraQuick® revenues (dollars in thousands) during the third quarters of 2013 and 2012.

Market	Three Months Ended September 30,		
	2013	2012	% Change
Domestic HIV	\$ 8,093	\$ 8,527	(5)%
International HIV	1,157	884	31
Domestic OTC HIV	1,762		N/A
Domestic HCV	653	678	(4)
International HCV	924	241	283
Net OraQuick® revenues	\$ 12,589	\$ 10,330	22%

Domestic OraQuick® HIV sales decreased 5% to \$8.1 million for the three months ended September 30, 2013 from \$8.5 million for the three months ended September 30, 2012. This decrease was primarily caused by competition from

other rapid and automated laboratory-based HIV tests, reductions in government funding, and the timing of customer purchases. We expect that sales of our professional HIV product will continue to be challenged by these factors in future periods. International sales of our OraQuick® HIV test during the third quarter of 2013 increased 31% to \$1.2 million for the three months ended September 30, 2013 from \$884,000 for the three months ended September 30, 2012 primarily due to sales in support of a significant African testing program.



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During the third quarter of 2013, we recorded \$1.9 million in gross revenues from sales of our OraQuick® In-Home HIV test. These revenues were partially offset by \$172,000 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. Third quarter sales reflect retail customer purchases either in a store or over the internet and also include approximately \$217,000 of direct sales to certain public health customers. We anticipate that some health entities may choose to use a portion of their funding to purchase our OTC product in lieu of our or a competitor's professional rapid HIV testing product.

Domestic OraQuick® HCV sales decreased 4% to \$653,000 in the third quarter 2013 from \$678,000 in the third quarter of 2012, primarily as a result of variability in customer ordering patterns. International OraQuick® HCV sales increased 283% to \$924,000 in the third quarter of 2013 from \$241,000 in the third quarter of 2012, primarily as a result of a first-time order from a multi-national humanitarian organization. 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 10% to \$2.1 million in the third quarter of 2013 from \$2.3 million in the third quarter of 2012, 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 third quarters of 2013 and 2012.

Market	Three Months Ended September 30,		
	2013	2012	% Change
Domestic	\$ 1,495	\$ 1,499	0%
International	29	279	(90)
Net Intercept® revenues	\$ 1,524	\$ 1,778	(14)%

Domestic Intercept® sales for the third quarter of 2013 remained flat at \$1.5 million compared to 2012. International Intercept® sales decreased 90% to \$29,000 in the third quarter of 2013 from \$279,000 in 2012 largely due to lower purchases by our UK distributor, which totaled \$3,000 in the third quarter of 2013 compared to \$245,000 in the third quarter of 2012. In 2012, this UK distributor began selling its own competing oral specimen collection device and is expected to discontinue its purchases of our product in future periods.

**Cryosurgical Systems Market**

Sales of our products in the cryosurgical systems market (which includes both the physicians' office and OTC markets) decreased 13% to \$3.6 million in the third quarter of 2013, compared to \$4.2 million in the same period of the prior

year.

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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 2013 and 2012.

<b>Market</b>	<b>Three Months Ended September 30,</b>		
	<b>2013</b>	<b>2012</b>	<b>% Change</b>
Professional domestic	\$ 1,803	\$ 2,025	(11)%
Professional international	435	453	(4)
Over-the-counter	1,411	1,721	(18)
Net cryosurgical systems revenues	\$ 3,649	\$ 4,199	(13)%

Sales of our Histofreezer® product to physicians' offices in the United States decreased 11% to \$1.8 million in the third quarter 2013, compared to \$2.0 million in the third quarter of 2012. The decrease was the result of variability in distributor ordering patterns as two of our large distributors made large purchases in the third quarter of 2012 which did not repeat in the third quarter of 2013. During the third quarter of 2013, international sales of Histofreezer® decreased slightly to \$435,000, compared to \$453,000 in the same period of the prior year.

Sales of our OTC cryosurgical products during the third quarter of 2013 decreased 18% to \$1.4 million compared to \$1.7 million in the third quarter of 2012, largely due to lower sales to both our Latin American distributor, Genomma, and our European distributor, Reckitt Benckiser. In the third quarter of 2013, sales to Genomma decreased to \$754,000, compared to \$921,000 during the third quarter of 2012, primarily due to the timing of orders placed. Sales to Reckitt Benckiser decreased to \$606,000 in the third quarter of 2013 from \$750,000 in the third quarter of 2012 as a result of lower sales caused by a reallocation of advertising resources by the distributor partially offset by higher sales in certain new geographic territories.

**Insurance Risk Assessment Market**

Sales to the insurance risk assessment market decreased 16% to \$946,000 in the third quarter of 2013 from \$1.1 million in the third quarter of 2012, largely due to timing of orders from one of our large laboratory distributors, reduced demand in the domestic life insurance markets and a decline in testing in Canada.

**Licensing and Product Development**

Licensing and product development revenues decreased 62% to \$147,000 in the third quarter of 2013 from \$386,000 in the third quarter of 2012. Licensing revenues for these periods represent 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.

**DNAG Segment****Molecular Collection Systems**

Net molecular collection systems revenues, which primarily represent sales of our Oragene® product line, increased 48% to \$5.0 million in the third quarter of 2013 from \$3.4 million in the third quarter of 2012. Sales of Oragene® in

the commercial market increased in the third quarter of 2013 due to new orders received from an existing customer who did not purchase product in the same period of 2012. Sales to this returning customer are expected to continue throughout 2013.

**Consolidated Operating Results**

Consolidated gross margin was 61% for the third quarter of 2013 compared to 63% for the third quarter of 2012. This decrease was largely due to higher royalty expense and an unfavorable change in product mix partially offset by an improvement in overhead absorption and a decline in scrap and spoilage costs when compared to the prior year period.

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Consolidated operating loss for the third quarter of 2013 was \$2.1 million, an \$868,000 decrease from the \$2.9 million operating loss reported in the third quarter of 2012. This improvement in operating loss resulted primarily from higher revenues and lower research and development costs during the current quarter, partially offset by higher sales and marketing and general and administrative expenses.

## **Operating Loss by Segment**

### ***OSUR Segment***

OSUR's gross margin was 58% in the third quarter of 2013 compared to 62% in the third quarter of 2012. OSUR's 2013 margin was negatively impacted by an increase in lateral flow patent royalties on sales of our OraQuick® HIV products and an unfavorable change in product mix experienced in the third quarter of 2013. These negative effects on to gross margin were partially offset by an improvement in overhead absorption and lower scrap and spoilage costs.

Research and development expenses decreased 10% to \$2.0 million in the third quarter of 2013 from \$2.3 million in the third quarter of 2012 largely due to lower staffing and supply costs. Sales and marketing expenses increased 4% to \$7.4 million in the third quarter of 2013 from \$7.1 million in the third quarter of 2012. This increase was primarily the result of higher staffing costs partially offset by lower tradeshow expense. Advertising and promotional costs for our OraQuick® In-Home HIV test were \$1.9 million in the third quarter of 2013 compared to \$1.8 million in third quarter of 2012. General and administrative expenses increased 3% to \$4.6 million in the third quarter of 2013 from \$4.4 million in the third quarter of 2012 due to an increase in staffing expenses partially offset by lower legal and professional expenses.

All of the above contributed to OSUR's operating loss of \$2.5 million, which included non-cash charges of \$815,000 for depreciation and amortization and \$1.3 million for stock-based compensation.

### ***DNAG Segment***

DNAG's gross margin was 70% in the third quarter of 2013 compared to 68% in the third quarter of 2012. This increase was primarily the result of an increase in higher margin sales during the third quarter of 2013 when compared to the third quarter of 2012.

DNAG operating expenses decreased slightly to \$3.0 million in the third quarter of 2013 from \$3.1 million in the third quarter of 2012. Research and development expenses decreased 14% to \$631,000 in the third quarter of 2013 from \$731,000 in the third quarter of 2012 due to lower staffing expenses. Sales and marketing expenses increased 6% to \$1.6 million in the third quarter of 2013 from \$1.5 million in the third quarter of 2012 due to an increase in commission expense. General and administrative expenses declined slightly to \$775,000 in the third quarter of 2013 from \$801,000 in the third quarter of 2012.

All of the above contributed to DNAG's third quarter 2013 operating income of \$456,000, which included non-cash charges of \$810,000 for depreciation and amortization and \$61,000 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 OraSure's pre-tax loss in the third quarter of 2013 or 2012. A Canadian income tax benefit of \$127,000 and \$527,000 was recorded in the third quarter of 2013 and 2012, respectively, which was

associated with the DNAG loss before income taxes and certain Canadian research and development and investment tax credits. The Canadian income tax benefit is considered realizable based upon the scheduled reversal of the deferred tax liabilities recorded in connection with the acquisition of DNAG.

**Table of Contents****Nine months ended September 30, 2013 compared to September 30, 2012****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, 2013 and 2012.

	<b>Nine Months Ended September 30,</b>				
	<b>Dollars</b>			<b>Percentage of Total Revenues</b>	
	<b>2013</b>	<b>2012</b>	<b>% Change</b>	<b>2013</b>	<b>2012</b>
OSUR	\$ 55,999	\$ 53,814	4%	80%	82%
DNAG	13,550	9,992	36	19	15
Net product revenues	69,549	63,806	9	99	97
Licensing and product development	623	1,869	(67)	1	3
Net revenues	\$ 70,172	\$ 65,675	7%	100%	100%

Consolidated net revenues increased 7% to \$70.2 million in the first nine months of 2013 from \$65.7 million in the comparable period of 2012. Net product revenues increased 9% during the nine months ended September 30, 2013 when compared to the first nine months of 2012, primarily as a result of higher sales of our infectious disease testing and molecular collection systems products. These increases were partially offset by lower sales of our cryosurgical systems, substance abuse testing, and insurance risk assessment products. Licensing and product development revenues decreased in the current period compared to the prior year primarily as a result of the absence of a \$1.0 million milestone payment received in the first quarter of 2012 for the achievement of certain regulatory and commercial objectives pursuant to the terms of our HCV collaboration agreement with Merck. No similar payment was received in 2013 because the collaboration agreement with Merck has been terminated.

Consolidated net revenues derived from products sold to customers outside the U.S. were \$16.1 million and \$15.8 million, or 23% and 24% of total net revenues, during the nine months ended September 30, 2013 and 2012, 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.

**Table of Contents****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.

Market	Nine Months Ended September 30,			Percentage of Total Revenues	
	Dollars		%	2013	2012
	2013	2012			
Infectious disease testing	\$ 35,526	\$ 30,880	15%	63%	56%
Substance abuse testing	6,455	7,305	(12)	11	13
Cryosurgical systems	10,910	12,181	(10)	19	22
Insurance risk assessment	3,108	3,448	(10)	6	6
Net product revenues	55,999	53,814	4%	99	97%
Licensing and product development	623	1,869	(67)	1	3
Net revenues	\$ 56,622	\$ 55,683	2%	100%	100%

**Infectious Disease Testing Market**

Sales to the infectious disease testing market increased 15% to \$35.5 million in the first nine months of 2013 from \$30.9 million in the first nine months of 2012, primarily due to sales of our OraQuick® In-Home HIV test, which we began shipping to retail outlets at the end of September 2012, and increased sales of our OraQuick® HCV product in international markets.

The table below shows a breakdown of our total net OraQuick® revenues (dollars in thousands) during the nine months ended September 30, 2013 and 2012.

Market	Nine Months Ended September 30,		
	2013	2012	% Change
Domestic HIV	\$ 23,854	\$ 25,106	(5)%
International HIV	2,457	2,287	7
Domestic OTC HIV	5,196		N/A
Domestic HCV	1,772	1,958	(9)
International HCV	1,409	734	92
Net OraQuick® revenues	\$ 34,688	\$ 30,085	15%



Domestic OraQuick® HIV sales decreased 5% to \$23.9 million for the nine months ended September 30, 2013 from \$25.1 million for the nine months ended September 30, 2012. This decrease was primarily caused by competition from other rapid and automated laboratory-based HIV tests, reductions in government funding, and the timing of customer purchases. We expect that sales of our professional HIV product will continue to be challenged by these factors in future periods. International sales of our OraQuick® HIV test increased 7% to \$2.5 million in the first nine months of 2013 from \$2.3 million in the first nine months of 2012. This increase was largely related to the timing of orders and related project work in Africa, Latin America and Europe partially offset by lower sales in Asia.

During the first nine months of 2013, we recorded \$5.6 million in gross revenues from sales of our OraQuick® In-Home HIV test. These revenues were partially offset by \$415,000 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. Sales during the first nine months of 2013 reflect retail customer purchases either in a store or over the internet and also include approximately \$600,000 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 our or a competitor's professional rapid HIV testing product.

Domestic OraQuick® HCV sales decreased 9% to \$1.8 million in the first nine months of 2013 from \$2.0 million in the first nine months of 2012, primarily as a result of variability in customer ordering patterns and the lack of governmental funding for public health HCV testing. International OraQuick® HCV sales increased 92% to \$1.4 million in the

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first nine months of 2013 from \$734,000 in 2012, primarily as a result of a first-time order from a multi-national humanitarian organization. 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 substance abuse testing market decreased 12% to \$6.5 million in the first nine months of 2013 from \$7.3 million in the first nine months of 2012, 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, 2013 and 2012.

<b>Market</b>	<b>Nine Months Ended</b>		
	<b>2013</b>	<b>2012</b>	<b>% Change</b>
Domestic	\$ 4,240	\$ 4,981	(15)%
International	385	616	(38)
<b>Net Intercept® revenues</b>	<b>\$ 4,625</b>	<b>\$ 5,597</b>	<b>(17)%</b>

Domestic Intercept® sales decreased 15% to \$4.2 million in the first nine months of 2013 from \$5.0 million in the first nine months of 2012. In 2011, our largest laboratory distributor began selling its own competing oral specimen collection device and a panel of oral fluid drug assays suitable for use on fully-automated high throughput homogenous processing systems. As a result, by the end of 2012, this distributor had significantly reduced its purchases of our Intercept® product line. Intercept® sales to this distributor were \$1.3 million in the first nine months of 2012 compared to \$52,000 in the first nine months of 2013. Intercept® sales in the first nine months of 2013 were also negatively impacted by the continued consolidation of drug testing laboratories.

International Intercept® sales decreased 38% to \$385,000 in the first nine months of 2013 from \$616,000 in the first nine months of 2012 largely due to lower purchases by our UK distributor, which totaled \$534,000 in the first nine months of 2013 compared to \$286,000 in 2012. In 2012, this UK distributor began selling its own competing oral specimen collection device and is expected to discontinue its purchases of our product in future periods.

**Cryosurgical Systems Market**

Sales of our products in the cryosurgical systems market (which includes both the physicians office and OTC markets) decreased 10% to \$10.9 million in the first nine months of 2013, compared to \$12.2 million in the same period of the prior year.



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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, 2013 and 2012.

Market	Nine Months Ended September 30,		
	2013	2012	% Change
Professional domestic	\$ 4,192	\$ 5,342	(22)%
Professional international	1,039	1,110	(6)
Over-the-counter	5,679	5,729	(1)
Net cryosurgical systems revenues	\$ 10,910	\$ 12,181	(10)%

Sales of our Histofreezer® product to physicians' offices in the United States decreased 22% to \$4.2 million in the first nine months of 2013, compared to \$5.3 million in the first nine months of 2012. The decrease was the result of higher distributor purchases made in the fourth quarter of 2012 in anticipation of price increases implemented in early January 2013, a decline in sales to the military during the current period as a result of the U.S. withdrawal of troops overseas and lower sales to our Canadian distributor. During the nine months ended September 30, 2013, international sales of Histofreezer® decreased to \$1.0 million, compared to \$1.1 million in the same period of the prior year largely due to timing of orders from our Australian distributor.

Sales of our OTC cryosurgical products during the first nine months of 2013 remained flat at \$5.7 million as higher sales to our Latin American distributor, Genomma partially offset lower sales to our European distributor, Reckitt Benckiser. In the first nine months of 2013, Genomma purchased \$2.7 million, compared to \$2.6 million during the first nine months of 2012. Sales to Reckitt Benckiser decreased to \$2.8 million during the first nine months of 2013 from \$3.0 million during the first nine months of 2012 as a result of lower sales caused by a reallocation of advertising resources by the distributor partially offset by higher sales in new geographic territories.

**Insurance Risk Assessment Market**

Sales to the insurance risk assessment market decreased 10% to \$3.1 million in the first nine months of 2013 from \$3.4 million in the first nine months of 2012 as a result of reduced demand in the domestic life insurance markets.

**Licensing and Product Development**

Licensing and product development revenues decreased 67% to \$623,000 in the first nine months of 2013 from \$1.9 million in the first nine months of 2012. During the first quarter of 2012, we received a \$1.0 million milestone payment as a result of our achievement of certain regulatory and commercial objectives pursuant to our collaboration agreement with Merck for the development and promotion of our OraQuick® rapid HCV test in international markets. No similar milestone payment was received during 2013 because the collaboration agreement with Merck has been terminated.

The remaining licensing revenues for these periods represent 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.

**DNAG Segment**

### **Molecular Collection Systems**

Net molecular collection systems revenues, which primarily represent sales of our Oragene® product line, increased 36% to \$13.6 million in the first nine months of 2013 from \$10.0 million in the first nine months of 2012. Sales of Oragene® in the commercial market increased in the first nine months of 2013 due to new orders received from an existing customer who did not purchase product in the same period of 2012 and a first time order placed by a new pain management customer. Sales to the returning customer are expected to continue throughout 2013. Sales in the academic research market declined in the first nine months of 2013 when compared to 2012 due to continued constrained research funding, primarily in North America.

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### **Consolidated Operating Results**

Consolidated gross margin was 59% for the first nine months of 2013 compared to 64% for the first nine months of 2012. This decrease was largely due to higher royalty expense, an unfavorable change in product mix, and the absence of the \$1.0 million HCV milestone payment. These negative effects on gross margin were partially offset by an improvement in overhead absorption when compared to the prior year period.

Consolidated operating loss for the first nine months of 2013 was \$18.2 million, an \$8.1 million increase from the \$10.1 million operating loss reported in the first nine months of 2012. This increase was primarily the result of higher sales and marketing expenses associated with the commercialization of our OraQuick® In-Home HIV test.

### **Operating Loss by Segment**

#### ***OSUR Segment***

OSUR's gross margin was 57% in the first nine months of 2013 compared to 64% in the first nine months of 2012. OSUR's 2013 margin was negatively impacted by a number of items, including an increase in lateral flow patent royalties on sales of our OraQuick® HIV products, an unfavorable change in product mix, and the absence of the \$1.0 million HCV milestone payment received from Merck in the first quarter of 2012. The negative impact of these items was partially offset by an improvement in overhead absorption.

Research and development expenses decreased 7% to \$6.8 million in the first nine months of 2013 from \$7.3 million in the first nine months of 2012, largely due to lower staffing costs.

Sales and marketing expenses increased 46% to \$30.1 million in the first nine months of 2013 from \$20.6 million in the first nine months of 2012. This increase was primarily the result of higher spending associated with advertising and promotional activities for our OraQuick® In-Home HIV test. During 2013, we launched two large promotional campaigns including one in association with Earvin Magic Johnson and another multi-city promotional campaign to encourage consumers to get tested for HIV. We also increased our use of radio, television, print and digital advertising. Advertising and promotional costs for our OraQuick® In-Home HIV test were \$14.2 million in the first nine months of 2013, compared to \$4.7 million in the first nine months of 2012.

General and administrative expenses decreased 10% to \$13.5 million in the first nine months of 2013 from \$15.0 million in the first nine months of 2012 due to lower legal and consulting expenses, partially offset by higher staffing costs.

All of the above contributed to OSUR's operating loss of \$18.0 million, 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 67% in the first nine months of 2013 compared to 68% in the comparable period of 2012. This decrease was primarily the result of increased sales to a lower margin commercial customer.

Research and development expenses decreased 13% to \$1.9 million in the first nine months of 2013 from \$2.2 million in the first nine months of 2012 due to lower staffing costs. Sales and marketing expenses increased 5% to \$5.1 million in the first nine months of 2013 from \$4.9 million in the comparable period of 2012 due to higher sales commission expenses and increased travel and entertainment costs. General and administrative expenses remained

relatively flat at \$2.3 million in the first nine months of 2013 as compared to \$2.4 million in the first nine months of 2012.

All of the above contributed to DNAG's operating loss of \$213,000, which included non-cash charges of \$2.5 million for depreciation and amortization and \$175,000 for stock-based compensation.

**Table of Contents****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 nine months of 2013 and 2012. A Canadian income tax benefit of \$786,000 and \$1.1 million was recorded in the first nine months of 2013 and 2012, respectively, which was associated with the DNAG loss before income taxes and certain Canadian research and development and investment tax credits. The Canadian income tax benefit is considered realizable based upon the scheduled reversal of the deferred tax liabilities recorded in connection with the acquisition of DNAG.

**Liquidity and Capital Resources**

	<b>September 30, 2013</b>	<b>December 31, 2012</b>
	<b>(In thousands)</b>	
Cash	\$ 82,590	\$ 87,888
Working capital	92,072	103,483

Our cash balances decreased \$5.3 million to \$82.6 million at September 30, 2013 from \$87.9 million at December 31, 2012. Our working capital also decreased to \$92.1 million at September 30, 2013 from \$103.5 million at December 31, 2012.

During the first nine months of 2013, we used \$3.1 million in cash to finance our operating activities. Our net loss of \$17.4 million and deferred income tax benefit of \$786,000 were partially offset by non-cash stock-based compensation expense of \$4.2 million and depreciation and amortization expense of \$4.8 million. Additional uses of cash in operating activities included a \$1.1 million decrease in deferred revenue resulting from the recognition of previously deferred OraQuick® In-Home HIV test revenues and the realization of certain customer prepayments, and a \$554,000 increase in prepaid expenses primarily related to the discounted pre-payment of our aggregate annual medical insurance premium in the first quarter of 2013. Offsetting these uses of cash were a \$3.1 million decrease in accounts receivable resulting from the collection of outstanding balances due at the end of 2012, a \$3.3 million decrease in accrued expenses and other liabilities associated with payment of our 2012 royalty obligations, management incentive bonuses and certain year-end accruals, a \$745,000 decrease in inventory associated with our infectious disease products and a \$497,000 increase in accounts payable at DNAG related to the manufacture of inventory to meet increased sales demand.

We used a total of \$1.7 million in investing activities during the first nine months of 2013 to acquire property and equipment.

Net cash used in financing activities was \$500,000 for the nine months ended September 30, 2013, which resulted from the use of \$817,000 for the repurchase of common stock related to the vesting of restricted shares offset by \$317,000 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 time 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, 2012 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, 2012. As of September 30, 2013, 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 2012 Annual Report on Form 10-K filed with the SEC. During the first nine months of 2013, 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, 2013, we did not have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. We have operations in Canada, Europe and Africa, which are subject to foreign currency fluctuations. As currency rates change, translation of revenues and expenses for these operations from foreign currencies to U.S. dollars affects year-to-year comparability of operating results. Sales denominated in a foreign currency comprised 5% of our total revenues for the nine months ended September 30, 2013 (including revenues from DNAG). We expect the DNAG business, for which the functional currency is the Canadian dollar, will continue to grow and our exposure to fluctuations in foreign currency exchange rates may increase as a result of this growth.

### **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, 2013. 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 September 30, 2013 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 September 30, 2013 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, 2012.

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

During the quarter ended September 30, 2013, pursuant to the OraSure Technologies, Inc. Stock Award Plan, and in connection with the vesting of restricted shares, we retired 2,667 shares of our common stock to satisfy minimum tax withholding obligations at an average price paid per share of \$5.85.

**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: November 7, 2013

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

Date: November 7, 2013

*/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