

ORASURE TECHNOLOGIES INC  
Form 10-Q  
May 04, 2011  
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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 March 31, 2011.

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)

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**DELAWARE**  
(State or Other Jurisdiction of

**36-4370966**  
(IRS Employer

Incorporation or Organization)

Identification No.)

**220 East First Street, Bethlehem, Pennsylvania**  
(Address of Principal Executive Offices)

**18015**  
(Zip code)

**(610) 882-1820**

(Registrant's Telephone Number, Including Area Code)

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

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

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

Large accelerated filer  Accelerated filer

Non-accelerated filer  Smaller reporting company

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

Number of shares of Common Stock, par value \$.000001 per share, outstanding as of May 2, 2011: 46,688,307

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**Table of Contents****Item 1. FINANCIAL STATEMENTS****ORASURE TECHNOLOGIES, INC.****BALANCE SHEETS****(Unaudited)**

	<b>MARCH 31, 2011</b>	<b>DECEMBER 31, 2010</b>
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 70,544,284	\$ 73,843,402
Short-term investments	1,895,000	1,895,000
Accounts receivable, net of allowance for doubtful accounts of \$105,522 and \$105,954	12,119,960	12,471,249
Inventories	7,749,936	7,345,594
Prepaid expenses	1,937,898	1,930,108
Total current assets	94,247,078	97,485,353
PROPERTY AND EQUIPMENT, net	19,849,944	19,610,583
PATENTS AND PRODUCT RIGHTS, net	4,620,919	4,806,919
OTHER ASSETS	474,790	617,238
	\$ 119,192,731	\$ 122,520,093
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Current portion of long-term debt	\$ 7,666,680	\$ 7,791,680
Accounts payable	3,506,112	2,898,846
Accrued expenses and other	7,047,617	8,986,879
Total current liabilities	18,220,409	19,677,405
<b>COMMITMENTS AND CONTINGENCIES (Note 5)</b>		
<b>STOCKHOLDERS EQUITY</b>		
Preferred stock, par value \$.000001, 25,000,000 shares authorized, none issued		
Common stock, par value \$.000001, 120,000,000 shares authorized, 46,635,045 and 46,225,622 shares issued and outstanding	47	46
Additional paid-in capital	242,391,342	241,663,337
Accumulated other comprehensive loss	(235,533)	(235,264)
Accumulated deficit	(141,183,534)	(138,585,431)
Total stockholders equity	100,972,322	102,842,688
	\$ 119,192,731	\$ 122,520,093

See accompanying notes to the financial statements.

**Table of Contents****ORASURE TECHNOLOGIES, INC.****STATEMENTS OF OPERATIONS****(Unaudited)**

	<b>Three Months Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
<b>REVENUES:</b>		
Product	\$ 17,050,112	\$ 16,572,754
Licensing and product development	363,616	1,372,770
	17,413,728	17,945,524
<b>COST OF PRODUCTS SOLD</b>	<b>6,146,897</b>	<b>6,541,462</b>
Gross profit	11,266,831	11,404,062
<b>OPERATING EXPENSES:</b>		
Research and development	4,420,240	3,106,775
Sales and marketing	4,931,876	5,694,344
General and administrative	4,467,611	4,778,643
	13,819,727	13,579,762
Operating loss	(2,552,896)	(2,175,700)
<b>INTEREST EXPENSE</b>	<b>(78,187)</b>	<b>(75,795)</b>
<b>INTEREST INCOME</b>	<b>38,945</b>	<b>42,116</b>
<b>FOREIGN CURRENCY GAIN (LOSS)</b>	<b>(8,178)</b>	<b>14,689</b>
<b>OTHER INCOME (EXPENSE)</b>	<b>2,213</b>	<b>(684)</b>
Loss before income taxes	(2,598,103)	(2,195,374)
<b>INCOME TAXES</b>		
<b>NET LOSS</b>	<b>\$ (2,598,103)</b>	<b>\$ (2,195,374)</b>
<b>LOSS PER SHARE:</b>		
<b>BASIC AND DILUTED</b>	<b>\$ (0.06)</b>	<b>\$ (0.05)</b>
<b>SHARES USED IN COMPUTING LOSS PER SHARE</b>		
<b>BASIC AND DILUTED</b>	<b>46,517,531</b>	<b>46,112,061</b>

See accompanying notes to the financial statements.

**Table of Contents****ORASURE TECHNOLOGIES, INC.****STATEMENTS OF CASH FLOWS****(Unaudited)**

	<b>Three Months Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
<b>OPERATING ACTIVITIES:</b>		
Net loss	\$ (2,598,103)	\$ (2,195,374)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	972,552	891,373
Depreciation and amortization	829,079	649,538
Reserve for excess and obsolete inventories	117,290	(89,464)
Changes in assets and liabilities:		
Accounts receivable	351,789	1,589,712
Inventories	(521,632)	(375,331)
Prepaid expenses and other assets	134,658	(672,642)
Accounts payable	606,497	(253,794)
Accrued expenses and other liabilities	(1,941,622)	(4,547,585)
<b>Net cash used in operating activities</b>	<b>(2,049,492)</b>	<b>(5,003,567)</b>
<b>INVESTING ACTIVITIES:</b>		
Proceeds from maturities and redemptions of short-term investments		750,000
Purchases of property and equipment	(882,440)	(532,241)
<b>Net cash (used in) provided by investing activities</b>	<b>(882,440)</b>	<b>217,759</b>
<b>FINANCING ACTIVITIES:</b>		
Repayments of long-term debt	(125,000)	(134,760)
Proceeds from exercise of stock options	582,375	
Repurchase of common stock	(824,561)	(638,628)
<b>Net cash used in financing activities</b>	<b>(367,186)</b>	<b>(773,388)</b>
<b>NET DECREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(3,299,118)</b>	<b>(5,559,196)</b>
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD</b>	<b>73,843,402</b>	<b>74,933,630</b>
<b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>	<b>\$ 70,544,284</b>	<b>\$ 69,374,434</b>
<b>SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:</b>		
Cash paid for:		
Interest	\$ 80,430	\$ 85,645
Income taxes	\$	\$ 10,000

See accompanying notes to the financial statements.

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**ORASURE TECHNOLOGIES, INC.**

**Notes to the Financial Statements**

**(Unaudited)**

**1. The Company**

We develop, 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. We also manufacture and sell other medical devices used for the removal of benign skin lesions by cryosurgery, or freezing. Our diagnostic products include tests which are performed on a rapid basis at the point of care and tests which are processed in a laboratory. These products are sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, distributors, government agencies, physicians' offices, and commercial and industrial entities. One of our products has been sold in the over-the-counter or consumer retail markets in North America, Europe, Central and South America and Australia.

The economic downturn, including disruptions in the capital and credit markets, may continue indefinitely and intensify, and could adversely affect our results of operations, cash flows and financial condition or those of our customers and suppliers. These circumstances could adversely affect our access to liquidity needed to conduct or expand our business or conduct acquisitions or make other discretionary investments. They may also adversely impact the capital needs of 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. This could adversely affect our results of operations, cash flows and financial condition. The recent weak business climate could cause longer sales cycles and slower growth, and could expose us to increased business or credit risk in dealing with customers or suppliers adversely affected by economic conditions. Our ability to collect accounts receivable may be delayed or precluded if our customers are unable to pay their obligations.

**2. Summary of Significant Accounting Policies**

**Basis of Presentation.** The accompanying 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, 2010. Results of operations for the three months ended March 31, 2011 are not necessarily indicative of the results of operations expected for the full year.

**Use of Estimates.** The preparation of 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, inventories and intangible assets, as well as calculations related to contingencies, accruals and indemnifications, 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, foreign currency, and energy markets, and declines in consumer spending have combined to increase the uncertainty inherent in such estimates and assumptions. Since future events and their effects cannot be determined with precision, actual results could differ significantly from these estimates. Changes in these estimates resulting from continuing changes in the economic environment will be reflected in the financial statements in those future periods.

**Cash and Cash Equivalents.** We consider all highly liquid investments with a purchased maturity of ninety days or less to be cash equivalents. As of March 31, 2011 and December 31, 2010, cash equivalents consisted of money market accounts.

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

Our available-for-sale securities as of March 31, 2011 and December 31, 2010 consisted of certificates of deposits with amortized cost and fair value of \$1,895,000. These certificates of deposits mature within less than one year.

**Fair Value of Financial Instruments.** As of March 31, 2011, the carrying values of cash and cash equivalents, short-term investments, accounts receivable, accounts payable and accrued expenses approximate their respective fair values based on their short-term nature. In addition, we believe the carrying value of our debt instrument, which does not have a readily ascertainable market value, approximates fair value, given that the interest rate on outstanding borrowings approximates current market rates.

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).

All our available-for-sale securities were classified 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, 2011	December 31, 2010
Raw materials	\$ 4,410,894	\$ 4,453,560
Work in process	520,447	258,335
Finished goods	2,818,595	2,633,699
	\$ 7,749,936	\$ 7,345,594

**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 three 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 statement of operations. Accumulated depreciation of property and equipment as of March 31, 2011 and December 31, 2010 was \$20,241,929 and \$20,204,317, respectively.

**Patents and Product Rights.** Patents and product rights consist of costs associated with the acquisition of patents, licenses and product distribution rights. Patents and product rights are amortized using the straight-line method over



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their estimated useful lives of three to ten years. Accumulated amortization of patents and product rights as of March 31, 2011 and December 31, 2010 was \$5,827,701 and \$5,641,701, respectively.

**Impairment of Long-Lived Assets.** If indicators of impairment exist, we assess the recoverability of the affected long-lived assets, which include property and equipment and patents and product rights, by determining whether the carrying value of such assets can be recovered through the sum of the undiscounted future cash flows from the use and eventual disposition of the assets. If impairment is indicated, we measure the amount of such impairment by comparing the carrying value of the assets to the fair value of these assets, which is generally determined based on the present value of the expected future cash flows associated with the use of the assets.

**Revenue Recognition.** We recognize product revenues when there is persuasive evidence that an arrangement exists, the price is fixed or determinable, title has passed and collection is reasonably assured. Product revenues are recorded net of allowances for any discounts or rebates. 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.

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.

**Significant Customer Concentration.** The Company had no significant concentrations (greater than 10%) in revenues for both the three months ended March 31, 2011 and 2010. As of March 31, 2011 and December 31, 2010, one of our customers, Quest Diagnostics, Incorporated, accounted for 10% of our accounts receivable balance.

**Research and Development.** Research and development expenses consist of costs incurred in performing research and development activities including salaries and benefits, facilities expenses, overhead expenses, clinical trial and related clinical manufacturing expenses, contract services and other outside expenses. Research and development costs are charged to expense as incurred. Clinical trial expenses include expenses associated with contract research organizations, or CROs. The invoicing from CROs can precede the services provided or can lag the service period by several months. Invoices paid prior to service being provided are recorded as a prepaid expense and then expensed appropriately as services are provided. We accrue the cost of services rendered but unbilled by CROs based on purchase order estimates provided by the CROs. Differences between actual and estimated clinical trial expenses recorded are generally not material and would be adjusted for in the period in which they become known.

**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 7,205,126 and 6,966,125 shares were outstanding as of March 31, 2011 and March 31, 2010, respectively. As a result of our net losses for the three months ended March 31, 2011 and 2010, these shares were excluded from the computation of diluted loss per share, as their inclusion would have been anti-dilutive.

**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. Accumulated other comprehensive loss as of March 31, 2011 and December 31, 2010 consisted of currency translation adjustments. Comprehensive loss was \$2,598,372 and \$2,195,037 for the three months ended March 31, 2011 and 2010, respectively.

### **3. Stock-Based Compensation**

We grant stock-based awards under the OraSure Technologies, Inc. 2000 Stock Award Plan, as amended and restated (the "2000 Plan"). The 2000 Plan permits stock-based awards to employees, outside directors and consultants or other third-party advisors. Awards which may be granted under the 2000 Plan include qualified

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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 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.

The fair value of each stock option is estimated on the date of the grant using the Black-Scholes option-pricing model. The weighted average grant date fair value of stock options granted during the three months ended March 31, 2011 and 2010 was \$2.82 and \$2.26 per share, respectively.

Total compensation cost related to stock options for the three months ended March 31, 2011 and 2010 was \$341,948 and \$275,242, respectively, of which \$7,028 and \$13,807 was capitalized into inventory during the quarters ended March 31, 2011 and 2010, respectively. The amounts recognized in cost of products sold for amounts previously capitalized were \$9,680 and \$19,945 for the three months ended March 31, 2011 and 2010, respectively.

The following table summarizes the stock option activity for the three months ended March 31, 2011:

	<b>Options</b>
Outstanding on January 1, 2011	5,503,533
Granted	916,975
Exercised	(143,858)
Outstanding on March 31, 2011	6,276,650

As of March 31, 2011, there was \$4,117,472 of unrecognized compensation expense related to unvested option awards that is expected to be recognized over a weighted average period of 2.2 years.

Net cash proceeds from the exercise of stock options were \$582,375 for the three months ended March 31, 2011. As a result of the Company's net operating loss carryforward position, no actual income tax benefit was realized from the stock option exercises during this period. No options were exercised during the first quarter of 2010.

As mentioned above, the 2000 Plan also permits us to grant restricted shares of our common stock to eligible employees, including officers and outside directors. Generally, these shares are nontransferable until vested and are subject to vesting requirements and/or forfeiture, as determined by the Compensation Committee of our Board of Directors. The market value of these shares at the date of grant is recognized on a straight-line basis over the period during which the restrictions lapse. During the three months ended March 31, 2011, we granted 525,880 restricted shares of our common stock, with a weighted average grant date fair value of \$6.61 per share, to certain key officers, members of management and outside directors. Compensation cost of \$630,604 and \$616,131 related to restricted shares was recognized during the three months ended March 31, 2011 and 2010, respectively.

The following table summarizes restricted stock award activity for the three months ended March 31, 2011:

	<b>Shares</b>
Issued and unvested, January 1, 2011	792,156
Granted	525,880
Vested	(389,560)
Issued and unvested, March 31, 2011	928,476

As of March 31, 2011, there was \$5,065,892 of unrecognized compensation expense related to unvested restricted stock awards that is expected to be recognized over a weighted average period of 2.4 years. In connection with the vesting of restricted shares, during the three months ended March 31, 2011 and 2010, 123,995 and 121,529 shares,



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respectively, with aggregate values of \$824,561 and \$638,628, respectively, were withheld and retired in satisfaction of minimum tax withholding obligations.

**4. Accrued Expenses**

	March 31, 2011	December 31, 2010
Payroll and related benefits	\$ 2,047,850	\$ 4,343,350
Royalties	1,492,171	1,985,799
Deferred revenue	897,799	896,531
Clinical research obligations	857,117	400,860
Professional fees	530,075	213,308
Other	1,222,605	1,147,031
	\$ 7,047,617	\$ 8,986,879

Deferred revenue at March 31, 2011 and December 31, 2010 included customer prepayments of \$855,199 and \$851,031, respectively.

**5. Commitments and Contingencies**

Litigation. 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.

**6. Geographic Information**

We operate within one reportable segment. Our products are sold principally in the United States and Europe. Segmentation of operating income and identifiable assets is not applicable since our revenues outside the United States are export sales, and we do not have significant operating assets outside the United States.

The following table represents total revenues by geographic area, based on the location of the customer (amounts in thousands):

	Three Months Ended March 31,	
	2011	2010
United States	\$ 14,239	\$ 14,869
Europe	1,986	1,342
Other regions	1,189	1,735
	\$ 17,414	\$ 17,946

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*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 an internal, direct sales force or third parties; ability to manufacture products in accordance with applicable specifications, performance standards and quality 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 and success of direct sales efforts; inventory levels at distributors and other customers; impact of competitors, competing products and technology changes; impact of the economic downturn, high unemployment and poor credit conditions; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products; market acceptance of oral fluid testing or other products; changes in market acceptance of products based on product performance, extended shelf life 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 product components; availability of related products produced by third parties or products required for use of our products; 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; 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; loss or impairment of sources of capital; ability to meet financial covenants in agreements with financial institutions; 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; ability to identify, complete and realize the full benefits of potential acquisitions; 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, 2010, 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 the financial statements contained herein and the notes thereto, along with the Section entitled Critical Accounting Policies and Estimates, set forth below.

**Overview**

We operate primarily in the *in vitro* diagnostic business. Our business principally involves 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. We also manufacture and sell other medical devices used for

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the removal of benign skin lesions by cryosurgery, or freezing. Our diagnostic products include tests which are performed on a rapid basis at the point of care and tests which are processed in a laboratory. These products are sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, distributors, government agencies, physicians' offices, and commercial and industrial entities. One of our products is sold in the over-the-counter ( OTC ) or consumer retail market in North America, Europe, Central and South America, and Australia.

*In vitro* diagnostic testing is the process of analyzing oral fluid, blood, urine and other bodily fluids or tissue for the presence of specific substances or markers for infectious diseases, drugs of abuse or other conditions. However, we have targeted the use of oral fluid in our products as a differentiating factor and believe that it provides a significant competitive advantage over blood and urine. Our oral fluid tests have sensitivity and specificity comparable to blood and/or urine tests. When combined with their ease of use, non-invasive nature, and cost effectiveness, our oral fluid tests represent a very competitive alternative to the more traditional testing methods in the diagnostic space.

We rely heavily on distributors to purchase and resell many of our products. For example, Genomma Labs ( Genomma ) has exclusive rights to our wart removal product in the OTC market in Mexico, Argentina, Brazil and various other Central and South American countries and Reckitt Benckiser (formerly SSL International plc) has similar rights to our wart removal product in the OTC footcare market in Europe, Australia and New Zealand. We have contracted with several distributors to sell our OraQuick *ADVANCE*<sup>®</sup> HIV-1/2 test to the U.S. physician office market and our Intercept<sup>®</sup> and OraSure<sup>®</sup> product lines are sold by several laboratory distributors. We use distributors to sell our Histofreezer<sup>®</sup> product into the domestic and international physician office markets and we are engaging distributors to sell our OraQuick<sup>®</sup> rapid HCV test in Europe. We expect to enter into additional distribution agreements for existing and future products in the U.S. and internationally. If our distributors are unable or unwilling to meet the minimum purchase commitments set forth in their agreements or otherwise substantially reduce the volume of their purchases, our revenues and results of operations could be adversely affected.

Because of the regulatory approvals needed for most of our products, we often are required to rely on sole source providers for critical components and materials and on related products supplied by third parties. This is particularly true for our OraQuick *ADVANCE*<sup>®</sup> HIV-1/2 test, our OraQuick<sup>®</sup> HCV test, our OraSure<sup>®</sup> oral fluid collection device and our oral fluid Western blot HIV-1 confirmatory product. If we are unable to obtain necessary components or materials from these sole sources, the time required to develop replacements and obtain the required U.S. Food and Drug Administration ( FDA ) approvals could disrupt our ability to sell the affected products.

## **Current Financial Results**

During the three months ended March 31, 2011, our total revenues were \$17.4 million compared to \$17.9 million in the three months ended March 31, 2010. Product revenues during the three months ended March 31, 2011 increased 3% when compared to the first quarter of 2010, which was offset by lower licensing and product development revenues. The reduction in licensing and product development revenues was caused by the absence of a \$1.0 million in milestone payment received under the terms of our collaboration agreement with Merck & Co., Inc. ( Merck ) during the first quarter of 2010 for the development and promotion of our OraQuick<sup>®</sup> rapid HCV test in Europe. Our net loss for the three months ended March 31, 2011 was \$2.6 million, or \$0.06 per share, compared to a net loss of \$2.2 million, or \$0.05 per share, for the three months ended March 31, 2010.

Cash used in operating activities for the three months ended March 31, 2011 was approximately \$2.0 million, compared to the \$5.0 million used in operating activities for the three months ended March 31, 2010. As of March 31, 2011, we had \$72.4 million in cash, cash equivalents and short-term investments, compared to \$75.7 million at December 31, 2010.

## **Recent Developments**

### **OraQuick<sup>®</sup> HCV Test**

We have continued our efforts to obtain FDA approval of additional applications for our OraQuick<sup>®</sup> HCV test. To date our OraQuick<sup>®</sup> HCV test has received FDA approval for use in venous whole blood and fingerstick whole

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blood specimens. We also intend to pursue approval of an oral fluid claim for our OraQuick® HCV test. However, the filing of a pre-market approval supplement for oral fluid has been delayed pending the completion of additional testing and further discussions with the FDA.

In March 2011, we submitted to the FDA an application for waiver under the Clinical Laboratory Improvement Amendments of 1988 ( CLIA ) for our OraQuick® HCV test for use with venous whole blood and fingerstick whole blood specimens. This application remains pending.

### **OraQuick® HIV OTC Test**

We are conducting the final phase of clinical testing for an OraQuick® HIV OTC test. In this study individuals will conduct unsupervised self-testing using the investigational OTC version of our OraQuick *ADVANCE*® HIV test with an oral fluid collection. All clinical sites for this phase have been initiated and over 2,500 patients have been enrolled in the study. We have also identified over half of the 100 newly-diagnosed HIV-infected individuals required by the FDA as part of our protocol. Assuming enrollment continues as expected and we meet our anticipated prevalence rates among those enrolled, we believe this study will be completed during the third quarter of 2011.

### **Substance Abuse Testing**

In the first quarter of 2011, the FDA issued 510(k) clearances for use of high throughput oral fluid assays for PCP, opiates, cocaine and methamphetamines with our Intercept® oral fluid collection device. These are the first such clearances resulting from our collaboration with Roche Diagnostics. The FDA is in the final stages of review for one other assay for amphetamines and we expect the FDA to issue an additional 510(k) clearance for this product in the near future. Clinical work on an assay for marijuana (THC) is continuing, but is not expected to be completed until late 2011 at the earliest. We expect to begin selling a panel of 510(k) cleared assays together with our Intercept® device during the third quarter of this year.

### **OraSure QuickFlu Test**

In the first quarter of 2011, we added a new infectious disease testing product to our product portfolio. The OraSure QuickFlu Rapid Flu A+B is an FDA-cleared *in vitro* rapid qualitative test for the detection of influenza type A and type B, including H1N1 viral infections. We expect to sell this product principally into the U.S. hospital market. OraSure QuickFlu is manufactured and supplied to us under an agreement with Princeton BioMeditech Corporation.

### **Competitive and Economic Outlook**

Competition in the market for HIV testing is intense and is expected to increase. We believe that our principal competition will come from existing point-of-care rapid blood tests, laboratory-based blood tests, and urine assays or other oral fluid-based tests that may be developed. Our competitors include medical diagnostic companies and specialized biotechnology firms, as well as pharmaceutical companies with biotechnology divisions. Competing rapid blood tests are often sold at a lower price than we charge for our OraQuick® HIV test. This competition can result in lost sales and degradation of the price we can charge for our product (and the resulting profit margin).

Our OraQuick® HCV test is available in Europe and competes against laboratory-based HCV blood tests. Significant sales in Europe have not yet materialized principally because of differences in European healthcare systems compared to our U.S. systems. Unlike the U.S., adoption of rapid point-of-care diagnostics is not widespread in Europe because laboratory testing is entrenched and healthcare systems are structured around centralized testing models. We intend to continue working to build awareness and acceptance of our OraQuick® HCV test in European and other international markets. In non-U.S. countries outside of Europe, we expect the OraQuick® HCV product to compete against other rapid HCV blood tests and laboratory-based tests.

Two factors are likely to impact domestic sales of our OraQuick® HCV test. First, since our test is currently classified by the FDA as moderately complex, we can only sell it to laboratories certified or accredited as meeting the quality and training requirements under CLIA. However, with a CLIA waiver, we would be able to sell our test to many other

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customers that perform CLIA waived tests, such as outreach clinics, community-based organizations and physician offices. Thus, a CLIA waiver will be required for us to deploy the test extensively in both the public health and hospital markets and to enable penetration, with the assistance of our collaborator, Merck, into the physician office market. Second, in the near future, we expect the FDA to approve two new therapeutic treatments for HCV, both of which are reportedly more effective than currently available treatments. We believe the introduction of these new treatments will help drive more widespread awareness and testing for HCV, including with our OraQuick® rapid test.

In the substance abuse testing market, we expect competition for our products to intensify. Other companies have developed, and will continue to develop, competing oral fluid drug testing products. In particular, there are at least two competitors that sell high-throughput fully automated oral fluid drug testing products in unregulated settings in the United States. In addition, we also believe that at least one of these competitors has recently received 510(k) clearance of its product. These products will compete against both our Intercept® products and the high-throughput assays we intend to commercialize jointly with Roche Diagnostics.

Finally, the economic downturn, including disruptions in the capital and credit markets, may continue for the foreseeable future and intensify, and has adversely affected and could continue to adversely affect our financial performance and condition or those of our customers and suppliers. These circumstances could adversely affect our access to liquidity needed to conduct or expand our business or conduct acquisitions or make other discretionary investments. Many of our customers rely on public funding provided by 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, demand for our products may also be adversely affected by the economic downturn.

## **Results of Operations**

### **Three months ended March 31, 2011 compared to March 31, 2010**

Total revenues decreased to \$17.4 million in the first quarter of 2011 from \$17.9 million in the comparable quarter of 2010. Product revenues during the three months ended March 31, 2011 increased 3% when compared to product revenues in the first quarter of 2010. Increased sales in our infectious disease and substance abuse markets were partially offset by lower sales of our cryosurgical systems and insurance risk assessment products. In addition, the higher product revenues were offset by a \$1.0 million reduction in licensing and product development revenues during the quarter.

Revenues derived from products sold to customers outside the U.S. were \$3.2 million and \$3.1 million, or 18% and 17% of total revenues, in the first quarters of 2011 and 2010, 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 operating results.

The table below shows the amount of total revenues (dollars in thousands) generated in each of our principal markets and by licensing and product development activities.



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Market	Three Months Ended March 31,			Percentage of Total Revenues	
	Dollars		%	2011	2010
	2011	2010	Change		
Infectious disease testing	\$ 9,962	\$ 9,481	5%	57%	53%
Substance abuse testing	3,061	2,713	13	18	15
Cryosurgical systems	2,710	2,994	(9)	15	17
Insurance risk assessment	1,317	1,384	(5)	8	7
Product revenues	17,050	16,572	3	98	92
Licensing and product development	364	1,373	(73)	2	8
Total revenues	\$ 17,414	\$ 17,945	(3)%	100%	100%

**Infectious Disease Testing Market**

Sales to the infectious disease testing market increased 5% to \$10.0 million in the first quarter of 2011. OraQuick® HIV sales totaled \$9.6 million and \$9.1 million in the first quarters of 2011 and 2010, respectively.

The table below shows a breakdown of our total OraQuick® HIV revenues (dollars in thousands) during the first quarters of 2011 and 2010.

Market	Three Months Ended March 31,		
	2011	2010	% Change
Domestic	\$ 8,866	\$ 8,733	2%
International	698	324	115
Total OraQuick® HIV revenues	\$ 9,564	\$ 9,057	6%

During the three months ended March 31, 2011, sales of the OraQuick *ADVANCE*® HIV test in the U.S. market increased slightly by 2%, or \$133,000, when compared to the same period of 2010. International sales of our OraQuick® HIV test increased 115% to \$698,000 for the three months ended March 31, 2011 from \$324,000 for the three months ended March 31, 2010. This increase in the international market resulted from higher sales in Asia, Africa and Europe, as certain private and government customers were able to fund purchases.

Sales of our OraSure® oral fluid collection device decreased 23% from \$412,000 in the first quarter of 2010 to \$316,000 in the first quarter of 2011. Some customers who have purchased our OraSure® device for laboratory HIV-1 testing in the past are now electing to purchase our OraQuick *ADVANCE*® test. We believe this is the result of customers recognizing the benefits of rapid HIV testing, especially with oral fluid.

**Substance Abuse Testing Market**

Substance abuse testing revenues increased 13% from \$2.7 million in the first quarter of 2010 to \$3.1 million in the first quarter of 2011 as a result of increased domestic sales of our Intercept® drug testing system.

The table below shows a breakdown of our total Intercept® revenues (dollars in thousands) generated in each market during the first quarters of 2011 and 2010.

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Market	Three Months Ended March 31,		
	2011	2010	% Change
Domestic	\$ 1,877	\$ 1,528	23%
International	519	517	0
Total Intercept® revenues	\$ 2,396	\$ 2,045	17%

Domestic Intercept® revenues increased 23% from \$1.5 million in the first quarter of 2010 to \$1.9 million in the first quarter of 2011. This increase is largely the result of the resumption of more normal ordering patterns by a large laboratory customer. During the first quarter of 2010, our primary drug testing laboratory customer changed its business model by bringing device inventory storage in house. This change in the customer's reassessment of its inventory levels caused a temporary disruption to its ordering patterns during the first quarter of 2010.

International Intercept® revenues for the first quarter of 2011 and 2010 remained essentially flat.

Pursuant to a development agreement with Roche Diagnostics, homogenous fully-automated oral fluid drugs of abuse assays are being developed for use with our Intercept® collection device. The FDA has issued 510(k) clearances on the high throughput assays for PCP, opiates, cocaine and methamphetamines and an application for 510(k) clearance of an amphetamines assay for use with the Intercept® device is currently pending before the FDA. The assays use Roche's technology and will run on various automated analyzers to allow oral fluid samples to be processed with the same efficiency currently achieved with urine-based drug tests. We have also entered into a commercialization agreement with Roche pursuant to which a drug testing system comprised of our Intercept® device and the newly developed homogenous assays will be marketed and sold on a worldwide basis. At least two competitors have developed oral fluid tests suitable for use on fully automated homogeneous assay systems and these assays could represent a significant competitive threat to our Intercept® device and oral fluid microplate business and the assays being developed with Roche.

**Cryosurgical Systems Market**

Sales in the cryosurgical systems market (which includes both the physicians' office and OTC markets) decreased 9% to \$2.7 million in the first quarter of 2011, compared to \$3.0 million in the same period of the prior year.

The table below shows a breakdown of our total cryosurgical systems revenues (dollars in thousands) generated in each market during the first quarters of 2011 and 2010.

Market	Three Months Ended March 31,		
	2011	2010	% Change
Professional domestic	\$ 1,342	\$ 1,210	11%
Professional international	339	270	26
Over-the-counter	1,029	1,514	(32)
Total cryosurgical systems revenues	\$ 2,710	\$ 2,994	(9)%

Domestic physicians' office sales increased 11% or \$132,000 for the first three months of 2011 as compared to the first three months of 2010, as a result of our distribution partner's improved focus on our products and the continued impact of our manufacturer's sales representative organizations. In early 2010, we signed agreements with two manufacturer's sales representative organizations to support sales of our Histofreezer® product in the U.S. Under these arrangements, over 40 additional sales representatives have been working with our physicians' office distributors throughout the United States, which resulted in additional sales growth during the quarter.

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During the three months ended March 31, 2011, sales of Histofreezer<sup>®</sup> in the international market increased 26% as compared to the first quarter of 2010. This increase was largely experienced in the European market as a result of increased pricing and improved economic conditions in some local markets.

Sales of our cryosurgical OTC products during the first quarter of 2011 decreased 32% primarily due to the absence of sales to our Latin America OTC distributor, Genomma. This decrease was partially offset by higher sales to our European OTC distributor, Reckitt Benckiser (formerly, SSL International).

In the first quarter of 2010, Genomma had purchases totaling \$1.1 million. In late 2010, the Mexican government placed limitations on the advertising Genomma could use for our product. In addition, during the first quarter of 2011, Genomma informed us of some changes required by the Brazilian government to our package insert, which have since been made. Both events negatively impacted sales of our product during the first quarter of 2011. The lower Genomma purchases also resulted from the absence of sales to Genomma in the first quarter of 2010 required for the initial commercial launch of our product in Brazil.

Sales to our European OTC distributor Reckitt Benckiser increased \$458,000 during the first quarter of 2011 compared to the first quarter of 2010, largely due to variability in ordering patterns. Our distribution contract with Reckitt Benckiser was subject to an annual renewal at the end of 2010 and has been extended through June 2011. We are currently in negotiations to extend this contract.

## **Insurance Risk Assessment Market**

Sales to the insurance risk assessment market decreased 5% to \$1.3 million in the first quarter of 2011 from \$1.4 million in the first quarter of 2010 due to a decrease in the issuance of new insurance policies.

## **Licensing and Product Development**

Licensing and product development revenues decreased 73% to \$364,000 during the first quarter of 2011 from \$1.4 million during the first quarter of 2010. During the first quarter of 2010, we received a \$1.0 million milestone payment as a result of our achievement of certain regulatory objectives pursuant to our collaboration agreement with Merck for the development and promotion of our OraQuick<sup>®</sup> rapid HCV test in Europe. The remaining licensing revenues for these periods represent royalties received on domestic outsales of Merck's OTC cryosurgical wart removal product, pursuant to our license and settlement agreement executed in January 2008.

## **Gross Margin**

Gross margin in the first quarter of 2011 was 65% compared to 64% for the first quarter of 2010. Margins in the first quarter of 2011 benefited from increased manufacturing efficiencies and improved product mix, partially offset by the decrease in licensing and product development revenues. Gross margins in the first quarter of 2010 had benefitted from the \$1.0 million HCV milestone payment described above.

## **Operating Expenses**

Research and development expenses increased 42% from \$3.1 million in the first quarter of 2010 to \$4.4 million in the same period in 2011, primarily as a result of higher clinical trial costs related to the development of our OraQuick<sup>®</sup> HIV OTC test. This increase was partially offset by lower clinical trial costs related to our OraQuick<sup>®</sup> HCV test.

Sales and marketing expenses decreased 13% to \$4.9 million in the first quarter of 2011 from \$5.7 million in the first quarter of 2010, as a result of lower staffing, recruiting and market research costs.

General and administrative expenses decreased 7% to \$4.5 million in the first quarter of 2011 from \$4.8 million in the same period in 2010. This decrease was primarily attributable to lower consulting and staffing expenses, partially offset by an increase in legal expenses.

**Table of Contents****Income Taxes**

In 2008, we established a full valuation allowance against our total net deferred tax asset. Management has continued to evaluate whether the full valuation is still appropriate. As of March 31, 2011 and 2010, we concluded that the full valuation allowance remained appropriate as the facts and circumstances since establishing the allowance had not changed. As a result, no income tax benefit was recorded in the first quarters of 2011 or 2010.

**Liquidity and Capital Resources**

	March 31, 2011	December 31, 2010
	(In thousands)	
Cash and cash equivalents	\$ 70,544	\$ 73,843
Short-term investments	1,895	1,895
Working capital	76,027	77,808

Our cash, cash equivalents and short-term investments decreased \$3.3 million from \$75.7 million as of December 31, 2010 to \$72.4 million as of March 31, 2011. Our working capital declined as a result of the reduction in our cash, cash equivalents and short-term investments offset by a reduction in accrued expenses associated with the payment of various 2010 year-end accruals.

During the first three months of 2011, we used \$2.0 million in cash to finance our operating activities. Cash used in operating activities resulted from our net loss of \$2.6 million, offset by non-cash stock-based compensation expense of \$973,000, depreciation and amortization of \$829,000, and an increase in our scrap and spoilage reserve of \$117,000. Also contributing to the cash used in operating activities were a \$1.9 million decrease in accrued expenses and other liabilities associated with payment of our 2010 royalty obligations, management incentive bonuses and other accruals and a \$522,000 increase in inventories. Offsetting these uses of cash were cash contributions from a \$352,000 decrease in accounts receivable, \$135,000 decrease in prepaid expenses and other assets as well as a \$606,000 increase in accounts payable.

Net cash used in investing activities of \$882,000 during the first three months of 2011 was a result of purchases of property and equipment.

Net cash used in financing activities was \$367,000 for the three months ended March 31, 2011, primarily as a result of \$125,000 in loan principal repayments and \$825,000 used for the repurchase of common stock related to the vesting of restricted shares offset by \$582,000 of proceeds received from the exercise of stock options.

As of March 31, 2011, we had in place a \$10,000,000 credit facility with Comerica Bank ( Comerica ). Pursuant to the terms of the facility, principal, and interest fixed at 4.15% per annum are payable monthly through June 2011, at which time the remaining unpaid principal balance is payable and the facility will expire. As of March 31, 2011, we had no available borrowings under this credit facility. We are evaluating possible options to address the upcoming expiration of the facility, including refinancing with a new credit facility or other borrowings.

All borrowings from Comerica are collateralized by a first priority security interest in all of our assets, including present and future accounts receivable, chattel paper, contracts and contract rights, equipment and accessories, general intangibles, investments, instruments, inventories, and a mortgage on our three facilities in Bethlehem, Pennsylvania. The Comerica agreement contains certain covenants that set forth minimum requirements for our quick ratio, liquidity, and tangible net worth. We were in full compliance with all covenants as of March 31, 2011. The agreement also restricts our ability to pay dividends, to make certain investments, to incur additional indebtedness, to sell or otherwise dispose of a substantial portion of assets, and to merge or consolidate operations with an unaffiliated entity, without the consent of Comerica.

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The combination of our current cash, cash equivalents and short-term investments is expected to be more than sufficient to fund our operating and capital needs through at least the next twelve months. Our cash requirements, however, may vary materially from those now planned due to many factors, including, but not limited to, the scope and timing of strategic acquisitions, the cost and timing of the expansion of our manufacturing capacity, 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, the timing of market launch of new products, market acceptance of new products, competing technological and market developments, the impact of the ongoing economic downturn and other factors.

### **Summary of Contractual Obligations**

A summary of our obligations to make future payments under contracts existing at December 31, 2010 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, 2010. As of March 31, 2011, 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 financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these 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 bad debts, inventories, investments, intangible assets, income taxes and realization of the related deferred tax assets, revenue recognition, restructuring costs, contingencies and litigation. 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 2010 Annual Report on Form 10-K filed with the SEC. During the first three months of 2011, 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.

The majority of our assets are comprised of cash and cash equivalents and as a result we have little exposure to market risks associated with available-for-sale securities.

In January 2008, we elected to fix the interest rate on our long-term debt at 4.15% until the debt's maturity in June 2011. As a result, we have no exposure to interest rate changes.

As of March 31, 2011, we did not have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. We have operations in Europe and Africa, which are subject to foreign currency fluctuations. Sales denominated in a foreign currency were immaterial as a percentage of our total revenues for the quarter ended March 31, 2011. We do not expect the risk of foreign currency fluctuations to be material to us in the near future.

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**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, 2011. 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, 2011 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, 2011 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

**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, 2010.

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

During the quarter ended March 31, 2011, pursuant to our 2000 Stock Award Plan and in connection with the vesting of restricted shares, we retired 123,995 shares of our Common Stock to satisfy minimum tax withholding obligations at an average price paid per share of \$6.65.

**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 4, 2011

*/s/ Ronald H. Spair*  
Ronald H. Spair

Chief Operating Officer and

Chief Financial Officer

*(Principal Financial Officer)*

Date: May 4, 2011

*/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.