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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 10-Q**

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(Mark One)

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

For the quarterly period ended June 30, 2010.

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

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**ORASURE TECHNOLOGIES, INC.**

(Exact Name of Registrant as Specified in Its Charter)

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**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)

**18015**  
(Zip code)

**(610) 882-1820**

(Registrant's Telephone Number, Including Area Code)

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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

Number of shares of Common Stock, par value \$.000001 per share, outstanding as of August 3, 2010: 46,211,062

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## Item 1. FINANCIAL STATEMENTS

ORASURE TECHNOLOGIES, INC.  
BALANCE SHEETS  
(Unaudited)

	<u>JUNE 30, 2010</u>	<u>DECEMBER 31, 2009</u>
<b>ASSETS</b>		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 72,550,814	\$ 74,933,630
Short-term investments	1,995,000	4,736,730
Accounts receivable, net of allowance for doubtful accounts of \$237,608 and \$256,572	13,021,235	13,693,340
Inventories	8,881,441	8,844,492
Prepaid expenses and other	2,403,289	2,609,518
Total current assets	98,851,779	104,817,710
PROPERTY AND EQUIPMENT, net	19,957,553	20,014,466
PATENTS AND PRODUCT RIGHTS, net	4,137,252	809,252
OTHER ASSETS	987,043	1,349,319
	<u>\$ 123,933,627</u>	<u>\$ 126,990,747</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
CURRENT LIABILITIES:		
Current portion of long-term debt	\$ 8,041,680	\$ 509,761
Accounts payable	3,004,671	3,370,604
Accrued expenses and other	10,796,401	11,502,802
Total current liabilities	21,842,752	15,383,167
LONG-TERM DEBT	—	7,791,679
OTHER LIABILITIES	2,162	8,911
STOCKHOLDERS' EQUITY		
Preferred stock, par value \$.000001, 25,000,000 shares authorized, none issued	—	—
Common stock, par value \$.000001, 120,000,000 shares authorized, 46,211,062 and 45,929,511 shares issued and outstanding	46	46
Additional paid-in capital	240,158,023	239,126,422
Accumulated other comprehensive loss	(232,690)	(230,992)
Accumulated deficit	(137,836,666)	(135,088,486)
Total stockholders' equity	102,088,713	103,806,990
	<u>\$ 123,933,627</u>	<u>\$ 126,990,747</u>

The accompanying notes are an integral part of these statements.

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

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2010</u>	<u>2009</u>	<u>2010</u>	<u>2009</u>
<b>REVENUES:</b>				
Product	\$17,703,803	\$16,748,235	\$34,276,557	\$33,669,437
Licensing and product development	1,514,033	525,326	2,886,803	860,575
	<u>19,217,836</u>	<u>17,273,561</u>	<u>37,163,360</u>	<u>34,530,012</u>
<b>COST OF PRODUCTS SOLD</b>	<u>7,040,201</u>	<u>7,393,657</u>	<u>13,581,663</u>	<u>13,678,036</u>
Gross profit	<u>12,177,635</u>	<u>9,879,904</u>	<u>23,581,697</u>	<u>20,851,976</u>
<b>OPERATING EXPENSES:</b>				
Research and development	3,028,658	2,432,640	6,135,433	5,785,138
Sales and marketing	5,610,352	5,289,032	11,304,696	10,311,797
General and administrative	4,073,941	4,434,679	8,852,584	8,891,730
Impairment of patent and product rights	—	3,028,375	—	3,028,375
	<u>12,712,951</u>	<u>15,184,726</u>	<u>26,292,713</u>	<u>28,017,040</u>
Operating loss	(535,316)	(5,304,822)	(2,711,016)	(7,165,064)
INTEREST EXPENSE	(77,955)	(90,285)	(153,750)	(179,949)
INTEREST INCOME	48,702	239,134	90,818	574,504
FOREIGN CURRENCY GAIN (LOSS)	11,763	(3,719)	25,768	(7,144)
Loss before income taxes	(552,806)	(5,159,692)	(2,748,180)	(6,777,653)
INCOME TAX BENEFIT	—	—	—	—
NET LOSS	<u>\$ (552,806)</u>	<u>\$ (5,159,692)</u>	<u>\$ (2,748,180)</u>	<u>\$ (6,777,653)</u>
<b>LOSS PER SHARE:</b>				
BASIC AND DILUTED	<u>\$ (0.01)</u>	<u>\$ (0.11)</u>	<u>\$ (0.06)</u>	<u>\$ (0.15)</u>
<b>SHARES USED IN COMPUTING LOSS PER SHARE</b>				
BASIC AND DILUTED	<u>46,201,638</u>	<u>45,870,720</u>	<u>46,157,097</u>	<u>45,854,255</u>

The accompanying notes are an integral part of these statements.

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

	<u>Six Months Ended June 30,</u>	
	<u>2010</u>	<u>2009</u>
<b>OPERATING ACTIVITIES:</b>		
Net loss	\$ (2,748,180)	\$ (6,777,653)
Adjustments to reconcile net loss to net cash used in operating activities:		
Impairment of patent and product rights	—	3,028,375
Stock-based compensation	1,696,618	2,093,697
Depreciation and amortization	1,330,672	1,672,784
Reserve for excess and obsolete inventories	(96,664)	(220,971)
Changes in assets and liabilities:		
Accounts receivable	671,602	507,273
Inventories	59,715	2,262,387
Prepaid expenses and other assets	579,636	151,907
Accounts payable	(366,677)	(1,786,392)
Accrued expenses and other liabilities	(4,206,401)	(2,572,764)
Net cash used in operating activities	<u>(3,079,679)</u>	<u>(1,641,357)</u>
<b>INVESTING ACTIVITIES:</b>		
Purchases of short-term investments	—	(5,986,000)
Proceeds from maturities and redemptions of short-term investments	2,741,000	32,713,000
Purchases of property and equipment	<u>(1,112,611)</u>	<u>(741,184)</u>
Net cash provided by investing activities	<u>1,628,389</u>	<u>25,985,816</u>
<b>FINANCING ACTIVITIES:</b>		
Repayments of long-term debt	(259,760)	(278,804)
Proceeds from issuance of common stock	5,455	17,898
Withholding and retirement of common stock	(677,221)	(320,905)
Purchase and retirement of common stock	<u>—</u>	<u>(308,605)</u>
Net cash used in financing activities	<u>(931,526)</u>	<u>(890,416)</u>
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(2,382,816)	23,454,043
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	<u>74,933,630</u>	<u>39,565,218</u>
CASH AND CASH EQUIVALENTS, END OF PERIOD	<u>\$72,550,814</u>	<u>\$63,019,261</u>
<b>SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:</b>		
Cash paid (received) for:		
Interest	\$ 171,825	\$ 182,840
Income taxes	\$ (585,893)	\$ 32,500

The accompanying notes are an integral part of these statements.

**ORASURE TECHNOLOGIES, INC.**  
**Notes to 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 *in vitro* diagnostic tests that are used on other specimen types, and other medical devices used for the removal of warts and other 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 the United States, Canada, Europe, Mexico and Australia.

The current economic downturn, including disruptions in the capital and credit markets as well as in state and local governmental funding, may continue for the foreseeable future 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 current 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, 2009. Results of operations for the three and six months ended June 30, 2010 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. 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 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 June 30, 2010 and December 31, 2009, 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 and corporate bonds, all 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 reported in stockholders' equity as a component of accumulated other comprehensive loss.

The following is a summary of our available-for-sale securities at June 30, 2010 and December 31, 2009:

	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Fair Value</u>
<b>June 30, 2010</b>				
Certificates of deposit	\$1,995,000	\$ —	\$ —	\$1,995,000
<b>Total available-for-sale securities</b>	<u>\$1,995,000</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$1,995,000</u>
<b>December 31, 2009</b>				
Certificates of deposit	\$3,986,000	\$ —	\$ —	\$3,986,000
Corporate bonds	750,278	452	—	750,730
<b>Total available-for-sale securities</b>	<u>\$4,736,278</u>	<u>\$ 452</u>	<u>\$ —</u>	<u>\$4,736,730</u>
<b>At June 30, 2010, maturities of our available-for-sale securities were as follows:</b>				
Less than one year	\$1,995,000	\$ —	\$ —	\$1,995,000
One to two years	—	—	—	—
<b>Total available-for-sale securities</b>	<u>\$1,995,000</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$1,995,000</u>

**Fair Value of Financial Instruments.** As of June 30, 2010, 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 instruments, which do not have readily ascertainable market values, approximate their fair values, given that the interest rates on outstanding borrowings approximate 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.

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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:

	<u>June 30,</u> <u>2010</u>	<u>December 31,</u> <u>2009</u>
Raw materials	\$4,967,968	\$4,911,570
Work in process	326,438	334,452
Finished goods	3,587,035	3,598,470
	<u>\$8,881,441</u>	<u>\$8,844,492</u>

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 June 30, 2010 and December 31, 2009 was \$18,884,881 and \$17,764,364, 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 their estimated useful lives of three to ten years. Accumulated amortization of patents and product rights as of June 30, 2010 and December 31, 2009 was \$5,311,368 and \$5,139,368, 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 and return rights granted to retail customers for our domestic cryosurgical wart removal product.

Historically, returns arising from warranty issues have been infrequent and immaterial. Accordingly, we expense warranty returns as incurred. For our cryosurgical product sold in the retail market, a provision for estimated product returns is recorded as a reduction of revenue in the same period in which the revenue is recognized. In addition, revenue from retail sales is also recorded net of promotional, advertising, and slotting allowances granted to the retail trade.

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.

Up-front licensing fees are deferred and recognized ratably over the related license period. Product development revenues are recognized over the period in which the related product development efforts are performed. Amounts received prior to the performance of product development efforts are recorded as deferred revenues. Grant revenue is recognized as the related work is performed and costs are incurred. 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.



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**Significant Customer Concentration.** The Company had no significant concentrations in accounts receivable as of June 30, 2010 or in revenues for both the three and six months ended June 30, 2010 and 2009. As of December 31, 2009, one of our customers, National Aids Control Program, accounted for 11% 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. As a result of our net losses for the three month periods ended June 30, 2010 and 2009, outstanding common stock options and unvested restricted stock, representing 5,284,535 and 6,079,154 shares, respectively, were excluded from the computation of diluted loss per share, as their inclusion would have been anti-dilutive. For the six months ended June 30, 2010 and 2009, outstanding common stock options and unvested restricted stock, representing 5,364,116 and 6,122,032 shares, respectively, 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 at June 30, 2010 and December 31, 2009 consisted of currency translation adjustments and net unrealized losses on short-term investments. Comprehensive loss was \$554,841 and \$5,155,437 for the three months ended June 30, 2010 and 2009, respectively, and \$2,749,878 and \$6,729,569 for the six months ended June 30, 2010 and 2009, respectively.

**Recent Accounting Pronouncements.** In April 2010, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2010-17, "Revenue Recognition – Milestone Method," which amended guidance on the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. A vendor can recognize consideration that is contingent upon achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone meets all criteria to be considered substantive. The amendments in this ASU are effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. Early adoption is permitted. Adoption of this ASU is not expected to have a material impact on our financial statements.

### **3. Patents and Product Rights**

In August 2005, we entered into a license agreement with third parties, pursuant to which we have been granted a limited, personal, non-transferable, non-exclusive license related to certain Hepatitis C Virus ("HCV") patents held by such parties. During the first quarter of 2010, we achieved a milestone under this agreement and have accrued and capitalized a \$1,000,000 payment. Commencing in April 2010, this payment will be amortized on a straight-line basis over ten years, which represents the expected life of the product.

During the second quarter of 2010, we achieved another milestone under this agreement and have accrued and capitalized a \$2,500,000 payment. Commencing in July 2010, this payment will be amortized on a straight line basis over ten years, which represents the expected life of the product. Under the

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terms of the license agreement, we will also be required to pay additional license fees of up to \$1,000,000, upon the achievement of specific development and/or commercial milestones.

#### 4. Prepaid Expenses and Other Noncurrent Assets

In January 2010, we entered into an agreement with the supplier of HIV peptides used in the manufacture of our OraQuick HIV test. This agreement was executed in connection with the supplier's bankruptcy and terminated our obligation to exclusively purchase peptides from the supplier and to pay royalties on worldwide sales of our OraQuick® tests. Pursuant to this agreement, we made a one-time payment of \$2.1 million to the supplier in full consideration of the termination of the original agreement with this supplier and satisfaction of all obligations, including our royalty obligations. We also received a fully paid-up worldwide, non-exclusive, non-transferable license to the supplier's patent rights related to the peptides which expires on July 8, 2011. We recorded the payment, net of the \$1,379,732 in royalties previously accrued, as prepaid royalties, which will be expensed in relation to sales of our OraQuick® HIV test through June 30, 2011.

#### 5. 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 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 June 30, 2010 and 2009 was \$2.77 and \$1.55 per share, respectively. The weighted average grant date fair value of stock options granted during the six months ended June 30, 2010 and 2009 was \$2.27 and \$1.19 per share, respectively.

Total compensation cost related to stock options for the three months ended June 30, 2010 and 2009 was \$200,377 and \$295,144, respectively, of which \$12,967 and \$5,388 was capitalized into inventory during the quarters ended June 30, 2010 and 2009, respectively. The amounts recognized in cost of products sold for amounts previously capitalized were \$12,042 and \$27,171 for the three months ended June 30, 2010 and 2009, respectively. Total compensation cost related to stock options for the six months ended June 30, 2010 and 2009 was \$475,619 and \$697,805, respectively, of which \$26,774 and \$37,407 was capitalized into inventory during the six months ended June 30, 2010 and 2009, respectively. The amounts recognized in cost of products sold for amounts previously capitalized were \$31,988 and \$94,002 for the six months ended June 30, 2010 and 2009, respectively.

The following table summarizes the stock option activity for the six months ended June 30, 2010:

	<u>Options</u>
Outstanding on January 1, 2010	5,431,665
Granted	674,230
Exercised	(1,327)
Forfeited	(230,352)
Outstanding on June 30, 2010	<u>5,874,216</u>

As of June 30, 2010, there was \$2,295,310 of unrecognized compensation expense related to unvested option awards that is expected to be recognized over a weighted average period of 2.0 years.

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Net cash proceeds from the exercise of stock options were \$5,455 and \$17,898 for the six months ended June 30, 2010 and 2009, respectively. 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 these periods.

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 six months ended June 30, 2010, we granted 454,715 restricted shares of our common stock, with a weighted average grant date fair value of \$5.19 per share, to certain key officers, members of management and outside directors. Compensation cost of \$604,869 and \$661,448 related to restricted shares was recognized during the three months ended June 30, 2010 and 2009, respectively. Compensation cost of \$1,221,000 and \$1,395,892 related to restricted shares was recognized during the six months ended June 30, 2010 and 2009, respectively.

The following table summarizes restricted stock award activity for the six months ended June 30, 2010:

	<u>Shares</u>
Issued and unvested, January 1, 2010	819,877
Granted	454,715
Vested	(408,849)
Forfeited	(45,893)
Issued and unvested, June 30, 2010	<u>819,850</u>

As of June 30, 2010, there was \$3,433,764 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 six months ended June 30, 2010 and 2009, 128,625 and 111,043 shares, respectively, with aggregate values of \$675,489 and \$320,905, respectively, were withheld and retired in satisfaction of minimum tax withholding obligations.

## **6. Share Repurchase Program**

On August 5, 2008, our Board of Directors approved a share repurchase program pursuant to which we are permitted to acquire up to \$25 million of our outstanding common shares. During the six months ended June 30, 2009, we purchased and retired 108,293 shares of our common stock at an average price of \$2.85 per share. Accordingly, we recorded a \$308,605 reduction to additional paid-in capital during the six month period ended June 30, 2009. No such purchases were made during the six months ended June 30, 2010.

[Table of Contents](#)**7. Accrued Expenses**

	<u>June 30, 2010</u>	<u>December 31, 2009</u>
Payroll and related benefits	\$ 2,674,892	\$ 4,867,716
Royalties	1,743,025	3,394,991
Deferred revenue	1,110,939	1,618,798
Licensing fee	3,500,000	—
Professional fees	666,583	290,208
Clinical research obligations	12,370	658,605
Other	1,088,592	672,484
	<u>\$10,796,401</u>	<u>\$ 11,502,802</u>

Deferred revenue at June 30, 2010 and December 31, 2009 included customer prepayments of \$1,046,039 and \$1,501,598, respectively.

**8. 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):

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2010</u>	<u>2009</u>	<u>2010</u>	<u>2009</u>
United States	\$16,457	\$13,848	\$31,325	\$28,686
Europe	1,852	1,872	3,194	3,372
Other regions	909	1,554	2,644	2,472
	<u>\$19,218</u>	<u>\$17,274</u>	<u>\$37,163</u>	<u>\$34,530</u>

**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 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; continued bulk purchases by customers, including governmental agencies, and the ability to fully deploy those purchases in a timely manner; 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, 2009, 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

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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 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 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 and dignified nature, and cost effectiveness, our oral fluid tests represent a very competitive alternative to the more traditional testing methods in the diagnostic marketplace.

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 SSL International plc ("SSL") 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® HIV-1/2 test to the U.S. physician office market and our Intercept® and OraSure® product lines are sold by several laboratory distributors. We use distributors to sell our Histofreezer® product into the domestic and international physician office markets and we are engaging distributors to sell our OraQuick® 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® HIV-1/2 test, our OraSure® 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.

### **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 price competition can result in lost sales and degradation of the price we can charge for our product.

Our OraQuick® HCV test that is now available in Europe is expected to compete against laboratory-based HCV blood tests. In non-U.S. countries outside of Europe, we expect this product to compete against other rapid HCV blood tests in addition to the laboratory-based tests. We have recently received FDA approval for use of the OraQuick® HCV test with venous whole blood specimens, and we expect this test to compete against laboratory-based HCV blood tests in the U.S.

The current 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

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investments. Some 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.

### **Current Financial Results**

During the six months ended June 30, 2010, our total revenues were \$37.2 million, which represents an 8% increase from the same period in 2009. Our 2010 revenues include \$2.0 million in milestone payments received under the terms of our collaboration agreement with Merck & Co., Inc. (formerly called Schering-Plough) (“Merck”) for the development and promotion of our OraQuick® rapid HCV test. In comparison to 2010, our 2009 revenues were negatively impacted by a manufacturing issue related to our OraQuick ADVANCE® rapid HIV-1/2 test, which was resolved during the third quarter of 2009. Our net loss for the six months ended June 30, 2010 was \$2.7 million or \$0.06 per share, compared to a net loss of \$6.8 million or \$0.15 per share for the six months ended June 30, 2009. The net loss for the first six months of 2009 included a \$3.0 million pre-tax charge for the impairment of certain patents and product rights.

Cash flow used in operating activities for the six months ended June 30, 2010 was \$3.1 million compared to the \$1.6 million used in operating activities for the six months ended June 30, 2009. As of June 30, 2010, we had \$74.5 million in cash, cash equivalents and short-term investments, compared to \$79.7 million at December 31, 2009.

### **Recent Developments**

#### **OraQuick® HCV Test**

In April 2010, we formally launched the commercialization of our OraQuick® rapid HCV antibody test in Europe at a meeting of the European Association for the Study of the Liver. We have now begun selling the OraQuick® HCV test internationally, and we are currently pursuing additional registrations in specific foreign countries where required. Our initial focus is on finding distributors and building awareness and acceptance for this product.

In June 2010, our OraQuick® HCV test received FDA approval for use in venous whole blood specimens, making it the first rapid HCV test approved by the FDA. We formally launched the commercialization of this product at the annual meeting of the American Association of Clinical Chemistry in July 2010 and we are actively selling this product to customers in the U.S.

We have continued our efforts to obtain FDA approval of additional applications for our OraQuick® HCV test. As previously disclosed, the FDA has required us to conduct additional clinical studies in support of a premarket approval (“PMA”) application for use of the OraQuick® HCV test with fingerstick whole blood and oral fluid specimens. We completed the studies and were prepared to submit a PMA supplement seeking approval of both claims once the venous whole blood claim was approved. In advance of submitting the PMA supplement, and in conjunction with discussions related to the CLIA (Clinical Laboratory Improvement Amendments of 1988) waiver protocols for the product, we shared our additional clinical data for fingerstick whole blood and oral fluid with the FDA. The FDA has recently provided us with feedback on this data.

The FDA’s primary comments related to the lower sensitivity of the OraQuick® HCV test for oral fluid and fingerstick whole blood when compared to venous whole blood. As a result of these comments, we have decided to separate the PMA submissions for the fingerstick whole blood and oral fluid claims. A separate PMA supplement was sent to the FDA for fingerstick whole blood in late July 2010.

We still intend to pursue approval of an oral fluid claim for our OraQuick® HCV test. However, the filing of a PMA supplement for oral fluid has been delayed pending additional discussions with the FDA. We believe it is likely that more clinical data will be needed to support our oral fluid submission.

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### OraQuick® HIV Test

During the second quarter, the FDA approved a dating extension for our OraQuick *ADVANCE*® HIV-1/2 test from 12 to 18 months. We also received approval from our notified body to extend dating to 18 months in Europe. As a result, we will soon be selling our OraQuick® HIV product with 18-month dating both in the U.S. and internationally. Real time stability studies are still in process for this product and, assuming the product continues to meet our stability criteria, we expect to seek approval of further shelf life extensions in the future.

In addition, the automated manufacturing equipment we installed in our Bethlehem, Pennsylvania facilities has now been validated and approved by the FDA for use in the manufacture of our OraQuick *ADVANCE*® HIV test. This equipment will enable us to produce larger quantities of this product at lower cost.

### Results of Operations

#### Three months ended June 30, 2010 compared to June 30, 2009

Total revenues increased 11% to \$19.2 million in the second quarter of 2010 from \$17.3 million in the comparable quarter of 2009 with sales increases experienced across all product lines. Revenues derived from products sold to customers outside the U.S. were \$2.8 million and \$3.4 million, or 14% and 20% of total revenues, in the second quarters of 2010 and 2009, 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.

Market	Three Months Ended June 30,				
	Dollars		% Change	Percentage of Total Revenues	
	2010	2009		2010	2009
Infectious disease testing	\$ 9,974	\$ 9,417	6%	52%	54%
Substance abuse testing	3,052	2,932	4	16	17
Cryosurgical systems	3,120	2,901	8	16	17
Insurance risk assessment	1,558	1,499	4	8	9
Product revenues	17,704	16,749	6	92	97
Licensing and product development	1,514	525	188	8	3
Total revenues	<u>\$19,218</u>	<u>\$17,274</u>	11%	<u>100%</u>	<u>100%</u>

#### Infectious Disease Testing Market

Sales to the infectious disease testing market increased 6% to \$10.0 million in the second quarter of 2010. OraQuick® HIV sales totaled \$9.6 million and \$8.8 million in the second quarters of 2010 and 2009, respectively. Sales of our OraSure® oral fluid collection device totaled \$409,000 and \$630,000 in the second quarters of 2010 and 2009, respectively.

As previously disclosed, an increasing number of our public health customers are supplying hospitals with OraQuick *ADVANCE*® HIV tests purchased from us. This is a positive development as it indicates increased support of hospital testing initiatives by public health agencies. However, this overlap is making it difficult to separately track OraQuick® sales into these markets. Since this trend is likely to continue, we are now reporting public health and



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hospitals sales of our OraQuick *ADVANCE*<sup>®</sup> HIV-1/2 test in the U.S. as a combined domestic market. Prior year amounts have been reclassified to conform to the current presentation.

The table below shows a breakdown of our total OraQuick<sup>®</sup> revenues (dollars in thousands) during the second quarters of 2010 and 2009.

<u>Market</u>	<u>Three Months Ended June 30,</u>		
	<u>2010</u>	<u>2009</u>	<u>% Change</u>
Domestic	\$9,248	\$8,291	12%
International	317	496	(36)
Total OraQuick <sup>®</sup> revenues	<u>\$9,565</u>	<u>\$8,787</u>	9%

During the three months ended June 30, 2010, sales of the OraQuick *ADVANCE*<sup>®</sup> HIV test in the U.S. market increased 12%, or \$957,000, when compared to sales reported in the same period of 2009. In the second quarter of 2009, however, we experienced inventory shortages as a result of an issue related to the manufacturing our OraQuick *ADVANCE*<sup>®</sup> test. This issue was corrected during the third quarter of 2009, but resulted in a \$2.2 million backlog of orders for OraQuick *ADVANCE*<sup>®</sup> from our domestic customers as of June 30, 2009. Had this revenue been recognized in the second quarter of 2009, we would have experienced a decrease in sales of our OraQuick *ADVANCE*<sup>®</sup> HIV test during the second quarter of 2010 compared to the same period in 2009 as a result of decreased volume resulting from reduced public health funding by state and local governments and lower average selling prices.

International sales of our OraQuick<sup>®</sup> HIV test decreased 36% to \$317,000 for the three months ended June 30, 2010 from \$496,000 for the three months ended June 30, 2009. This decrease resulted from customer losses caused by price competition, changes in government testing algorithms, and the non-recurrence of one-time customer orders from the prior year period.

Sales of our OraSure<sup>®</sup> oral fluid collection device decreased 35% from \$630,000 in the second quarter of 2009 to \$409,000 in the second quarter of 2010 largely due to reduced public health funding by state and local governments. In addition, some customers who have purchased our OraSure<sup>®</sup> device for laboratory HIV-1 testing in the past are now electing to purchase our OraQuick *ADVANCE*<sup>®</sup> test. We believe this is the result of customers recognizing the benefits of rapid HIV testing, especially with oral fluid. OraSure<sup>®</sup> sales are expected to continue to decline during the remainder of 2010.

### **Substance Abuse Testing Market**

Substance abuse testing revenues increased 4% from \$2.9 million in the second quarter of 2009 to \$3.1 million in the second quarter of 2010 as increased domestic sales of our Intercept<sup>®</sup> drug testing system were partially offset by lower Intercept<sup>®</sup> sales in international markets.

As a result of declining economic conditions and consolidations in the laboratory industry, several of our laboratory testing partners are performing substance abuse testing for both the criminal justice and workplace testing markets. As such, it is becoming increasingly difficult to track Intercept<sup>®</sup> revenues separately in these markets. We expect this trend to continue and, accordingly, we are now reporting Intercept<sup>®</sup> sales to the U.S. criminal justice and workplace testing markets on a combined basis. Prior year amounts have been reclassified to conform to the current presentation.

The table below shows a breakdown of our total Intercept<sup>®</sup> revenues (dollars in thousands) generated in each market during the second quarters of 2010 and 2009.

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<u>Market</u>	<u>Three Months Ended June 30,</u>		
	<u>2010</u>	<u>2009</u>	<u>% Change</u>
Domestic	\$1,949	\$1,771	10%
International	443	523	(15)
Total Intercept® revenues	<u>\$2,392</u>	<u>\$2,294</u>	4%

Domestic Intercept® revenues increased 10% from \$1.8 million in the second quarter of 2009 to \$1.9 million in the second quarter of 2010. During the second quarter of 2010, two of our drug testing laboratory customers increased their Intercept® assay purchases from us as a result of changes in their sample processing and assay purchasing methods. Another large laboratory customer also purchased additional devices from us during the second quarter, in excess of its normal ordering pattern.

International Intercept® revenues for the second quarter of 2010 decreased approximately \$80,000 primarily due to variability in ordering patterns experienced with our largest distributor.

We do not expect renewed growth in Intercept® sales until employment conditions in the U.S. recover and overall economic conditions improve. In addition, the microplate oral fluid drug assays, which are sold for use with the Intercept® collection device, have come under increasing competitive pressure from “home-brew” assays developed internally by our laboratory customers and compete with urine-based homogeneous assays that are run on fully-automated, random access analyzers. We believe our competitors are developing oral fluid tests suitable for use on these fully automated homogeneous assay systems and these assays, if and when they are developed and commercialized, could represent a significant competitive threat to our oral fluid microplate business. 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. Applications for 510(k) clearance of several of these assays for use with the Intercept® device are 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.

### **Cryosurgical Systems Market**

Sales in the cryosurgical systems market (which includes both the physicians’ office and OTC markets) increased 8% to \$3.1 million in the second quarter of 2010, compared to \$2.9 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 second quarters of 2010 and 2009.

<u>Market</u>	<u>Three Months Ended June 30,</u>		
	<u>2010</u>	<u>2009</u>	<u>% Change</u>
Professional domestic	\$1,575	\$ 807	95%
Professional international	270	636	(58)
Over-the-counter	<u>1,275</u>	<u>1,458</u>	(13)
Total cryosurgical systems revenues	<u>\$3,120</u>	<u>\$2,901</u>	8%

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The overall increase in cryosurgical systems revenues was primarily the result of a \$768,000 increase in sales into the domestic professional market due to the continued elimination of the diversion of less expensive international Histofreezer® product into the domestic market, the introduction of a newly reconfigured Histofreezer® product line in the U.S., an overall price increase implemented in April 2010, and the impact of our new manufacturer's sales representative organizations. As previously described, in early 2010, we signed agreements with two manufacturers' 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, resulting in additional sales growth during the second quarter.

During the three months ended June 30, 2010, sales of Histofreezer® in the international market decreased 58% as compared to the second quarter of 2009. This decline was largely experienced in the European market as a result of decreased sales into France and Germany and in the Latin American market where we lost our largest distributor due to a corporate acquisition.

In the European professional marketplace, healthcare reimbursement has been or may be reduced or eliminated for certain treatment types, including treatments for common warts. The reduction in or elimination of reimbursement for wart treatments has affected international sales of our Histofreezer® product. We are also seeing evidence that sales of OTC cryosurgical products may reduce the number of individuals that will seek to obtain treatment of their warts by a physician, which in turn could negatively affect sales of our Histofreezer® product in the domestic professional market. However, it is not possible at this time to estimate the likelihood or financial impact of these changes.

Sales of our cryosurgical OTC products decreased 13% primarily due to lower sales to our Latin American OTC distributor, Genomma, which were partially offset by an increase in sales to our European OTC distributor, SSL.

During 2008, Genomma ceased to purchase our OTC product in response to higher product returns from retailers in Mexico who overstocked during the winter months of 2007. Throughout 2008 and early in 2009, Genomma worked through its excess inventory levels and resumed purchasing product during the second quarter of 2009. Second quarter 2009 sales to Genomma were \$596,000 compared to \$304,000 for the second quarter of 2010.

Sales to SSL increased to \$959,000 in the second quarter of 2010 from \$740,000 in the comparable period of 2009, largely due to variability in SSL's ordering patterns.

### **Insurance Risk Assessment Market**

Sales to the insurance risk assessment market increased 4% to \$1.6 million in the second quarter of 2010 from \$1.5 million in the second quarter of 2009.

### **Licensing and Product Development**

Licensing and product development revenues increased to \$1.5 million during the second quarter of 2010 from \$525,000 during the second quarter of 2009. This increase was primarily due to a \$1.0 million milestone payment received as a result of our achievement of certain commercial objectives pursuant to our collaboration agreement with Merck for the development and promotion of an OraQuick® rapid HCV test. The remaining licensing revenues for the second quarters of both 2010 and 2009 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 second quarter of 2010 was 63% compared to 57% for the second quarter of 2009. Gross margin in the second quarter benefitted from higher licensing and product development revenues, a more favorable product revenue mix and an improvement in scrap and spoilage levels when compared to the second quarter of 2009. These benefits to gross margin were partially offset by an increase in unabsorbed overhead costs due to lower product production and severance costs related to a reduction in force during the second quarter of 2010.

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### **Operating Expenses**

Research and development expenses increased 25% from \$2.4 million in the second quarter of 2009 to \$3.0 million in the same period in 2010, primarily as a result of increased staffing costs, increased laboratory supplies expense related to the development of new infectious disease products, and increased clinical trial costs related to the development of our OraQuick® HIV OTC test. These increases were partially offset by lower clinical trial costs related to the ongoing clinical development of our OraQuick® HCV test. We expect our research and development costs will increase during the remaining six months of 2010 as a result of anticipated clinical work in support of our HIV OTC and OraQuick® HCV products, as well as the development of other new products.

Sales and marketing expenses increased 6% to \$5.6 million in the second quarter of 2010 from \$5.3 million in the second quarter of 2009, as a result of increased consulting and advertising costs partially offset by decreased staffing expenses.

General and administrative expenses decreased 8% to \$4.1 million in the second quarter of 2010 from \$4.4 million in the same period in 2009. This decrease was primarily attributed to lower legal expenses partially offset by an increase in staffing costs.

During the second quarter of 2009, we recorded an impairment charge of \$3.0 million related to license payments for certain HCV patents, which we previously capitalized. Management's intent in capitalizing these payments was to utilize this license in certain developing countries for the marketing and sale of an existing rapid HCV test supplied by a third party manufacturer. However, we were unable to penetrate this international marketplace with the third-party's rapid HCV test. Furthermore, given the impact of the current global recession and the deteriorating status of certain third-world economies, we no longer believed that we would be successful in selling a third-party's rapid HCV test in the foreseeable future. Accordingly, we recorded a non-cash impairment charge for the remaining unamortized book value of the patent and product rights in the quarter ended June 30, 2009.

### **Interest Income/Expense**

Interest expense decreased to \$78,000 in the second quarter of 2010 from \$90,000 in the second quarter of 2009 as a result of lower average debt balances. Interest income decreased to \$49,000 in the second quarter of 2010 from \$239,000 in the second quarter of 2009, primarily as a result of lower yields earned on our investment portfolio, lower investment balances and an overall conservative, shorter-term investment approach.

### **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. At the end of the three months ended June 30, 2010, we concluded that the full valuation allowance still remains appropriate as the facts and circumstances during 2010 have not changed. As a result, no income tax benefit was recorded in the second quarters of 2010 or 2009.

### **Six Months Ended June 30, 2010 Compared to June 30, 2009**

Total revenues increased 8% to \$37.2 million for the first six months of 2010 from \$34.5 million in the comparable period in 2009. Increased sales in the cryosurgical systems and substance abuse testing markets and higher licensing and product development revenues were partially offset by lower revenues from our infectious disease testing and insurance risk assessment businesses. Revenues derived from products sold to customers outside the U.S. were \$5.8 million, or 16% of total revenues, during the first six months of 2010 and \$7.2 million, or 17% of total revenues, during the first six months of 2009. 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	Six Months Ended June 30,				
	Dollars			Percentage of Total Revenues	
	2010	2009	% Change	2010	2009
Infectious disease testing	\$19,454	\$19,867	(2)%	52%	58%
Substance abuse testing	5,766	5,622	3	16	16
Cryosurgical systems	6,114	5,046	21	16	15
Insurance risk assessment	2,942	3,134	(6)	8	9
Product revenues	34,276	33,669	2	92	98
Licensing and product development	2,887	861	235	8	2
Total revenues	<u>\$37,163</u>	<u>\$34,530</u>	8%	<u>100%</u>	<u>100%</u>

**Infectious Disease Testing Market**

Sales to the infectious disease testing market decreased 2% to \$19.5 million in the first six months of 2010. OraQuick® HIV sales totaled \$18.6 million in the first six months of 2010 and \$18.5 million for the first six months of 2009. Sales of our OraSure® oral fluid collection device totaled \$820,000 and \$1.3 million in the first six months of 2010 and 2009, respectively.

As previously disclosed, an increasing number of our public health customers are supplying hospitals with OraQuick ADVANCE® HIV tests purchased from us. This is a positive development as it indicates increased support of hospital testing initiatives by public health agencies. However, this overlap is making it more difficult to separately track OraQuick® sales into these markets. Since this trend is likely to continue, we are now reporting public health and hospitals sales of our OraQuick ADVANCE® HIV-1/2 test in the U.S. as a combined domestic market. Prior year amounts have been reclassified to conform to the current presentation.

The table below shows a breakdown of our total OraQuick® revenues (dollars in thousands) during the first six months of 2010 and 2009.

Market	Six Months Ended June 30,		
	2010	2009	% Change
Domestic	\$17,979	\$17,591	2%
International	655	953	(31)
Total OraQuick® revenues	<u>\$18,634</u>	<u>\$18,544</u>	0%

During the first half of 2010, sales of the OraQuick ADVANCE® HIV test in the U.S. market increased 2%, or \$388,000, when compared to the same period in 2009. In the first half of 2009, we experienced inventory shortages as a result of an issue related to the manufacturing of our OraQuick ADVANCE® test. This issue was corrected during the third quarter of 2009, but resulted in a \$2.2 million backlog of orders for OraQuick ADVANCE® from our domestic customers as of June 30, 2009. Had this revenue been recognized in the second quarter of 2009, we would have experienced a decrease in sales of our OraQuick ADVANCE® test during the first six months of 2010 compared to the first six months of 2009 as a result of decreased volume resulting from reduced public health funding by state and local governments and lower average selling prices.

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International sales of our OraQuick® HIV test decreased 31% to \$655,000 for the six months ended June 30, 2010 from \$953,000 for the six months ended June 30, 2009. This decrease resulted from customer losses caused by price competition, changes in government testing algorithms, and the non-recurrence of one-time customer orders from the prior year period.

Sales of our OraSure® oral fluid collection device decreased 38% from \$1.3 million in the first half of 2009 to \$820,000 in the first half of 2010 largely due to reduced public health funding by state and local governments. In addition, 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 fluids. OraSure® sales are expected to continue to decline during the remainder of 2010.

### **Substance Abuse Testing Market**

Substance abuse testing revenues increased 3% to \$5.8 million in the first half of 2010 from \$5.6 million in the first half of 2009 due to increased sales of our Intercept® drug testing system and Q.E.D.® rapid point-of-care saliva alcohol test.

As a result of declining economic conditions and consolidations in the laboratory industry, several of our laboratory testing partners are performing substance abuse testing for both the criminal justice and workplace testing markets. As such, it is becoming increasingly difficult to track Intercept® revenues separately in these markets. We expect this trend to continue and, accordingly, we are now reporting Intercept® sales to the U.S. criminal justice and workplace testing markets on a combined basis. Prior year amounts have been reclassified to conform to the current presentation.

The table below shows a breakdown of our total Intercept® revenues (dollars in thousands) generated in each market during the first six months of 2010 and 2009.

<u>Market</u>	<u>Six Months Ended June 30,</u>		
	<u>2010</u>	<u>2009</u>	<u>% Change</u>
Domestic	\$3,477	\$3,348	4%
International	960	1,045	(8)
Total Intercept® revenues	<u>\$4,437</u>	<u>\$4,393</u>	1%

Domestic Intercept® revenues increased 4% from \$3.3 million in the first half of 2009 to \$3.5 million in the first half of 2010 due to the ordering patterns of some of our larger laboratory drug testing customers, growth in sales of pain management assays, and the conversion of some of our smaller customers from rapid urine products to our oral fluid device.

International Intercept® revenues for the second half of 2010 decreased approximately \$85,000 due to variability in ordering patterns experienced with our largest distributor.

We do not expect renewed growth in Intercept® sales until employment conditions in the U.S. recover and overall economic conditions improve. In addition, the microplate oral fluid drug assays, which are sold for use with the Intercept® collection device, have come under increasing competitive pressure from “home-brew” assays developed internally by our laboratory customers and compete with urine-based homogeneous assays that are run on fully-automated, random access analyzers. We believe our competitors are developing oral fluid tests suitable for use on these fully automated homogeneous assay systems and these assays, if and when they are developed and commercialized, could represent a significant competitive threat to our oral fluid microplate business. Pursuant to a development agreement with Roche Diagnostics, homogenous fully-automated oral fluid drugs of abuse assays are

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being developed for use with our Intercept® collection device. Applications for 510(k) clearance of several of these assays for use with the Intercept® device are 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.

### **Cryosurgical Systems Market**

Sales in the cryosurgical systems market (which includes both the physicians' office and OTC markets) increased 21% to \$6.1 million in the first six months of 2010, compared to \$5.0 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 six months of 2010 and 2009.

<u>Market</u>	<u>Six Months Ended June 30.</u>		
	<u>2010</u>	<u>2009</u>	<u>% Change</u>
Professional domestic	\$2,787	\$1,749	59%
Professional international	539	1,265	(57)
Over-the-counter	<u>2,788</u>	<u>2,032</u>	37
Total cryosurgical systems revenues	<u>\$6,114</u>	<u>\$5,046</u>	21%

Sales of our Histofreezer® product to physicians' offices in the United States increased 59% to \$2.8 million in the first half of 2010, compared to \$1.7 million in 2009, largely due to increased purchases early in 2010 by our distributors in anticipation of price increases implemented in January and April 2010, and the continued elimination of the diversion of less expensive international Histofreezer® product into the domestic market. In addition, the introduction of our newly reconfigured Histofreezer® product line in the domestic market also contributed to the increase in revenues experienced in the current six-month period. Also in early 2010, we signed agreements with two manufacturers' 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, resulting in additional domestic Histofreezer® sales growth during the first half of this year.

Sales of Histofreezer® in the international market decreased 57% in the first half of 2010, as compared to the first half of 2009. This decline was largely due to a discontinuance of sales to certain foreign distributors that we believe were diverting product to the U.S. market. The selling prices for our Histofreezer® product are lower in some foreign countries due to differences in the healthcare systems in those countries. During 2008 and early 2009, some distributors in these countries purchased English-labeled Histofreezer® product and resold it into the domestic distribution network to distributors who employ alternate sourcing programs. We also experienced a decline in the European market as a result of decreased sales into France and Germany and into the Latin American market where we lost our largest distributor due to a corporate acquisition.

In the European professional marketplace, healthcare reimbursement has been or may be reduced or eliminated for certain treatment types, including treatments for common warts. The reduction in or elimination of reimbursement for wart treatments has affected international sales of our Histofreezer® product. We are also seeing evidence that sales of OTC cryosurgical products may reduce the number of individuals that will seek to obtain treatment of their warts by a physician, which in turn could negatively affect sales of our Histofreezer® product in the domestic professional market. However, it is not possible at this time to estimate the likelihood or financial impact of these changes.

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During the six months ended June 30, 2010, our OTC cryosurgical sales increased 37% primarily due to increased sales to both our Latin American OTC distributor, Genomma, and to our European OTC distributor, SSL. During the first half of 2010, Genomma's purchases increased by \$770,000, largely representing product required to support Genomma's launch of our OTC cryosurgical wart removal product in Brazil. Sales to SSL were \$1.4 million and \$1.3 million in the first half of 2010 and 2009, respectively. This increase is largely the result of variability in SSL's ordering patterns.

### **Insurance Risk Assessment Market**

Sales to the insurance risk assessment market decreased 6% to \$2.9 million in 2010 from \$3.1 million in the first half of 2009, due to variations in laboratory ordering patterns and a decrease in the issuance of new insurance policies.

### **Licensing and Product Development**

Licensing and product development revenues increased to \$2.9 million during the first half of 2010 from \$861,000 during the first half of 2009. This increase was primarily due to \$2.0 million in milestone payments received 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 an OraQuick® rapid HCV test. The remaining licensing revenues for the first six months of both 2010 and 2009 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 half of 2010 was 63%, compared to 60% for the first half of 2009. Gross margin in 2010 benefitted from the higher licensing and product development revenues, a more favorable product revenue mix and an improvement in scrap and spoilage levels when compared to 2009. These benefits to gross margin were partially offset by an increase in unabsorbed overhead costs due to lower product production and severance costs related to a reduction in force during the second quarter of 2010.

### **Operating Expenses**

Research and development expenses increased 6% from \$5.8 million in the first half of 2009 to \$6.1 million in the same period of 2010, primarily as a result of higher laboratory supplies expense related to the development of new infectious disease products, increased staffing costs and higher clinical trial costs related to the development of our OraQuick® HIV OTC test. These increases were partially offset by decreased validation, vendor qualification and clinical trial costs related to the development of our OraQuick® HCV test. We expect our research and development costs will increase during the remaining six months of 2010 as a result of our anticipated clinical work in support of our HIV OTC and OraQuick® HCV products, as well as the development of other new products.

Sales and marketing expenses increased 10% from \$10.3 million in the first half of 2009 to \$11.3 million in the first half of 2010. This increase was the result of increased consulting costs, additional market research activities, and the commissions paid to the two new manufacturers' sales representative organizations that we retained during the first quarter of 2010 to support sales of our Histofreezer® product in the U.S. physician office market.

General and administrative expenses remained relatively flat at \$8.9 million in the first six months of 2010 and 2009. Increases in consulting and staffing costs were offset by lower legal expenses.

During the second quarter of 2009, we recorded an impairment charge of \$3.0 million related to license payments for certain HCV patents, which we previously capitalized. Management's intent in capitalizing these payments was to utilize this license in certain developing countries for the marketing and sale of an existing rapid HCV test supplied by a third party manufacturer. However, we were unable to penetrate this international marketplace with the third-party's rapid HCV test. Furthermore, given the impact of the current global recession and the deteriorating status of certain third-world economies, we no longer believed that we would be successful in selling a third-party's rapid



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HCV test in the foreseeable future. Accordingly, we recorded a non-cash impairment charge for the remaining unamortized book value of the patent and product rights in the quarter ended June 30, 2009.

### **Interest Income/Expense**

Interest expense decreased to \$154,000 in the first half of 2010 from \$180,000 in the first half of 2009 as a result of lower average debt balances. Interest income decreased to \$91,000 in the first half of 2010 from \$575,000 in the first half of 2009, primarily as a result of lower yields earned on our investment portfolio, lower investment balances, and an overall conservative, shorter-term investment approach.

### **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. At the end of the six-month period ended June 30, 2010, we concluded that the full valuation allowance still remains appropriate as the facts and circumstances during 2010 have not changed. As a result, no income tax benefit was recorded in the first six months of 2010 or 2009.

### **Liquidity and Capital Resources**

	<u>June 30,</u> <u>2010</u>	<u>December 31,</u> <u>2009</u>
	(In thousands)	
Cash and cash equivalents	\$72,551	\$ 74,934
Short-term investments	1,995	4,737
Working capital	77,009	89,435

Our cash, cash equivalents and short-term investments decreased \$5.1 million to \$74.5 million at June 30, 2010, primarily as a result of \$3.1 million in net cash used in operations during the first half of 2010, \$1.1 million in property and equipment purchases, \$677,000 associated with the retirement of common stock to pay minimum tax withholding obligations on the vesting of restricted shares, and \$260,000 for debt repayments. Our working capital declined as a result of the reduction of our cash, cash equivalents and short-term investments as well as the reclassification of the remaining unpaid principal balance of our debt obligation to a current liability as a result of its maturity date in June 2011.

The \$3.1 million of net cash used in operating activities in the first half of 2010 represented an increase of \$1.4 million when compared to the same period in 2009. The current period usage of cash resulted from our net loss of \$2.7 million and a reduction in our scrap and spoilage reserve of \$97,000, partially offset by non-cash stock-based compensation expense of \$1.7 million and depreciation and amortization of \$1.3 million. Also contributing to the higher net cash used in operations were a decrease in accounts payable of \$367,000 and a \$4.2 million decrease in accrued expenses and other liabilities associated with payment of our 2009 royalty obligations, management incentive bonuses and other accruals. Offsetting these uses of cash during the same period were a \$672,000 decrease in accounts receivable, resulting from the timely collection of amounts due and a decrease in product revenues, a \$580,000 decrease in prepaid expenses due to the collection of a federal tax refund of \$673,000, and a \$60,000 decrease in inventories.

Net cash provided by investing activities during the first six months of 2010 was \$1.6 million. Proceeds of \$2.7 million from maturities and redemptions of short-term investments were partially offset by \$1.1 million in purchases of property and equipment.

During the remainder of the year ending December 31, 2010, we expect to invest approximately \$800,000 in additional capital expenditures, primarily related to purchases of additional new equipment and improvements to our facilities.

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Net cash used in financing activities was \$932,000 for the six months ended June 30, 2010, primarily as a result of \$260,000 in loan principal repayments and \$677,000 used for the withholding and retirement of common stock related to the vesting of restricted shares.

At December 31, 2009, we had in place a \$10,000,000 credit advance with Comerica Bank (“Comerica”). Pursuant to the terms of the advance, principal, and interest fixed at 4.15%, are payable monthly through June 2011, at which time the remaining unpaid principal balance is payable. Accordingly, at June 30, 2010, our remaining unpaid principal balance was classified as a current liability as it will be payable within the ensuing twelve months. As of June 30, 2010, we had \$8.0 million in outstanding borrowings under this advance.

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 at June 30, 2010. 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.

At December 31, 2009, we had NOL carryforwards of approximately \$54.1 million for federal income tax purposes. In the fourth quarter of 2008, we recorded a full valuation allowance against the deferred tax asset generated by these NOLs. Establishment of this valuation allowance does not change our view of the Company’s long-term financial outlook or the expected utilization of our NOL carryforwards.

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, 2009 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, 2009. As of June 30, 2010, there were no significant changes to this information.

### **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

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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 2009 Annual Report on Form 10-K filed with the SEC. During the first six months of 2010, 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 is 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 June 30, 2010, 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. 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 were minimal compared to our total revenues for the six months ended June 30, 2010. We do not expect the risk of foreign currency fluctuations to be material to us in the near future.

### **Item 4. CONTROLS AND PROCEDURES**

(a) Evaluation of Disclosure Controls and Procedures. The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) as of June 30, 2010. 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 June 30, 2010 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 June 30, 2010 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, 2009.

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

During the quarter ended June 30, 2010, pursuant to our 2000 Stock Award Plan and in connection with the vesting of restricted shares, we retired 7,096 shares of our Common Stock to satisfy minimum tax withholding obligations at an average price paid per share of \$5.19.

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On August 5, 2008, our Board of Directors approved a share repurchase program pursuant to which we are permitted to acquire up to \$25.0 million of outstanding shares. We did not purchase any shares under this program during the three months ended June 30, 2010. As of June 30, 2010, we had remaining authority to purchase up to \$19,570,287 of shares under this share repurchase program. We have no commitments to purchase any additional shares and the share repurchase program may be discontinued at any time.

**Item 6. EXHIBITS**

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

**SIGNATURES**

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

ORASURE TECHNOLOGIES, INC.

Date: August 5, 2010

*/s/ Ronald H. Spair*

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

Date: August 5, 2010

*/s/ Mark L. Kuna*

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

**EXHIBIT INDEX**

**Exhibit**

- 31.1 Certification of Douglas A. Michels required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
- 31.2 Certification of Ronald H. Spair required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
- 32.1 Certification of Douglas A. Michels required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Certification of Ronald H. Spair required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Certification

I, Douglas A. Michels, certify that:

1. I have reviewed this report on Form 10-Q of OraSure Technologies, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within the entity, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 5, 2010

*/s/ Douglas A. Michels*

\_\_\_\_\_  
Douglas A. Michels  
President and Chief Executive Officer  
(Principal Executive Officer)

Certification

I, Ronald H. Spair, certify that:

1. I have reviewed this report on Form 10-Q of OraSure Technologies, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within the entity, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 5, 2010

*/s/ Ronald H. Spair*

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



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

In connection with the Quarterly Report of OraSure Technologies, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2010 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Douglas A. Michels, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

*/s/ Douglas A. Michels*

Douglas A. Michels  
President and Chief Executive Officer

August 5, 2010

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

In connection with the Quarterly Report of OraSure Technologies, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2010 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ronald H. Spair, Chief Operating Officer and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

*/s/ Ronald H. Spair*

Ronald H. Spair  
Chief Operating Officer and Chief Financial Officer

August 5, 2010