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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2011.

OR

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

For the transition period from _____ to _____.

Commission File Number 001-16537

ORASURE TECHNOLOGIES, INC.

(Exact Name of Registrant as Specified in Its Charter)

DELAWARE
(State or Other Jurisdiction of
Incorporation or Organization)

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

36-4370966
(IRS Employer
Identification No.)

18015
(Zip code)

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

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>

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 2, 2011: 47,016,428

[Table of Contents](#)

PART I. FINANCIAL INFORMATION

	<u>Page No.</u>
Item 1. Financial Statements (unaudited)	
Balance Sheets at June 30, 2011 and December 31, 2010	3
Statements of Operations for the three and six months ended June 30, 2011 and 2010	4
Statements of Cash Flows for the three and six months ended June 30, 2011 and 2010	5
Notes to Financial Statements	6
Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations	12
Item 3 . Quantitative and Qualitative Disclosures About Market Risk	24
Item 4. Controls and Procedures	24

PART II. OTHER INFORMATION

Item 1A. Risk Factors	25
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	25
Item 6. Exhibits	25
Signatures	26

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

	<u>JUNE 30, 2011</u>	<u>DECEMBER 31, 2010</u>
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 75,399,491	\$ 73,843,402
Short-term investments	—	1,895,000
Accounts receivable, net of allowance for doubtful accounts of \$132,539 and \$105,954	11,744,080	12,471,249
Inventories	8,146,605	7,345,594
Prepaid expenses	1,718,705	1,930,108
Total current assets	97,008,881	97,485,353
PROPERTY AND EQUIPMENT, net	19,478,446	19,610,583
PATENTS AND PRODUCT RIGHTS, net	4,434,919	4,806,919
OTHER ASSETS	333,456	617,238
	<u>\$ 121,255,702</u>	<u>\$ 122,520,093</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	\$ 7,541,680	\$ 7,791,680
Accounts payable	3,723,978	2,898,846
Accrued expenses and other	8,788,184	8,986,879
Total current liabilities	20,053,842	19,677,405
COMMITMENTS AND CONTINGENCIES (Note 6)		
STOCKHOLDERS' EQUITY		
Preferred stock, par value \$.000001, 25,000,000 shares authorized, none issued	—	—
Common stock, par value \$.000001, 120,000,000 shares authorized, 46,951,200 and 46,225,622 shares issued and outstanding	47	46
Additional paid-in capital	245,057,576	241,663,337
Accumulated other comprehensive loss	(233,829)	(235,264)
Accumulated deficit	(143,621,934)	(138,585,431)
Total stockholders' equity	101,201,860	102,842,688
	<u>\$ 121,255,702</u>	<u>\$ 122,520,093</u>

See accompanying notes to the financial statements.

ORASURE TECHNOLOGIES, INC.
STATEMENTS OF OPERATIONS
(Unaudited)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2011</u>	<u>2010</u>	<u>2011</u>	<u>2010</u>
REVENUES:				
Product	\$18,699,285	\$17,703,803	\$35,749,397	\$34,276,557
Licensing and product development	364,275	1,514,033	727,891	2,886,803
	<u>19,063,560</u>	<u>19,217,836</u>	<u>36,477,288</u>	<u>37,163,360</u>
COST OF PRODUCTS SOLD	<u>6,802,596</u>	<u>7,040,201</u>	<u>12,949,493</u>	<u>13,581,663</u>
Gross profit	<u>12,260,964</u>	<u>12,177,635</u>	<u>23,527,795</u>	<u>23,581,697</u>
OPERATING EXPENSES:				
Research and development	5,142,987	3,028,658	9,563,227	6,135,433
Sales and marketing	5,351,841	5,610,352	10,283,717	11,304,696
General and administrative	4,125,516	4,073,941	8,593,127	8,852,584
	<u>14,620,344</u>	<u>12,712,951</u>	<u>28,440,071</u>	<u>26,292,713</u>
Operating loss	(2,359,380)	(535,316)	(4,912,276)	(2,711,016)
INTEREST EXPENSE	(79,556)	(77,955)	(157,743)	(153,750)
INTEREST INCOME	18,475	48,702	57,420	90,818
FOREIGN CURRENCY GAIN (LOSS)	(10,196)	14,237	(18,374)	28,926
OTHER EXPENSE	(7,743)	(2,474)	(5,530)	(3,158)
Loss before income taxes	(2,438,400)	(552,806)	(5,036,503)	(2,748,180)
INCOME TAXES	—	—	—	—
NET LOSS	<u>\$ (2,438,400)</u>	<u>\$ (552,806)</u>	<u>\$ (5,036,503)</u>	<u>\$ (2,748,180)</u>
LOSS PER SHARE:				
BASIC AND DILUTED	<u>\$ (0.05)</u>	<u>\$ (0.01)</u>	<u>\$ (0.11)</u>	<u>\$ (0.06)</u>
SHARES USED IN COMPUTING LOSS PER SHARE				
BASIC AND DILUTED	<u>46,814,379</u>	<u>46,201,638</u>	<u>46,666,895</u>	<u>46,157,097</u>

See accompanying notes to the financial statements.

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

	<u>Six Months Ended June 30,</u>	
	<u>2011</u>	<u>2010</u>
OPERATING ACTIVITIES:		
Net loss	\$ (5,036,503)	\$ (2,748,180)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,930,692	1,696,618
Depreciation and amortization	1,683,955	1,330,672
Changes in assets and liabilities:		
Accounts receivable	728,401	671,602
Inventories	(801,011)	(36,949)
Prepaid expenses and other assets	495,185	579,636
Accounts payable	825,335	(366,677)
Accrued expenses and other liabilities	<u>(199,351)</u>	<u>(4,206,401)</u>
Net cash used in operating activities	<u>(373,297)</u>	<u>(3,079,679)</u>
INVESTING ACTIVITIES:		
Proceeds from maturities and redemptions of short-term investments	1,895,000	2,741,000
Purchases of property and equipment	<u>(1,179,818)</u>	<u>(1,112,611)</u>
Net cash provided by investing activities	<u>715,182</u>	<u>1,628,389</u>
FINANCING ACTIVITIES:		
Repayments of long-term debt	(250,000)	(259,760)
Proceeds from exercise of stock options	2,312,023	5,455
Repurchase of common stock	<u>(847,819)</u>	<u>(677,221)</u>
Net cash provided by (used in) financing activities	<u>1,214,204</u>	<u>(931,526)</u>
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	1,556,089	(2,382,816)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	<u>73,843,402</u>	<u>74,933,630</u>
CASH AND CASH EQUIVALENTS, END OF PERIOD	<u>\$75,399,491</u>	<u>\$72,550,814</u>
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid (received) for:		
Interest	\$ 105,719	\$ 171,825
Income taxes	\$ 25,000	\$ (585,893)

See accompanying notes to the financial statements.

ORASURE TECHNOLOGIES, INC.
Notes to the Financial Statements
(Unaudited)

1. The Company

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

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

2. Summary of Significant Accounting Policies

Basis of Presentation. The accompanying financial statements are unaudited and, in the opinion of management, include all adjustments (consisting only of normal and recurring adjustments) necessary for a fair presentation of our financial position and results of operations for these interim periods. These financial statements should be read in conjunction with the financial statements and notes thereto included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010. Results of operations for the three and six months ended June 30, 2011 are not necessarily indicative of the results of operations expected for the full year.

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

Cash and Cash Equivalents. We consider all highly liquid investments with a purchased maturity of ninety days or less to be cash equivalents. As of June 30, 2011 and December 31, 2010, cash equivalents consisted of money market accounts.

Table of Contents

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

Our available-for-sale securities as of December 31, 2010 consisted of certificates of deposits with amortized cost and fair value of \$1,895,000. These certificates of deposits matured during the second quarter of 2011.

Fair Value of Financial Instruments. As of June 30, 2011, the carrying values of cash and cash equivalents, accounts receivable, accounts payable and accrued expenses approximate their respective fair values based on their short-term nature. In addition, we believe the carrying value of our debt instrument, which does not have a readily ascertainable market value, approximates fair value, given that the interest rate on outstanding borrowings approximates current market rates and it has a short-term maturity date.

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 as of December 31, 2010.

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>2011</u>	<u>December 31,</u> <u>2010</u>
Raw materials	\$4,537,032	\$4,453,560
Work in process	740,226	258,335
Finished goods	<u>2,869,347</u>	<u>2,633,699</u>
	<u>\$8,146,605</u>	<u>\$7,345,594</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, 2011 and December 31, 2010 was \$20,883,285 and \$20,204,317, respectively.

Patents and Product Rights. Patents and product rights consist of costs associated with the acquisition of patents, licenses and product distribution rights. Patents and product rights are amortized using the straight-line method over their estimated useful lives of three to ten years. Accumulated amortization of patents and product rights as of June 30, 2011 and December 31, 2010 was \$6,013,701 and \$5,641,701, respectively.

[Table of Contents](#)

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

Revenue Recognition. We recognize product revenues when there is persuasive evidence that an arrangement exists, the price is fixed or determinable, title has passed and collection is reasonably assured. Product revenues are recorded net of allowances for any discounts or rebates. We do not grant price protection or product return rights to our customers, except for warranty returns. Historically, returns arising from warranty issues have been infrequent and immaterial. Accordingly, we expense warranty returns as incurred.

Royalty income from the grant of license rights is recognized during the period in which the revenue is earned and the amount is determinable from the licensee.

We record shipping and handling charges billed to our customers as product revenue and the related expense as cost of products sold. Taxes assessed by governmental authorities, such as sales or value-added taxes, are excluded from product revenues.

Significant Customer Concentration. We had no significant concentrations (greater than 10%) in revenues for either the three or six months ended June 30, 2011 and 2010. As of June 30, 2011 and December 31, 2010, one of our customers, Quest Diagnostics, Incorporated, accounted for 11% and 10% of our accounts receivable balances, respectively.

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 are adjusted for in the period in which they become known.

Loss Per Share. Basic and diluted loss per share is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during the period. Diluted loss per share is generally computed assuming the exercise or vesting of all dilutive securities such as common stock options and unvested restricted stock. Common stock options and unvested restricted stock totaling 6,813,649 and 6,694,066 shares were outstanding as of June 30, 2011 and 2010, respectively. As a result of our net losses for the three and six months ended June 30, 2011 and 2010, these shares were excluded from the respective periods' computation of diluted loss per share, as their inclusion would have been anti-dilutive. Had we reported a profit for the three and six months ended June 30, 2011, outstanding common stock options and unvested restricted stock, representing 1,531,179 and 2,588,024 equivalent shares, respectively, would have been excluded from the computation of diluted earnings per share, as their inclusion would have been anti-dilutive. Had we reported a profit for the three and six months ended June 30, 2010, outstanding common stock options and unvested restricted stock, representing 4,578,979 and 4,718,770 equivalent shares, respectively, would have been excluded from the computation of diluted earnings per share, as their inclusion would have been anti-dilutive.

Other Comprehensive Loss. We classify items of other comprehensive loss by their nature and disclose the accumulated balance of other comprehensive loss separately from accumulated deficit and additional paid-in capital in the stockholders' equity section of our balance sheet. Accumulated other comprehensive loss as of June 30, 2011 and December 31, 2010 consisted of currency translation adjustments. Comprehensive loss was \$2,436,696 and \$554,841 for the three months ended June 30, 2011 and 2010, respectively, and \$5,035,068 and \$2,749,878 for the six months ended June 30, 2011 and 2010, respectively.

3. Stock-Based Compensation

We grant stock-based awards under the OraSure Technologies, Inc. Stock Award Plan, as amended and restated (the "Plan"). The Plan permits stock-based awards to employees, outside directors and consultants or other third-party advisors. Awards which may be granted under the 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, 2011 and 2010 was \$3.51 and \$2.77 per share, respectively. The weighted average grant date fair value of stock options granted during the six months ended June 30, 2011 and 2010 was \$2.86 and \$2.27 per share, respectively.

Total compensation cost related to stock options for the three months ended June 30, 2011 and 2010 was \$342,814 and \$200,377, respectively, of which \$17,242 and \$12,967 was capitalized into inventory during the quarters ended June 30, 2011 and 2010, respectively. The amounts recognized in cost of products sold for amounts previously capitalized were \$15,266 and \$12,042 for the three months ended June 30, 2011 and 2010, respectively.

Total compensation cost related to stock options for the six months ended June 30, 2011 and 2010 was \$684,762 and \$475,619, respectively, of which \$24,270 and \$26,774 was capitalized into inventory during the six months ended June 30, 2011 and 2010, respectively. The amounts recognized in cost of products sold for amounts previously capitalized were \$24,946 and \$31,988 for the six months ended June 30, 2011 and 2010, respectively.

The following table summarizes the stock option activity for the six months ended June 30, 2011:

	<u>Options</u>
Outstanding on January 1, 2011	5,503,533
Granted	973,225
Exercised	(455,045)
Forfeited	(113,720)
Outstanding on June 30, 2011	<u>5,907,993</u>

As of June 30, 2011, there was \$3,927,138 of unrecognized compensation expense related to unvested option awards that is expected to be recognized over a weighted average period of 2.1 years.

Net cash proceeds from the exercise of stock options were \$2,312,023 and \$5,455 for the six months ended June 30, 2011 and 2010, 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 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, 2011, we granted 525,880 restricted shares of our common stock, with a weighted average grant date fair value of \$6.61 per share, to certain key officers, members of management and outside directors. Compensation cost of \$615,325 and \$604,869 related to restricted shares was recognized during the three months ended June 30, 2011 and 2010, respectively. Compensation cost of \$1,245,929 and \$1,221,000 related to restricted shares was recognized during the six months ended June 30, 2011 and 2010, respectively.

[Table of Contents](#)

The following table summarizes restricted stock award activity for the six months ended June 30, 2011:

	<u>Shares</u>
Issued and unvested, January 1, 2011	792,156
Granted	525,880
Vested	(397,380)
Forfeited	(15,000)
Issued and unvested, June 30, 2011	<u>905,656</u>

As of June 30, 2011, there was \$4,351,192 of unrecognized compensation expense related to unvested restricted stock awards that is expected to be recognized over a weighted average period of 2.2 years. In connection with the vesting of restricted shares, during the six months ended June 30, 2011 and 2010, 126,847 and 128,625 shares, respectively, with aggregate values of \$847,819 and \$677,221, respectively, were withheld and retired in satisfaction of minimum tax withholding obligations.

4. Accrued Expenses

	<u>June 30, 2011</u>	<u>December 31, 2010</u>
Payroll and related benefits	\$3,382,115	\$4,343,350
Royalties	1,970,320	1,985,799
Deferred revenue	1,645,564	896,531
Professional fees	720,354	213,308
Clinical research obligations	20,000	400,860
Other	1,049,831	1,147,031
	<u>\$8,788,184</u>	<u>\$8,986,879</u>

Deferred revenue at June 30, 2011 and December 31, 2010 included customer prepayments of \$1,594,464 and \$851,031, respectively.

5. Long-term Debt

As of June 30, 2011, we had in place a \$10,000,000 credit facility (the "Credit Facility") with Comerica Bank ("Comerica"). Pursuant to the terms of the Credit Facility, principal and interest fixed at 4.15% per annum were payable monthly through June 27, 2011. An amendment to the Credit Facility was executed with Comerica on June 24, 2011, extending the current terms of the Credit Facility and its maturity date to September 27, 2011. As of June 30, 2011, we had no available borrowings under this Credit Facility. We are evaluating possible options to address the upcoming expiration of the Credit Facility, including refinancing with a new credit facility or other borrowings.

All borrowings under the Credit Facility 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 Credit Facility contains certain covenants that set forth minimum requirements for our quick ratio, liquidity, and tangible net worth. We were in compliance with all covenants as of June 30, 2011. The Credit Facility 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.

[Table of Contents](#)**6. Commitments and Contingencies**

From time-to-time, we are involved in certain legal actions arising in the ordinary course of business. In management's opinion, based upon the advice of counsel, the outcomes of such actions are not expected to have a material adverse effect on our future financial position or results of operations.

7. Geographic Information

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
United States	\$16,341	\$16,457	\$30,579	\$31,325
Europe	1,293	1,852	3,279	3,194
Other regions	1,430	909	2,619	2,644
	<u>\$19,064</u>	<u>\$19,218</u>	<u>\$36,477</u>	<u>\$37,163</u>

8. Subsequent Event

On July 25, 2011, we announced that we will acquire DNA Genotek Inc. ("DNAG"), a privately-held provider of oral fluid sample collection, stabilization and preparation products for molecular diagnostic applications. Pursuant to the terms of a definitive Support Agreement, we will acquire all of the outstanding capital stock of DNAG for approximately \$53,000,000 in cash, subject to certain working capital, debt and escrow adjustments. The transaction is expected to be completed in the third quarter of 2011. DNAG is based in Ottawa, Canada and will operate as a wholly-owned subsidiary of our company.

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; ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; ability to comply with applicable regulatory requirements; changes in relationships, including disputes or disagreements, with strategic partners or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements; failure of distributors or other customers to meet purchase forecasts or minimum purchase requirements for the Company's products; impact of replacing distributors and success of direct sales efforts; inventory levels at distributors and other customers; ability to identify, complete, integrate, and realize the full benefits of potential future acquisitions, including the Company's acquisition of DNA Genotek; impact of competitors, competing products and technology changes; impact of the economic downturn, high unemployment and poor credit conditions; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products; market acceptance of oral fluid testing or other products; changes in market acceptance of products based on product performance, extended shelf life or other factors; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical product components; availability of related products produced by third parties or products required for use of our products; 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 refinance outstanding debt under expiring credit facilities on acceptable terms or at all; ability to retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; and general political, business and economic conditions. These and other factors are discussed more fully in our Securities and Exchange Commission ("SEC") filings, including our registration statements, Annual Report on Form 10-K for the year ended December 31, 2010, Quarterly Reports on Form 10-Q, and other filings with the SEC. Although forward-looking statements help to provide information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. The forward-looking statements are made as of the date of this Report and we undertake no duty to update these statements.

The following discussion should be read in conjunction with the financial statements contained herein and the notes thereto, along with the Section entitled "Critical Accounting Policies and Estimates," set forth below.

Overview

[Table of Contents](#)

We operate primarily in the *in vitro* diagnostic business. Our business principally involves the development, manufacture, marketing and sale of oral fluid diagnostic products and specimen collection devices using our proprietary oral fluid technologies, as well as other diagnostic products including immunoassays and *in vitro* diagnostic tests that are used on other specimen types. We also manufacture and sell 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 nature, and cost effectiveness, our oral fluid tests represent a very competitive alternative to the more traditional testing methods in the diagnostic space.

We rely heavily on distributors to purchase and resell many of our products. For example, Genomma Labs ("Genomma") has exclusive rights to our wart removal product in the OTC market in Mexico, Argentina, Brazil and various other Central and South American countries and Reckitt Benckiser (formerly SSL International plc) has similar rights to our wart removal product in the OTC footcare market in Europe, Australia and New Zealand. We have contracted with several distributors to sell our OraQuick *ADVANCE*[®] 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 OraQuick[®] HCV 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.

Current Financial Results

During the six months ended June 30, 2011, our total revenues were \$36.5 million compared to \$37.2 million in the six months ended June 30, 2010. Product revenues during the six months ended June 30, 2011 increased 4% when compared to the first half of 2010, which was offset by lower licensing and product development revenues. The reduction in licensing and product development revenues primarily resulted from the absence of \$2.0 million in milestone payments received under the terms of our collaboration agreement with Merck & Co., Inc. ("Merck") during the first half of 2010 for the development and promotion of our OraQuick[®] rapid HCV test in Europe. Our net loss for the six months ended June 30, 2011 was \$5.0 million, or \$0.11 per share, compared to a net loss of \$2.7 million, or \$0.06 per share, for the six months ended June 30, 2010.

Cash used in operating activities for the six months ended June 30, 2011 was approximately \$373,000, compared to the \$3.1 million used in operating activities for the six months ended June 30, 2010. As of June 30, 2011, we had \$75.4 million in cash, cash equivalents and short-term investments, compared to \$75.7 million at December 31, 2010.

Recent Developments

[Table of Contents](#)

Acquisition of DNA Genotek Inc.

On July 25, 2011, we announced that we will acquire DNA Genotek Inc. (“DNAG”), a privately-held provider of oral fluid sample collection, stabilization and preparation products for molecular diagnostic applications. Pursuant to the terms of a definitive Support Agreement, we will acquire all of the outstanding capital stock of DNAG for approximately \$53,000,000 in cash, subject to certain working capital, debt and escrow adjustments. The transaction is expected to close in the third quarter of 2011, subject to customary closing conditions. DNAG is based in Ottawa, Canada and will operate as a wholly-owned subsidiary of our Company.

OraQuick® HCV Test

In March 2011, we submitted to the FDA an application for waiver under the Clinical Laboratory Improvement Amendments of 1988 (“CLIA”) for our OraQuick® HCV test for use with venous and fingerstick whole blood specimens. This application remains pending and we are in active dialogue with the FDA regarding our submission. We have received a request for additional data from the FDA, which will require us to design and perform a relatively small study. While the study should last only about a week, there are set-up and close-out activities that will require until the fourth quarter of 2011 to complete. We intend to provide the requested data to the FDA as quickly as possible to facilitate the prompt completion of the agency’s review of our application.

OraQuick® HIV OTC Test

We are conducting the final phase of clinical testing for an OraQuick® HIV OTC test. In this study individuals conduct unsupervised self-testing using the investigational OTC version of our OraQuick *ADVANCE*® HIV test with an oral fluid collection. One of the study objectives specified by the FDA was to identify at least 100 HIV infected, but undiagnosed individuals. In order to meet this requirement, we expected to enroll and test approximately 4,000 to 5,000 participants in our study. This trial is progressing, and we remain on track to complete this study during the third quarter of 2011.

In planning for our FDA submission, we have decided to split our filing into three separate parts or modules, the filing of which will be spaced to allow the FDA sufficient review time between modules. The first module, which we expect to file later in August 2011, will contain data from all studies performed prior to the final phase that is currently under way. The second module will contain information about our manufacturing and Customer Care Call Center. The final module will contain the results of the unobserved clinical trial and is expected to be filed near the end of this year.

Substance Abuse Testing

In the first quarter of 2011, the FDA issued 510(k) clearances for use of high throughput oral fluid assays for PCP, opiates, cocaine and methamphetamines with our Intercept® oral fluid collection device. These were the first such clearances resulting from our collaboration with Roche Diagnostics. In the second quarter of 2011, the FDA issued an additional 510(k) clearance for an amphetamines assay. We expect to begin selling a panel of 510(k) cleared assays together with our Intercept® device during the fourth quarter of this year. Clinical work on an assay for marijuana (THC) is continuing, and is expected to be completed in late 2011 or the first quarter of 2012.

Competitive and Economic Outlook

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

Our OraQuick® HCV test is available in Europe and competes against laboratory-based HCV blood tests. Significant sales in Europe have not yet materialized principally because of differences in European healthcare systems

[Table of Contents](#)

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

Two factors are likely to impact domestic sales of our OraQuick® HCV test. First, since our test is currently classified by the FDA as “moderately complex,” we can only sell it to laboratories certified or accredited as meeting the quality and training requirements under CLIA. However, with a CLIA waiver, we would be able to sell our test to many other customers that perform CLIA waived tests, such as outreach clinics, community-based organizations and physician offices. Thus, a CLIA waiver will be required for us to deploy the test extensively in both the public health and hospital markets and to enable penetration, with the assistance of our collaborator, Merck, into the physician office market. Second, we believe the recent FDA approval of two new therapeutic treatments for HCV, both of which are more effective than previously available treatments, will help drive more widespread awareness and testing for HCV, including with our OraQuick® rapid test.

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

Finally, current economic conditions, 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 future acquisitions or make other discretionary investments. Many of our customers rely on public funding provided by state and local governments, and this funding has been and may continue to be reduced or deferred as a result of current economic conditions. These circumstances may adversely impact our customers and suppliers, which, in turn, could adversely affect their ability to purchase our products or supply us with necessary equipment, raw materials or components. In addition, demand for our products may also be adversely affected by current economic conditions.

Results of Operations

Three months ended June 30, 2011 compared to June 30, 2010

Total revenues decreased to \$19.1 million in the second quarter of 2011 from \$19.2 million in the comparable quarter of 2010. Product revenues during the three months ended June 30, 2011 increased 6% when compared to the second quarter of 2010. Increased sales of our infectious disease and substance abuse testing products were partially offset by lower sales of our cryosurgical systems and insurance risk assessment products. In addition, the higher product revenues were offset by a \$1.2 million reduction in licensing and product development revenues during the second quarter.

Revenues derived from products sold to customers outside the U.S. were \$2.7 million and \$2.8 million, or 14% of total revenues, in the second quarters of 2011 and 2010. 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.

[Table of Contents](#)

Market	Three Months Ended June 30,				
	Dollars			Percentage of Total Revenues	
	2011	2010	% Change	2011	2010
Infectious disease testing	\$11,284	\$ 9,974	13%	59%	52%
Substance abuse testing	3,185	3,052	4	17	16
Cryosurgical systems	2,802	3,120	(10)	15	16
Insurance risk assessment	1,429	1,558	(8)	7	8
Product revenues	18,700	17,704	6	98	92
Licensing and product development	364	1,514	(76)	2	8
Total revenues	<u>\$19,064</u>	<u>\$19,218</u>	(1)%	<u>100%</u>	<u>100%</u>

Infectious Disease Testing Market

Sales to the infectious disease testing market increased 13% to \$11.3 million in the second quarter of 2011. OraQuick® sales totaled \$11.0 million and \$9.6 million in the second quarters of 2011 and 2010, respectively.

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

Market	Three Months Ended June 30,		
	2011	2010	% Change
Domestic	\$10,168	\$9,248	10%
International	858	317	171
Total OraQuick® revenues	<u>\$11,026</u>	<u>\$9,565</u>	15%

During the three months ended June 30, 2011, sales of OraQuick® in the U.S. market increased by 10%, or \$920,000, when compared to the same period of 2010. The increase in OraQuick® sales was largely the result of new or expanded HIV-testing programs implemented in the U.S., as well as variability of customer ordering patterns. International sales of our OraQuick® HIV test increased 171% to \$858,000 for the three months ended June 30, 2011 from \$317,000 for the three months ended June 30, 2010. This increase reflects higher product sales in Asia, Africa, Latin America and Europe, as certain private and government customers were able to fund purchases.

Sales of our OraSure® oral fluid collection device decreased 37% from \$409,000 in the second quarter of 2010 to \$258,000 in the second quarter of 2011. Some customers who have purchased our OraSure® device for laboratory HIV-1 testing in the past are now electing to purchase our OraQuick ADVANCE® test. We believe this is the result of customers recognizing the benefits of rapid HIV testing, especially with oral fluid.

Substance Abuse Testing Market

Substance abuse testing revenues increased 4% from \$3.1 million in the second quarter of 2010 to \$3.2 million in the second quarter of 2011 as a result of increased domestic sales of our Intercept® drug testing system.

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

[Table of Contents](#)

Market	Three Months Ended June 30,		
	2011	2010	% Change
Domestic	\$2,083	\$1,949	7%
International	514	443	16
Total Intercept® revenues	<u>\$2,597</u>	<u>\$2,392</u>	9%

Domestic Intercept® revenues increased 7% from \$1.9 million in the second quarter of 2010 to \$2.1 million in the second quarter of 2011. This increase is largely the result of growth in the workplace market segment as hiring conditions have slowly begun to improve and we have seen the results of focused sales and marketing efforts.

International Intercept® revenues increased 16% from \$443,000 in the second quarter of 2010 to \$514,000 in the second quarter of 2011 as result of variability in customer ordering patterns.

Pursuant to a development agreement with Roche Diagnostics, homogenous fully-automated oral fluid drugs of abuse assays have been developed for use with our Intercept® collection device. The FDA recently has issued 510(k) clearance of high throughput assays for PCP, opiates, cocaine, methamphetamines, and amphetamines. The assays use Roche's technology and will run on various automated analyzers to allow oral fluid samples to be processed with the same efficiency currently achieved with urine-based drug tests. We have also entered into a commercialization agreement with Roche pursuant to which a drug testing system comprised of our Intercept® device and the newly developed homogenous assays will be marketed and sold on a worldwide basis. At least two competitors have developed oral fluid tests suitable for use on fully automated homogeneous assay systems and one competitor has received FDA 510(k) clearance of its products. We believe one of our laboratory distributors will begin offering this 510(k) cleared product line later this year and will reduce purchases of our Intercept® system. These new products represent a significant competitive threat to our Intercept® device and oral fluid microplate business and the assays being developed with Roche.

Cryosurgical Systems Market

Sales in the cryosurgical systems market (which includes both the physicians' office and OTC markets) decreased 10% to \$2.8 million in the second quarter of 2011, compared to \$3.1 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 2011 and 2010.

Market	Three Months Ended June 30,		
	2011	2010	% Change
Professional domestic	\$1,713	\$1,575	9%
Professional international	247	270	(9)
Over-the-counter	842	1,275	(34)
Total cryosurgical systems revenues	<u>\$2,802</u>	<u>\$3,120</u>	(10)%

Domestic physicians' office sales increased 9% or \$138,000 for the second quarter of 2011 as compared to the second quarter of 2010, as a result of increased penetration in the cryosurgical market resulting from the continued efforts of our manufacturers' sales representatives and improved focus by our distributors. 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. Furthermore, during the second quarter of 2011, we

[Table of Contents](#)

received orders from certain customers that have worked through their previously purchased inventory of less expensive international product that was diverted into the domestic professional market in 2009 and part of 2010.

During the three months ended June 30, 2011, sales of Histofreezer® in the international market decreased 9% as compared to the second quarter of 2010. This decrease was largely the result of lower sales in Asia and Australia, partially offset by increased sales in the European market.

Sales of our cryosurgical OTC products during the second quarter of 2011 decreased 34% primarily due to variability in ordering patterns of our European OTC distributor, Reckitt Benckiser (formerly, SSL International). Sales to Reckitt Benckiser decreased \$578,000 during the second quarter of 2011 compared to the second quarter of 2010. This decrease was partially offset by a 39% increase in sales to our Latin American distributor, Genomma.

The terms of our distribution contract with Reckitt Benckiser, which was subject to an annual renewal at the end of 2010, has been extended through July 2011. We are currently in negotiations to extend this contract further.

Insurance Risk Assessment Market

Sales to the insurance risk assessment market decreased 8% to \$1.4 million in the second quarter of 2011 from \$1.6 million in the second quarter of 2010 as a result of variability in the timing of orders and general softness in the life insurance market.

Licensing and Product Development

Licensing and product development revenues decreased 76% to \$364,000 during the second quarter of 2011 from \$1.5 million during the second quarter of 2010. During the second quarter of 2010, we received a \$1.0 million milestone payment as a result of our achievement of certain commercial objectives pursuant to our collaboration agreement with Merck for the development and promotion of our OraQuick® rapid HCV test in Europe. No such payment was received in the same period of 2011. The remaining licensing revenues for these periods represent royalties received on domestic outsales of Merck's OTC cryosurgical wart removal product, pursuant to our license and settlement agreement executed in January 2008.

Gross Margin

Gross margin in the second quarter of 2011 was 64% compared to 63% for the second quarter of 2010. Gross margin in the second quarter of 2010 benefitted from the \$1.0 million HCV milestone payment described above. Margin in the second quarter of 2011 benefitted from lower direct labor costs and improved absorption of overhead costs as a result of staffing optimization and a change to automated manufacturing during 2011. These changes accounted for 3.2% of margin for the second quarter of 2011. This improvement more than offset the negative margin impact associated with the absence of the HCV milestone revenues in 2011.

Operating Expenses

Research and development expenses increased 70% from \$3.0 million in the second quarter of 2010 to \$5.1 million in the same period in 2011, primarily as a result of higher clinical trial costs related to the development of our OraQuick® HIV OTC test.

Sales and marketing expenses decreased 5% to \$5.4 million in the second quarter of 2011 from \$5.6 million in the second quarter of 2010, as a result of lower consulting costs, partially offset by higher staffing costs.

General and administrative expenses remained flat at \$4.1 million for the second quarters of 2011 and 2010.

Income Taxes

In 2008, we established a full valuation allowance against our total net deferred tax asset. Management has continued to evaluate whether the full valuation is still appropriate. As of June 30, 2011 and 2010, we concluded that the full

[Table of Contents](#)

valuation allowance remained appropriate since the facts and circumstances necessitating the allowance had not changed. As a result, no income tax benefit was recorded in the second quarters of 2011 or 2010.

Six months ended June 30, 2011 compared to June 30, 2010

Total revenues decreased to \$36.5 million in the first half of 2011 from \$37.2 million in the comparable period of 2010. Product revenues during the six months ended June 30, 2011 increased 4% when compared to product revenues in the first half of 2010. Increased sales of our infectious disease and substance abuse testing products were partially offset by lower sales of our cryosurgical systems and insurance risk assessment products. In addition, higher product revenues were offset by a \$2.2 million reduction in licensing and product development revenues during the first half of 2011 as compared to 2010.

Revenues derived from products sold to customers outside the U.S. were \$5.9 million and \$5.8 million, or 16% of total revenues, in the first six months of 2011 and 2010. 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	Six Months Ended June 30,			Percentage of Total Revenues	
	Dollars		% Change	2011	2010
	2011	2010			
Infectious disease testing	\$21,246	\$19,454	9%	58%	52%
Substance abuse testing	6,246	5,766	8	17	16
Cryosurgical systems	5,512	6,114	(10)	15	16
Insurance risk assessment	2,745	2,942	(7)	8	8
Product revenues	35,749	34,276	4	98	92
Licensing and product development	728	2,887	(75)	2	8
Total revenues	<u>\$36,477</u>	<u>\$37,163</u>	<u>(2)%</u>	<u>100%</u>	<u>100%</u>

Infectious Disease Testing Market

Sales to the infectious disease testing market increased 9% to \$21.2 million in the first half of 2011. OraQuick® sales totaled \$20.7 million and \$18.6 million in the first six months of 2011 and 2010, respectively.

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

Market	Six Months Ended June 30,		
	2011	2010	% Change
Domestic	\$19,069	\$17,979	6%
International	1,604	655	145
Total OraQuick® revenues	<u>\$20,673</u>	<u>\$18,634</u>	<u>11%</u>

[Table of Contents](#)

During the six months ended June 30, 2011, sales of OraQuick® in the U.S. market increased by 6%, or \$1.1 million, when compared to the same period of 2010. The increase in domestic OraQuick® sales was largely the result of new or expanded HIV testing programs implemented in the U.S. as well as variability in customer ordering patterns. International sales of our OraQuick® HIV test increased 145% to \$1.6 million for the six months ended June 30, 2011 from \$655,000 for the six months ended June 30, 2010. This increase reflects higher product sales in Asia, Africa, Latin America, and Europe, as certain private and government customers were able to fund purchases.

Sales of our OraSure® oral fluid collection device decreased 30% from \$820,000 in the first half of 2010 to \$573,000 in the first half of 2011. Some customers who have purchased our OraSure® device for laboratory HIV-1 testing in the past are now electing to purchase our OraQuick ADVANCE® test. We believe this is the result of customers recognizing the benefits of rapid HIV testing, especially with oral fluid.

Substance Abuse Testing Market

Substance abuse testing revenues increased 8% from \$5.8 million in the first half of 2010 to \$6.2 million in the first half of 2011 as a result of increased domestic sales of our Intercept® drug testing system.

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

Market	Six Months Ended June 30,		
	2011	2010	% Change
Domestic	\$3,962	\$3,477	14%
International	1,035	960	8
Total Intercept® revenues	\$4,997	\$4,437	13%

Domestic Intercept® revenues increased 14% from \$3.5 million in the first half of 2010 to \$4.0 million in the first half of 2011. This increase is largely the result of variability in the ordering patterns of one of our larger laboratory drug testing customers and growth achieved within the workplace market segment as hiring conditions have slowly begun to improve.

International Intercept® revenues for the first half of 2011 and 2010 increased from \$960,000 in the first half of 2010 to \$1.0 million in the first half of 2011, as result of variability in customer ordering patterns.

Pursuant to a development agreement with Roche Diagnostics, homogenous fully-automated oral fluid drugs of abuse assays have been developed for use with our Intercept® collection device. The FDA recently has issued 510(k) clearance for high throughput assays for PCP, opiates, cocaine, methamphetamines, and amphetamines. The assays use Roche's technology and will run on various automated analyzers to allow oral fluid samples to be processed with the same efficiency currently achieved with urine-based drug tests. We have also entered into a commercialization agreement with Roche pursuant to which a drug testing system comprised of our Intercept® device and the newly developed homogenous assays will be marketed and sold on a worldwide basis. At least two competitors have developed oral fluid tests suitable for use on fully automated homogeneous assay systems and one competitor has received 510(k) clearance of its products. We believe one of our laboratory distributors will begin offering this 510(k) cleared product line later this year and will reduce purchases of our Intercept® system. These new products represent a significant competitive threat to our Intercept® device and oral fluid microplate business and the assays being developed with Roche.

Cryosurgical Systems Market

[Table of Contents](#)

Sales in the cryosurgical systems market (which includes both the physicians' office and OTC markets) decreased 10% to \$5.5 million in the first six months of 2011, compared to \$6.1 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 2011 and 2010.

Market	Six Months Ended June 30,		
	2011	2010	% Change
Professional domestic	\$3,055	\$2,787	10%
Professional international	587	539	9
Over-the-counter	1,870	2,788	(33)
Total cryosurgical systems revenues	<u>\$5,512</u>	<u>\$6,114</u>	(10)%

Domestic physicians' office sales increased 10% or \$268,000 for the first six months of 2011 as compared to the first six months of 2010, as a result of increased penetration in the cryosurgical market resulting from the continued efforts of our manufacturers' sales representatives and improved focus on our products by our distribution partners. 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.

During the six months ended June 30, 2011, sales of Histofreezer® in the international market increased 9% as compared to the first six months of 2010. This increase was largely experienced in the European market as a result of increased pricing and improved economic conditions in some local markets.

Sales of our cryosurgical OTC products during the first half of 2011 decreased 33% primarily due to the decline in sales to both our Latin America OTC distributor, Genomma, and our European OTC distributor, Reckitt Benckiser (formerly, SSL International).

In the first half of 2010, Genomma had purchases totaling \$1.4 million compared to \$422,000 in the first half of 2011. In late 2010, the Mexican government placed limitations on the advertising Genomma could use for our product. In addition, during the first quarter of 2011, Genomma informed us of some changes required by the Brazilian government to our package insert, which have since been made. Both events negatively impacted sales of our product during 2011. When compared to the first six months of 2010, sales to Genomma during the same period of 2011 were also lower as a result of an initial order fulfilled in the first quarter of 2010 for the commercial launch of our product in Brazil during that same period.

Sales to our European OTC distributor Reckitt Benckiser decreased \$122,000 during the first half of 2011 compared to the first half of 2010, largely due to variability in ordering patterns. The terms of our distribution contract with Reckitt Benckiser, which was subject to an annual renewal at the end of 2010, has been extended through July 2011. We are currently in negotiations to extend this contract.

Insurance Risk Assessment Market

Sales to the insurance risk assessment market decreased 7% to \$2.7 million in the first six months of 2011 from \$2.9 million in the first six months of 2010 as a result of variability in the timing of orders and general softness in the life insurance market.

Licensing and Product Development

Licensing and product development revenues decreased 75% to \$728,000 during the first half of 2011 from \$2.9 million during the first half of 2010. During the first six months of 2010, we received \$2.0 million in milestone

[Table of Contents](#)

payments as a result of our achievement of certain regulatory and commercial objectives pursuant to our collaboration agreement with Merck for the development and promotion of our OraQuick® rapid HCV test in Europe. The remaining licensing revenues for these periods represent royalties received on domestic outsales of Merck's OTC cryosurgical wart removal product, pursuant to our license and settlement agreement executed in January 2008.

Gross Margin

Gross margin in the six months ended June 30, 2011 was 64% compared to 63% for the six months ended June 30, 2010. Gross margin in the first half of 2010 benefitted from the \$2.0 million in HCV milestone payments described above. Margin in the first half of 2011 benefitted from lower direct labor costs and improved absorption of overhead costs as a result of staffing optimization and a change to automated manufacturing during 2011. These changes accounted for 2.8% of margin for the first half of 2011. This improvement more than offset the negative margin impact associated with the absence of the HCV milestone revenues in 2011.

Operating Expenses

Research and development expenses increased 56% from \$6.1 million in the first six months of 2010 to \$9.6 million in the same period in 2011, primarily as a result of higher clinical trial costs related to the development of our OraQuick® HIV OTC test. This increase was partially offset by lower clinical trial costs related to our OraQuick® HCV test.

Sales and marketing expenses decreased 9% to \$10.3 million in the first six months of 2011 from \$11.3 million in the first six months of 2010, as a result of lower consulting, recruiting and market research costs, partially offset by an increase in staffing costs.

General and administrative expenses decreased 3% to \$8.6 million in the first six months of 2011 from \$8.9 million in the same period in 2010. This decrease was primarily attributable to lower consulting and staffing expenses, partially offset by an increase in legal expenses.

Income Taxes

In 2008, we established a full valuation allowance against our total net deferred tax asset. Management has continued to evaluate whether the full valuation is still appropriate. As of June 30, 2011 and 2010, we concluded that the full valuation allowance remained appropriate since the facts and circumstances necessitating the allowance had not changed. As a result, no income tax benefit was recorded in the first six months of 2011 or 2010.

Liquidity and Capital Resources

	June 30, 2011	December 31, 2010
	(In thousands)	
Cash and cash equivalents	\$ 75,399	\$ 73,843
Short-term investments	—	1,895
Working capital	76,955	77,808

Our cash, cash equivalents and short-term investments decreased \$339,000 from \$75.7 million at December 31, 2010 to \$75.4 million at June 30, 2011. Our working capital declined slightly from \$77.8 million at December 31, 2010 compared to \$77.0 million at June 30, 2011.

During the first six months of 2011, we used \$373,000 in cash to finance our operating activities. Cash used in operating activities resulted from funding our net loss of \$5.0 million, partially offset by non-cash stock-based

[Table of Contents](#)

compensation expense of \$1.9 million and depreciation and amortization of \$1.7 million. Also contributing to the cash used in operating activities were an \$801,000 increase in inventory largely due to stocking of our OraQuick® HIV and HCV tests and a \$199,000 decrease in accrued expenses and other liabilities. Offsetting these uses of cash were a \$728,000 decrease in accounts receivable, a \$495,000 decrease in prepaid expenses and other assets, and an \$825,000 increase in accounts payable.

Net cash provided by investing activities of \$715,000 during the first six months of 2011 resulted from the maturity of \$1.9 million of certificates of deposit, partially offset by purchases of property and equipment of \$1.2 million.

Net cash provided by financing activities was \$1.2 million for the six months ended June 30, 2011, primarily as a result of \$2.3 million in proceeds received from the exercise of stock options, partially offset by \$250,000 in loan principal repayments and \$848,000 used for the repurchase of common stock related to the vesting of restricted shares.

As of June 30, 2011, we had in place a \$10,000,000 credit facility (the "Credit Facility") with Comerica Bank ("Comerica"). Pursuant to the terms of the Credit Facility, principal, and interest fixed at 4.15% per annum, were payable monthly through June 27, 2011. An amendment to the Credit Facility was executed with Comerica on June 24, 2011, extending the current terms of the Credit Facility and its maturity date to September 27, 2011. As of June 30, 2011, we had no available borrowings under this Credit Facility. We are evaluating possible options to address the upcoming expiration of the Credit Facility, including refinancing with a new credit facility or other borrowings.

All borrowings from Comerica are collateralized by a first priority security interest in all of our assets, including present and future accounts receivable, chattel paper, contracts and contract rights, equipment and accessories, general intangibles, investments, instruments, inventories, and a mortgage on our three facilities in Bethlehem, Pennsylvania. The Comerica agreement contains certain covenants that set forth minimum requirements for our quick ratio, liquidity, and tangible net worth. We were in full compliance with all covenants as of June 30, 2011. The agreement also restricts our ability to pay dividends, to make certain investments, to incur additional indebtedness, to sell or otherwise dispose of a substantial portion of assets, and to merge or consolidate operations with an unaffiliated entity, without the consent of Comerica.

The combination of our current cash and cash equivalents is expected to be sufficient to fund our operating and capital needs through at least the next twelve months, including funding the expected \$53 million purchase price of DNA Genotek Inc. Our cash requirements, however, may vary materially from those now planned due to many factors, including, but not limited to, the scope and timing of future strategic acquisitions, the cost and timing of the expansion of our manufacturing capacity, the progress of our research and development programs, the scope and results of clinical testing, the cost of any future litigation, the magnitude of capital expenditures, changes in existing and potential relationships with business partners, the time and cost of obtaining regulatory approvals, the costs involved in obtaining and enforcing patents, proprietary rights and any necessary licenses, the cost and timing of expansion of sales and marketing activities, the timing of market launch of new products, market acceptance of new products, competing technological and market developments, the impact of the ongoing economic downturn and other factors.

Summary of Contractual Obligations

A summary of our obligations to make future payments under contracts existing at December 31, 2010 is included in Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations, of our Annual Report on Form 10-K for the year ended December 31, 2010. As of June 30, 2011, there were no significant changes to this information, including the absence of any off-balance sheet arrangements. For a summary of our obligations to make future payments to DNAG under that certain Support Agreement, dated July 25, 2011, see Note 8 to the financial statements included herein.

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

[Table of Contents](#)

United States of America. The preparation of these financial statements requires that we make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. On an on-going basis, we evaluate our judgments and estimates, including those related to bad debts, inventories, investments, intangible assets, income taxes and realization of the related deferred tax assets, revenue recognition, restructuring costs, contingencies and litigation. We base our judgments and estimates on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

A more detailed review of our critical accounting policies is contained in our 2010 Annual Report on Form 10-K filed with the SEC. During the first six months of 2011, there were no material changes in our critical accounting policies.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

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

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

As of June 30, 2011, we did not have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. We have operations in Europe and Africa, which are subject to foreign currency fluctuations. Sales denominated in a foreign currency were immaterial as a percentage of our total revenues for the six months ended June 30, 2011. We do not expect the risk of foreign currency fluctuations to be material to us in the near future.

On July 25, 2011, we announced that we entered into a definitive Support Agreement to acquire all of the outstanding capital stock of DNA Genotek Inc. The purchase price set forth in the Support Agreement is 50,000,000 Canadian dollars, or approximately US\$53,000,000 at the July 25, 2011 exchange rate. Given this purchase price is payable in Canadian dollars, fluctuations in the exchange rate of the U.S. and Canadian dollar could have a material impact on the final U.S. dollar equivalent paid for this acquisition. For example, a one percent decline in the current exchange rate between the U.S. and Canadian dollar would increase the cash paid for this acquisition by approximately \$521,000. We are closely monitoring this exchange rate risk and we are evaluating strategies to mitigate it, if necessary.

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, 2011. Based on that evaluation, the Company's management, including such officers, concluded that the Company's disclosure controls and procedures were adequate and effective as of June 30, 2011 to ensure that information required to be disclosed by the Company in the reports that we file or submit under the Securities Exchange Act of 1934 was accumulated and communicated to the Company's management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure and was recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC.

(b) Changes in Internal Control Over Financial Reporting. There was no change in the Company's internal control over financial reporting that occurred during the three months ended June 30, 2011 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1A. RISK FACTORS

Except as noted below, there have been no material changes to the factors disclosed in Item 1A., entitled "Risk Factors," in our Annual Report on Form 10-K for the year ended December 31, 2010:

There are risks associated with our recent entry into a definitive agreement to acquire DNA Genotek Inc.

On July 25, 2011, we entered into a definitive Support Agreement to acquire all of the outstanding capital stock of DNAG, a leading provider of oral fluid sample collection, stabilization and preparation products for molecular diagnostic applications. There are risks associated with our having entered into this agreement.

We cannot assure you that all conditions to the proposed acquisition will be completed and the proposed acquisition consummated. The proposed acquisition is subject to the satisfaction of customary closing conditions. In the event that the proposed acquisition is not completed, we may be subject to risks, including the costs related to the proposed acquisition, such as legal, accounting, and advisory fees, which must be paid even if the acquisition is not completed. If the proposed acquisition is not completed, the market price of our Common Stock could decline.

We and DNAG entered into the Support Agreement with the expectation that the acquisition will result in benefits to both companies. Because of difficulties associated with combining or managing geographically distant operations, we may not achieve successful integration of DNAG in a timely manner, or at all, and we may not realize the benefits of the acquisition to the extent, or in the timeframe, anticipated. It is possible that the integration process could result in the loss of key employees, diversion of each company's management's attention, the disruption or interruption of, or the loss of momentum in, each company's ongoing business or inconsistencies in standards, controls, procedures and policies, any of which could adversely affect either company's ability to maintain relationships with licensors, collaborators, partners, suppliers and employees or our ability to achieve the anticipated benefits of the acquisition, or could reduce our earnings or otherwise adversely affect the business and financial results of the combined company and, as a result, adversely affect the market price of our Common Stock.

We may incur costs integrating DNAG's business operations, technology, development programs, products and personnel with those of OraSure's. These costs are difficult to estimate, may be higher than expected, and may harm the financial results of the combined company. We have incurred substantial direct transaction costs associated with the proposed acquisition and we expect to continue to incur substantial costs for these purposes. If the total costs of the proposed acquisition exceed estimates or if the benefits of the proposed acquisition do not exceed the total costs of the proposed acquisition, our financial results could be adversely affected.

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

During the quarter ended June 30, 2011, pursuant to the OraSure Technologies, Inc. Stock Award Plan, and in connection with the vesting of restricted shares, we retired 2,735 shares of our Common Stock to satisfy minimum tax withholding obligations at an average price paid per share of \$8.50.

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, 2011

/s/ Ronald H. Spair

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

Date: August 5, 2011

/s/ Mark L. Kuna

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

EXHIBIT INDEX

Exhibit

2.1	Support Agreement, dated July 25, 2011, by and among OraSure Technologies, Inc., 7924569 Canada Inc., DNA Genotek, Inc. (“DNAG”), 1548674 Ontario Inc., the shareholders of 1548674 Ontario Inc. and certain representatives of DNAG shareholders, is incorporated by reference to Exhibit 2.1 to the Company’s Current Report on Form 8-K filed July 25, 2011.
2.2	Form of Offer to Purchase and Share Purchase Agreement, between 7924569 Canada Inc. and the DNAG shareholder signatory thereto is incorporated by reference to Exhibit 2.2 to the Company’s Current Report on Form 8-K filed July 25, 2011.
10.1	OraSure Technologies, Inc. Stock Award Plan, amended and restated effective as of May 17, 2011, is incorporated by reference to Exhibit 10 to the Company’s Current Report on Form 8-K filed May 5, 2011.*
10.2	Form of Restricted Share Grant Agreement (Executive Officers).*
10.3	Form of Restricted Share Grant Agreement (Non-Employee Directors).*
10.4	Nonqualified Stock Option Award General Terms and Conditions (Executive Officers).*
10.5	Nonqualified Stock Option Award General Terms and Conditions (Non-Employee Directors).*
10.6	Sixth Amendment to Loan and Security Agreement, dated as of June 24, 2011, between OraSure Technologies, Inc. and Comerica Bank is incorporated by reference to Exhibit 10 to the Company’s Current Report on Form 8-K filed June 27, 2011.
31.1	Certification of Douglas A. Michels required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Ronald H. Spair required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
32.1	Certification of Douglas A. Michels required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Ronald H. Spair required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Management contract or compensatory plan or arrangement.

RESTRICTED SHARE GRANT AGREEMENT**(Executive Officers)**

This Restricted Share Grant Agreement (“Agreement”) is entered into as of [DATE] between ORASURE TECHNOLOGIES, INC., a Delaware corporation (“OraSure” or the “Company”), and [NAME] (“Participant”).

The OraSure Technologies, Inc. Stock Award Plan (the “Plan”) is administered by the Compensation Committee (the “Committee”) of the Board of Directors (the “Board”) of OraSure. This Agreement evidences the Committee’s grant of an Award of Restricted Shares to Participant under the Plan. Capitalized terms not otherwise defined in this Agreement have the meanings given in the Plan.

OraSure and Participant agree as follows:

1. Grant of Restricted Shares. Subject to the terms and conditions of this Agreement and the Plan, OraSure shall issue to Participant [# OF SHARES] shares of OraSure common stock (the “Restricted Shares”).

2. Terms of Restricted Shares. The Restricted Shares shall be subject to all the provisions of the Plan and to the following terms and conditions:

2.1 Transfer Restrictions. Except as expressly provided in Section 2.2, none of the Restricted Shares, or any rights under this Agreement, may be sold, assigned, transferred, pledged, encumbered, or otherwise disposed of, voluntarily or involuntarily, by Participant. The foregoing restrictions are in addition to any other restrictions on transfer of the Restricted Shares arising under federal or state securities laws or other agreements with OraSure. Any purported sale, assignment, transfer, pledge, encumbrance, or other disposition of Restricted Shares in violation of this Agreement shall be null and void and may and should be enjoined.

2.2 Vesting of Restricted Shares. The Restricted Shares shall become Vested, and the restrictions set forth in Section 2.1 shall expire, (a) (i) on [DATE] with respect to [# OF SHARES] of the Restricted Shares, (ii) on [DATE] with respect to the next [# OF SHARES] Restricted Shares and (iii) on [DATE] with respect to the remaining [# OF SHARES] Restricted Shares or (b) immediately as to 50% of the Restricted Shares which are not then Vested upon termination of Participant’s employment by the Company without Cause (as defined below) or by Participant for Good Reason (as defined below), in each case during a period other than a Change of Control Period (as defined below), or (c) immediately as to all Restricted Shares which are not then Vested upon (i) any Change of Control (as defined below) or (ii) upon termination of Participant’s employment by the Company without Cause or by Participant for Good Reason, in each case during a Change of Control Period, or (d) immediately as to all Restricted Shares which are not then Vested upon Participant’s earlier death or Disability. When the

Restricted Shares have become Vested, OraSure shall deliver to Participant one or more share certificates evidencing the Vested Restricted Shares, without the legend described in Section 4, and shall return the corresponding stock power or stock powers described in Section 4. The terms of this Agreement, including, but not limited to, the number of such Restricted Shares which shall become Vested in accordance with this Section 2.2, shall be subject to adjustment pursuant to Section 14.2 of the Plan.

2.3 Employment Requirement—Forfeiture. If Participant's employment with OraSure terminates for any reason other than an event described in Section 2.2(b) or 2.2(c) or 2.2(d) at any time prior to the date the Restricted Shares become Vested, all of the Restricted Shares that are not then Vested after giving effect (if any) to Section 2.2(b), 2.2(c) and 2.2(d) above shall be forfeited to OraSure with no payment to Participant.

3. Rights as Stockholder. Except as expressly provided in this Agreement, Participant shall be entitled to all the rights of a stockholder with respect to the Restricted Shares, including the right to vote the Restricted Shares and to receive cash dividends, if any, payable with respect to the Restricted Shares, subject to the restrictions described in Section 9.6 of the Plan. Any stock dividends issued with respect to the Restricted Shares before the Restricted Shares have become Vested shall be treated as additional Restricted Shares subject to this Agreement and shall become Vested as the Restricted Shares with respect to which such stock dividends were issued become Vested.

4. Share Certificates. Certificates for the Restricted Shares shall be issued in Participant's name and shall be held by OraSure until the Restricted Shares are Vested or forfeited as provided in this Agreement. Participant shall execute and deliver to OraSure a separate stock power in blank with respect to each certificate for the Restricted Shares. All certificates for Restricted Shares that have not yet become Vested shall bear a legend in substantially the following form:

THE SHARES EVIDENCED BY THIS CERTIFICATE WERE ISSUED AS RESTRICTED SHARES UNDER THE ORASURE TECHNOLOGIES, INC., STOCK AWARD PLAN (THE "PLAN") AND ARE SUBJECT TO RESTRICTIONS ON THEIR SALE, ASSIGNMENT, TRANSFER, PLEDGE, ENCUMBRANCE, OR OTHER DISPOSITION SET FORTH IN A RESTRICTED SHARE GRANT AGREEMENT UNDER THE PLAN. A COPY OF THE RESTRICTED SHARE GRANT AGREEMENT MAY BE OBTAINED UPON WRITTEN REQUEST FROM ORASURE TECHNOLOGIES, INC.

Certificates for the Restricted Shares may also bear any other restrictive legends required by law or any other agreement.

5. Federal Tax Election. Participant agrees to promptly notify OraSure if Participant makes an election under Internal Revenue Code Section 83(b) with respect to the Restricted Shares. Participant acknowledges that such an election must be made within 30 days after the issuance of the Restricted Shares.

6. Withholding Taxes. Participant shall pay to OraSure, or permit OraSure to withhold from other amounts payable to Participant, as compensation or otherwise, an amount sufficient to satisfy all federal, state, and local withholding tax requirements or tax liability with respect to the issuance or the Vesting of the Restricted Shares. Alternatively, Participant may, by written notice to the Committee that complies with any applicable timing restrictions imposed pursuant to Rule 16b-3 under the Exchange Act, elect to satisfy all or a part of the withholding tax obligations incident to the issuance or Vesting of the Restricted Shares by having OraSure withhold a portion of the Restricted Shares that would otherwise be issuable to Participant. Such Restricted Shares will be valued based on their Fair Market Value on the date the tax withholding is required to be made. Any stock withholding with respect to Participant will be subject to such limitations as the Committee may impose to comply with the requirements of the Exchange Act.

7. Other Documents. Participant agrees to furnish OraSure any documents or representations OraSure may require related to the Restricted Shares or this Agreement to assure compliance with applicable laws and regulations.

8. Service Period. Except as otherwise provided in Section 2.2, the period of service to be performed by Participant as an employee in connection with the issuance of the Restricted Shares to Participant is (i) the one (1) year period beginning on the date of this Agreement and ending on [DATE] with respect to the Restricted Shares referred to in clause 2.2(a)(i); (ii) the two (2) year period beginning on the date of this Agreement and ending on [DATE] with respect to the Restricted Shares referred to in clause 2.2(a)(ii); and (iii) the three (3) year period beginning on the date of this Agreement and ending on [DATE] with respect to the Restricted Shares referred to in clause 2.2(a)(iii).

9. Certain Defined Terms. When used in this Agreement, the following terms have the meanings specified below:

- 9.1 “**Cause**” shall have the meaning set forth in the Employment Agreement.
- 9.2 “**Change of Control**” shall have the meaning set forth in the Employment Agreement.
- 9.3 “**Change of Control Period**” shall have the meaning set forth in the Employment Agreement.
- 9.4 “**Employment Agreement**” means the Employment Agreement dated as of [DATE] between the Company and Participant.
- 9.5 “**Good Reason**” shall have the meaning set forth in the Employment Agreement.

10. No Employment Contract. Neither the Plan nor this Agreement constitutes a contract of employment of Participant by OraSure.

11. Notices. Any notices under this Agreement shall be in writing and shall be effective when actually delivered personally or, if mailed, when deposited as certified mail, directed to

OraSure at its principal offices, to Participant at the address maintained in OraSure's records, or to such other address as either party may specify by notice to the other party.

12. Choice of Law. This Agreement shall be governed by the laws of the Commonwealth of Pennsylvania, without regard to any contrary conflicts of laws rules.

13. Successorship. Subject to the restrictions on transferability of the Restricted Shares set forth in this Agreement and the Plan, this Agreement shall be binding upon and benefit the parties, their successors and assigns.

ORASURE TECHNOLOGIES, INC.

[NAME OF EMPLOYEE]

By: _____
Title: _____

RESTRICTED SHARE GRANT AGREEMENT**(Non-Employee Directors)**

This Restricted Share Grant Agreement (“Agreement”) is entered into as of [DATE] between ORASURE TECHNOLOGIES, INC., a Delaware corporation (“OraSure” or the “Company”), and [NAME] (“Participant”).

The OraSure Technologies, Inc. Stock Award Plan (the “Plan”) is administered by the Compensation Committee (the “Committee”) of the Board of Directors of OraSure (the “Board”). This Agreement evidences the Committee’s grant of an Award of Restricted Shares to Participant under the Plan. Capitalized terms not otherwise defined in this Agreement have the meanings given in the Plan.

OraSure and Participant agree as follows:

1. Grant of Restricted Shares. Subject to the terms and conditions of this Agreement and the Plan, OraSure shall issue to Participant [# OF SHARES] shares of OraSure common stock (the “Restricted Shares”).

2. Terms of Restricted Shares. The Restricted Shares shall be subject to all the provisions of the Plan and to the following terms and conditions:

- 2.1 Transfer Restrictions.** Except as expressly provided in Section 2.2, none of the Restricted Shares, or any rights under this Agreement, may be sold, assigned, transferred, pledged, encumbered, or otherwise disposed of, voluntarily or involuntarily, by Participant. The foregoing restrictions are in addition to any other restrictions on transfer of the Restricted Shares arising under federal or state securities laws or other agreements with OraSure. Any purported sale, assignment, transfer, pledge, encumbrance, or other disposition of Restricted Shares in violation of this Agreement shall be null and void and may and should be enjoined.
- 2.2 Vesting of Restricted Shares.** Provided that the Restricted Shares have not been previously forfeited, the Restricted Shares shall become Vested, and the restrictions set forth in Section 2.1 shall expire upon the earlier of: (a) [DATE], or (b) the occurrence of a Change of Control (as defined below). When the Restricted Shares have become Vested, OraSure shall deliver to Participant one or more share certificates evidencing the Vested Restricted Shares, without the legend described in Section 4, and shall return the corresponding stock power or stock powers described in Section 4. The terms of this Agreement, including, but not limited to, the number of such Restricted Shares which shall become Vested in accordance with this Section 2.2, shall be subject to adjustment pursuant to Section 14.2 of the Plan.
- 2.3 Service Requirement—Forfeiture.** If Participant’s service on the Board terminates for any reason prior to the date the Restricted Shares become Vested,

all of the Restricted Shares that are not then Vested shall be forfeited to OraSure with no payment to Participant.

3. Rights as Stockholder. Except as expressly provided in this Agreement, Participant shall be entitled to all the rights of a stockholder with respect to the Restricted Shares, including the right to vote the Restricted Shares and to receive cash dividends, if any, payable with respect to the Restricted Shares, subject to the restrictions described in Section 9.6 of the Plan. Any stock dividends issued with respect to the Restricted Shares before the Restricted Shares have become Vested shall be treated as additional Restricted Shares subject to this Agreement and shall become Vested as the Restricted Shares with respect to which such stock dividends were issued become Vested.

4. Share Certificates. Certificates for the Restricted Shares shall be issued in Participant's name and shall be held by OraSure until the Restricted Shares are Vested or forfeited as provided in this Agreement. Participant shall execute and deliver to OraSure a separate stock power in blank with respect to each certificate for the Restricted Shares. All certificates for Restricted Shares that have not yet become Vested shall bear a legend in substantially the following form:

THE SHARES EVIDENCED BY THIS CERTIFICATE WERE ISSUED AS RESTRICTED SHARES UNDER THE ORASURE TECHNOLOGIES, INC., STOCK AWARD PLAN (THE "PLAN") AND ARE SUBJECT TO RESTRICTIONS ON THEIR SALE, ASSIGNMENT, TRANSFER, PLEDGE, ENCUMBRANCE, OR OTHER DISPOSITION SET FORTH IN A RESTRICTED SHARE GRANT AGREEMENT UNDER THE PLAN. A COPY OF THE RESTRICTED SHARE GRANT AGREEMENT MAY BE OBTAINED UPON WRITTEN REQUEST FROM ORASURE TECHNOLOGIES, INC.

Certificates for the Restricted Shares may also bear any other restrictive legends required by law or any other agreement.

5. Federal Tax Election. Participant agrees to promptly notify OraSure if Participant makes an election under Internal Revenue Code Section 83(b) with respect to the Restricted Shares. Participant acknowledges that such an election must be made within 30 days after the issuance of the Restricted Shares.

6. Withholding Taxes. Participant shall pay to OraSure, or permit OraSure to withhold from other amounts payable to Participant, as compensation or otherwise, an amount sufficient to satisfy all federal, state, and local withholding tax requirements or tax liability with respect to the issuance or the Vesting of the Restricted Shares. Alternatively, Participant may, by written notice to the Committee that complies with any applicable timing restrictions imposed pursuant to Rule 16b-3 under the Exchange Act, elect to satisfy all or a part of the withholding tax obligations incident to the issuance or Vesting of the Restricted Shares by having OraSure withhold a portion of the Restricted Shares that would otherwise be issuable to Participant. Such Restricted Shares will be valued based on their Fair Market Value on the date the tax withholding is required to be made. Any stock withholding with respect to Participant will be subject to such limitations as the Committee may impose to comply with the requirements of the Exchange Act.

7. Other Documents. Participant agrees to furnish OraSure any documents or representations OraSure may require related to the Restricted Shares or this Agreement to assure compliance with applicable laws and regulations.

8. Service Period. Except as otherwise provided in Section 2.2, the period of service to be performed by Participant as a member of the Board in connection with the issuance of the Restricted Shares pursuant to Section 1 is the one (1) year period beginning on the date of this Agreement and ending on [DATE].

9. No Employment Contract. Neither the Plan nor this Agreement constitutes a contract of employment of Participant by OraSure.

10. Notices. Any notices under this Agreement shall be in writing and shall be effective when actually delivered personally or, if mailed, when deposited as certified mail, directed to OraSure at its principal offices, to Participant at the address maintained in OraSure's records, or to such other address as either party may specify by notice to the other party.

11. Choice of Law. This Agreement shall be governed by the laws of the Commonwealth of Pennsylvania, without regard to any contrary conflicts of laws rules.

12. Successorship. Subject to the restrictions on transferability of the Restricted Shares set forth in this Agreement and the Plan, this Agreement shall be binding upon and benefit the parties, their successors and assigns.

ORASURE TECHNOLOGIES, INC.

By: _____

Title: _____

[NAME OF DIRECTOR]

**Nonqualified Stock Option Award
General Terms and Conditions
(Executive Officers)**

The OraSure Technologies, Inc. Stock Award Plan (“Plan”) is administered by the compensation committee (the “Committee”) of the board of directors of Corporation (the “Board”). Capitalized terms not otherwise defined have the meanings assigned in Section 11 of these Nonqualified Stock Option Award General Terms and Conditions (“Agreement Terms”).

1. Option Type and Term.

- 1.1 Type of Option.** The Option is not intended to be an incentive stock option as described in Internal Revenue Code Section 422.
- 1.2 Term.** The Option term will expire on the expiration date shown on the cover sheet unless earlier terminated pursuant to this Agreement.
- 1.3 Vesting.** Except as otherwise provided in this Agreement, the Option will be vested as to, and accordingly may be exercised from time to time during the term to purchase, Shares up to the number shown on the cover page as vested as of the date of exercise.

2. Employment Requirement.

- 2.1 General.** Except as provided in Section 3 of this Agreement, the Option may not be exercised and will not be deemed vested unless the recipient of the Option (the “Participant”) is employed by Corporation and/or one or more of its Subsidiaries (an “Employer”) continuously for at least one year after the Grant Date, unless employment is terminated by death or Disability. “Employment” for purposes of the Option will include periods of illness or other leaves of absence authorized by an Employer or by law.
- 2.2 No Employment Contract.** Neither the Plan nor the Option constitutes a contract of employment of Participant by any Employer.
- 2.3 Expiration After Termination of Employment.** If Participant ceases to be an active employee of the Employer, the right to exercise the Option will expire upon the earlier of (i) the end of the original term as specified in Section 1.2 above, and (ii) the end of the following periods as applicable:

<u>After Termination On Account Of</u>	<u>Period</u>
Death	1 year
Retirement	5 years

Disability
Any other reason

1 year
1 year

2.4 Effect of Termination on Vesting. Subject to Sections 2.1 and 3, the Option will continue vesting in accordance with Section 1.3 and will cease vesting upon termination of Participant's employment with Employer. The Shares as to which the Option is exercisable under Section 2.3 will be those as to which the Option is vested at the time of exercise.

2.5 Adjustments. The Shares, the exercise price for the Shares and other terms of this Option shall be subject to adjustment pursuant to Section 14.2 of the Plan

3. Acceleration of Exercisability. If (i) a Change of Control Date occurs while Participant is employed by Employer, (ii) Participant's employment with Employer is terminated by Employer without Cause or by Participant for Good Reason, in each case during a Change of Control Period, or (ii) Participant dies or suffers a Disability, the Option will become immediately and fully vested and exercisable as to all Shares covered by the Option. In the event Participant's employment with the Employer is terminated by Employer without Cause or by Participant for Good Reason, in each case during a period other than a Change of Control Period, then the Option will become immediately vested and exercisable as to 50% of the number of Shares with respect to which the Option had not then vested and will not otherwise become vested during the period set forth in Section 2.4. To the extent the terms of the Employment Agreement provide for the accelerated vesting of the Option on terms other than as set forth herein, such terms shall be effective and incorporated herein.

4. Method of Exercise.

4.1 Exercise of Option. All or any portion of the Option may be exercised, to the extent it has become exercisable pursuant to this Agreement, by delivery of written notice to Corporation in the attached form stating the number of Shares, form of payment, and proposed date of closing.

4.2 Other Documents. Participant must furnish Corporation, before closing of any exercise of the Option, such other documents or representations as Corporation may require to assure compliance with applicable laws and regulations.

4.3 Payment. The exercise price for the Shares purchased upon exercise of the Option must be paid in full at or before closing by one or a combination of the following:

- (a) Payment in cash;

(b) By delivery (in a form approved by the Committee) of an irrevocable direction to a securities broker acceptable to the Committee:

(i) To sell Shares subject to the Option and to deliver all or a part of the sales proceeds to Corporation in payment of all or a part of the exercise price and withholding taxes due; or

(ii) To pledge Shares subject to the Option to the broker as security for a loan and to deliver all or a part of the loan proceeds to Corporation in payment of all or a part of the exercise price and withholding taxes due; or

(c) Delivery of previously acquired Shares having a Fair Market Value at least equal to the exercise price.

4.4 Previously Acquired Shares. Delivery of previously acquired Shares surrendered in full or partial payment of the exercise price of all or any portion of the Option, will be subject to the following conditions:

(a) The Shares tendered must be in good delivery form;

(b) The Fair Market Value of the Shares, together with the amount of cash, if any, tendered must equal or exceed the exercise price of the Option;

(c) Any Shares remaining after satisfying payment of the exercise price will be reissued in the same manner as the Shares tendered; and

(d) No fractional Shares will be issued and cash will not be paid to Participant for any fractional Share value not used to satisfy payment of the exercise price.

5. Transferability.

5.1 Restriction.

(a) The Option is not transferable by Participant other than by testamentary will or the laws of descent and distribution and, during Participant's lifetime, may be exercised only by Participant or Participant's guardian or legal representative;

(b) No assignment or transfer of the Option, whether voluntary, involuntary, or by operation of law or otherwise, except by testamentary will or the laws of descent and distribution, will vest in the assignee or transferee any interest or right; and

(c) Immediately upon any attempt to assign or transfer the Option, the Option will terminate and be of no force or effect.

5.2 Exercise in the Event of Death or Disability. Whenever the word "Participant" is used in any provision of this Agreement under circumstances when the provision should logically be construed to apply to Participant's guardian, legal representative, executor, administrator, or the person or persons to whom the Option may be transferred by testamentary will or by the laws of descent and distribution, the word "Participant" will be deemed to include such person or persons.

6. Securities Laws. Corporation will not be required to issue any Shares upon exercise of the Option, or any portion thereof, until Corporation has taken any action required to comply with the provisions of the Securities Act of 1933 or any other then applicable federal or state securities laws.

7. Tax Reimbursement. In the event any withholding or similar tax liability is imposed on Corporation in connection with or with respect to the exercise of the Option or the disposition by Participant of the Shares acquired upon exercise of the Option, Participant will pay to Corporation an amount sufficient to satisfy such tax liability or may direct the Corporation to withhold from the Shares acquired upon exercise Shares having a Fair Market Value as of such date equal to such tax liability.

8. Conditions Precedent. Corporation will use its best efforts to obtain any required approvals of the Plan and the Option by any state or federal agency or authority that Corporation determines has jurisdiction. If Corporation determines that any required approval cannot be obtained, all Awards to Participant will terminate on notice to Participant to that effect.

9. Termination for Cause; Competition.

9.1 Annulment of Awards. The grant of the Option is provisional until Participant becomes entitled to a certificate for Shares in settlement of the Option. In the event the employment of Participant is terminated for Cause, any portion of the Option that is provisional will be annulled as of the date of such termination for Cause.

9.2 Engaging in Competition With Corporation. If Participant terminates employment with an Employer for any reason whatsoever, and within 12 months after the date of termination Participant materially breaches Section 9(c) of the Employment Agreement, the Committee, in its sole discretion, may require Participant to return to Corporation the economic value of any Award that is realized or obtained (measured at the date of exercise) by Participant at any time during the period beginning on the date that is six months prior to the date of Participant's termination of

employment with the Employer through the date of the Committee's action.

10. **Successorship.** Subject to the restrictions on transferability of the Option set forth in this Agreement and in the Plan, this Agreement will be binding upon and benefit the parties, their successors, and assigns.
11. **Defined Terms.** When used in this Agreement, the following terms have the meanings specified below:
 - 11.1 "**Agreement**" means the agreement evidencing an Option governed by these Agreement Terms.
 - 11.2 "**Cause**" shall have the meaning set forth in the Employment Agreement.
 - 11.3 "**Change of Control**" shall have the meaning set forth in the Employment Agreement.
 - 11.4 "**Change of Control Date**" means the first date following the date of the Agreement on which a Change in Control has occurred.
 - 11.5 "**Change of Control Period**" shall have the meaning set forth in the Employment Agreement.
 - 11.6 "**Disability**" shall have the meaning set forth in the Employment Agreement.
 - 11.7 "**Employment Agreement**" means the currently effective Employment Agreement between Corporation and Participant, as the same may be amended or supplemented.
 - 11.8 "**Good Reason**" shall have the meaning set forth in the Employment Agreement.
 - 11.9 "**Grant Date**" means the date of the Agreement, which is the date the Option is granted to Participant.
 - 11.10 "**Option**" means the Nonqualified Stock Option granted to Participant evidenced by this Agreement.
 - 11.11 Capitalized terms not otherwise defined in this Agreement have the meanings given them in the Plan.
12. **Option Subject to Plan.** The Option is issued under the Plan and shall be governed by its terms. Except as specifically set forth herein, in the event of any inconsistency between the Plan and this Agreement, the Plan's terms shall control.

13. **Notices.** Any notices regarding the Option must be in writing and will be effective when actually delivered personally or, if mailed, when deposited as certified mail directed to the address maintained in Corporation's records or to such other address as a party may certify by notice to the other party.

Attachment: Exercise Form

ELECTION TO EXERCISE NONQUALIFIED STOCK OPTION

To: OraSure Technologies, Inc.
220 East First Street
Bethlehem, PA 18015

The undersigned hereby exercises the NonQualified Stock Option _____ evidenced
(option number)
by the NonQualified Stock Option Award Agreement dated _____ (the "NonQualified
(date options were granted)
Agreement"), for _____ shares (the "Shares") of common stock of OraSure
(# of shares you wish to purchase)
Technologies, Inc. (the "Company") at the price of \$_____ per share and agrees to tender payment
(option price)
therefor in the amount of \$_____ (the "Exercise Price") and required withholding taxes in
(# of shares purchased X option price)
accordance with the terms of the NonQualified Stock Option Award Agreement for closing on
_____.
(approximately 10 days after exercise)

Mark the appropriate responses below:

1. Payment

- Payment in the amount of the Exercise Price and required withholding taxes is enclosed.
Payment in the amount of the Exercise Price and required withholding taxes will be made to the Company within ten business days by
("Broker"), to which I have given irrevocable instructions to sell enough of the Shares for such purpose and to deliver
proceeds in the amount of the Exercise Price and withholding taxes to the Company. If the Broker does not make such payment within such time, I
agree to pay the Exercise Price and withholding taxes to the Company within an additional five business days.
Payment shall be made as described on the page attached hereto.

2. Delivery of Shares.

- The shares have been sold. Please deliver the stock certificate to, and made out in the name of the following:
(e.g., Broker, Address, Account Number)
The Shares have not been sold. Please deliver the stock certificate to, and made out in the name of:
(e.g., your name)

DATED: _____

(Printed Name)
(Signature of Participant)

EXERCISE OF NONQUALIFIED STOCK OPTIONS

OraSure Technologies, Inc.
220 East First Street
Bethlehem, PA 18015

For Federal Income Tax purposes, ORASURE TECHNOLOGIES, INC. is required to include on each Participant's year-end tax Form W-2 or 1099-MISC and on the Company's tax return, an amount equal to the difference between the fair market value of stock purchased upon exercise of a NonQualified Stock Option on the exercise date and the option exercise price (the "Option Spread").

If you sold any of these option shares **on the same day that you exercised them**, please provide the following information and return a copy of this form to the Accounting department. This information will assist in the determination of the fair market value of the shares at the time of exercise to be used to calculate the Option Spread and proper withholding amounts.

Option Number _____ **Date** _____ **Sale price per share** _____

Option Number _____ **Date** _____ **Sale price per share** _____

Option Number _____ **Date** _____ **Sale price per share** _____

Option Number _____ **Date** _____ **Sale price per share** _____

Printed Name

Signature of Participant

**Nonqualified Stock Option Award
General Terms and Conditions
(Non-Employee Directors)**

OraSure Technologies, Inc. (the "Company") maintains the Stock Award Plan (the "Plan"). These Non-Qualified Stock Option Award General Terms and Conditions (the "Award Terms") govern the Award of an Option to Participant as a Non-Employee Director pursuant to the Plan. Capitalized terms not otherwise defined shall have the meanings set forth in Section 10 of these Award Terms.

1. Option Type and Term.

- 1.1 Type of Option.** The Option is not intended to be an incentive stock option as described in Internal Revenue Code Section 422.
- 1.2 Term.** The Option term will expire on the expiration date shown on the cover sheet unless earlier terminated pursuant to this Agreement.
- 1.3 Vesting.** Except as otherwise provided in this Agreement, the Option will be vested as to, and accordingly may be exercised from time to time during the term to purchase, Shares up to the number shown on the cover page as vested as of the date of exercise.

2. Service As Director.

- 2.1 Expiration After Termination of Service.** If the recipient of the Option ("Participant") ceases to be a member of the Board of Directors of the Company (the "Board") for any reason, the right to exercise the Option will expire upon the earlier of (i) the end of the original term as specified in Section 1.2 above, and (ii) the end of the following periods as applicable:

<u>After Termination On Account Of</u>	<u>Period</u>
Death	1 year
Retirement	5 years
Disability	1 year
Any other reason	1 year

- 2.2 Effect of Termination on Vesting.** Subject to Section 3, the Option will continue vesting in accordance with Section 1.3 and will cease vesting upon termination of Participant's service as a member of the Board. The Shares as to which the Option is exercisable will be those as to which the Option is vested at the time of exercise.
- 2.3 Adjustments.** The Shares, the exercise price for the Shares and other terms of the Option shall be subject to adjustment pursuant to Section 14.2 of the Plan.

- 2.4 **No Employment Contract.** Neither the Plan nor the Option constitutes a contract of employment of Participant by the Company or its affiliates.
3. **Acceleration of Exercisability.** The Option will become immediately and fully vested and exercisable as to all Shares covered by the Option, (a) if a Change in Control Date occurs while Participant serves on the Board or (b) upon Participant's death or Disability.
4. **Method of Exercise.**
- 4.1 **Exercise of Option.** All or any portion of the Option may be exercised, to the extent it has become exercisable pursuant to this Agreement, by delivery of written notice to the Company in the attached form stating the number of Shares, form of payment, and proposed date of closing.
- 4.2 **Other Documents.** Participant must furnish the Company, before closing of any exercise of the Option, such other documents or representations as the Company may require to assure compliance with applicable laws and regulations.
- 4.3 **Price and Payment.** The exercise price for the Shares purchased upon exercise of the Option shall be as set forth on the cover sheet and must be paid in full at or before closing by one or a combination of the following:
- (a) Payment in cash;
 - (b) Delivery (in a form approved by the Committee) of an irrevocable direction to a securities broker acceptable to the Committee:
 - (i) To sell Shares subject to the Option and to deliver all or a part of the sales proceeds to the Company in payment of all or a part of the exercise price and withholding taxes due; or
 - (ii) To pledge Shares subject to the Option to the broker as security for a loan and to deliver all or a part of the loan proceeds to the Company in payment of all or a part of the exercise price and withholding taxes due; or
 - (c) Delivery of previously acquired Shares having a Fair Market Value at least equal to the exercise price.
- 4.4 **Previously Acquired Shares.** Delivery of previously acquired Shares surrendered in full or partial payment of the exercise price of all or any portion of the Option, will be subject to the following conditions:
- (a) The Shares tendered must be in good delivery form;

- (b) The Fair Market Value of the Shares, together with the amount of cash, if any, tendered must equal or exceed the exercise price of the Option;
- (c) Any Shares remaining after satisfying payment of the exercise price will be reissued in the same manner as the Shares tendered; and
- (d) No fractional Shares will be issued and cash will not be paid to Participant for any fractional Share value not used to satisfy payment of the exercise price.

5. **Transferability.**

5.1 **Restriction.** Except for Permitted Transfers, as defined in Section 5.2:

- (a) The Option is not transferable by Participant other than by testamentary will or the laws of descent and distribution and, during Participant's lifetime, may be exercised only by Participant or Participant's guardian or legal representative;
- (b) No assignment or transfer of the Option, whether voluntary, involuntary, or by operation of law or otherwise, except by testamentary will or the laws of descent and distribution, will vest in the assignee or transferee any interest or right; and
- (c) Immediately upon any attempt to assign or transfer the Option, the Option will terminate and be of no force or effect.

5.2 **Permitted Transfers.** Participant may transfer all or any portion of the Option, without payment of consideration, to Participant's family members, trusts for such family members, or a partnership or limited liability company in which Participant and members of Participant's family own more than 50% of the voting interests.

5.3 **Exercise in the Event of Death or Disability.** Whenever the word "Participant" is used in any provision of this Agreement under circumstances when the provision should logically be construed to apply to Participant's guardian, legal representative, executor, administrator, or the person or persons to whom the Option may be transferred by testamentary will or by the laws of descent and distribution, the word "Participant" will be deemed to include such person or persons.

6. **Securities Laws.** The Company will not be required to issue any Shares upon exercise of the Option, or any portion thereof, until the Company has taken any action required to comply with the provisions of the Securities Act of 1933 or any other then applicable federal or state securities laws.

7. **Tax Reimbursement.** In the event any withholding or similar tax liability is imposed on the Company in connection with or with respect to the exercise of the Option or the disposition by Participant of the Shares acquired upon exercise of the Option, Participant will pay to the Company an amount sufficient to satisfy such tax liability.
8. **Conditions Precedent.** The Company will use its best efforts to obtain any required approvals of the Plan and the Option by any state or federal agency or authority that the Company determines has jurisdiction. If the Company determines that any required approval cannot be obtained, all Awards to Participant will terminate on notice to Participant to that effect.
9. **Successorship.** Subject to the restrictions on transferability of the Option set forth in this Agreement and in the Plan, the Agreement will be binding upon and benefit the parties, their successors, and assigns.
10. **Defined Terms.** When used in this Agreement, the following terms have the meanings specified below:
 - 10.1 **“Agreement”** means the agreement evidencing an Option governed by these Award Terms.
 - 10.2 **“Change in Control”** shall have the meaning set forth in the Plan.
 - 10.3 **“Change in Control Date”** means the first date following the Grant Date on which a Change in Control has occurred.
 - 10.5 **“Committee”** means the Compensation Committee of the Board or any successor thereto.
 - 10.6 **“Disability”** shall have the meaning set forth in the Plan.
 - 10.7 **“Grant Date”** means the date of this Agreement, which is the date the Option is granted to Participant.
 - 10.8 **“Option”** means the Nonqualified Stock Option granted to Participant evidenced by this Agreement.
 - 10.9 Capitalized terms not otherwise defined in this Agreement have the meanings given them in the Plan.
11. **Option Subject to Plan.** The Option is issued under the Plan and shall be governed by its terms. Except as specifically set forth herein, in the event of any inconsistency between the Plan and this Agreement, the Plan’s terms shall control.
12. **Notices.** Any notices regarding the Option must be in writing and will be effective when actually delivered personally or, if mailed, when deposited as certified mail directed to the address maintained in the Company’s records or to such other address as a party may certify by notice to the other party.

ELECTION TO EXERCISE NONQUALIFIED STOCK OPTION

To: OraSure Technologies, Inc.
220 East First Street
Bethlehem, PA 18015

The undersigned hereby exercises the NonQualified Stock Option _____ evidenced
(option number)
by the NonQualified Stock Option Award Agreement dated _____ (the "NonQualified
(date options were granted)
Agreement"), for _____ shares (the "Shares") of common stock of OraSure
(# of shares you wish to purchase)
Technologies, Inc. (the "Company") at the price of \$ _____ per share and agrees to tender payment
(option price)
therefor in the amount of \$ _____ (the "Exercise Price") and required withholding taxes in
(# of shares purchased X option price)
accordance with the terms of the NonQualified Stock Option Award Agreement for closing on
_____. (approximately 10 days after exercise)

Mark the appropriate responses below:

1. Payment

- Payment in the amount of the Exercise Price and required withholding taxes is enclosed.
Payment in the amount of the Exercise Price and required withholding taxes will be made to the Company within ten business days by
("Broker"), to which I have given irrevocable instructions to sell enough of the Shares for such purpose and to
deliver proceeds in the amount of the Exercise Price and withholding taxes to the Company. If the Broker does not make such payment
within such time, I agree to pay the Exercise Price and withholding taxes to the Company within an additional five business days.
Payment shall be made as described on the page attached hereto.

2. Delivery of Shares.

- The shares have been sold. Please deliver the stock certificate to, and made out in the name of the following:

(e.g., Broker, Address, Account Number)

- The Shares have not been sold. Please deliver the stock certificate to, and made out in the name of:

(e.g., your name)

DATED: _____

(Printed Name)

(Signature of Participant)

EXERCISE OF NONQUALIFIED STOCK OPTIONS

OraSure Technologies, Inc.
220 East First Street
Bethlehem, PA 18015

For Federal Income Tax purposes, ORASURE TECHNOLOGIES, INC. is required to include on each Participant's year-end tax Form W-2 or 1099-MISC and on the Company's tax return, an amount equal to the difference between the fair market value of stock purchased upon exercise of a NonQualified Stock Option on the exercise date and the option exercise price (the "Option Spread").

If you sold any of these option shares **on the same day that you exercised them**, please provide the following information and return a copy of this form to the Accounting department. This information will assist in the determination of the fair market value of the shares at the time of exercise to be used to calculate the Option Spread and proper withholding amounts.

Option Number	_____	Date	_____	Sale price per share	_____
Option Number	_____	Date	_____	Sale price per share	_____
Option Number	_____	Date	_____	Sale price per share	_____
Option Number	_____	Date	_____	Sale price per share	_____

Printed Name

Signature of Participant

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, 2011

/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, 2011

/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, 2011 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, 2011

**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, 2011 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, 2011