ORASURE TECHNOLOGIES INC
Form 10-Q
November 09, 2010
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2010.

OR

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

For the transition period from _____ to _____.

Commission File Number 001-16537

ORASURE TECHNOLOGIES, INC.

(Exact Name of Registrant as Specified in Its Charter)

DELAWARE	36-4370966
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification No.)
220 East First Street, Bethlehem, Pennsylvania	18015
(Address of Principal Executive Offices)	(Zip code)

(610) 882-1820

(Registrant s Telephone Number, Including Area Code)

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

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

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

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨	Smaller reporting company ¨

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

Number of shares of Common Stock, par value $.000001 per share, outstanding as of November 5, 2010: 46,220,322

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Item 1. FINANCIAL STATEMENTS

ORASURE TECHNOLOGIES, INC.

BALANCE SHEETS

(Unaudited)

	SEPTEMBER 30, 2010	DECEMBER 31, 2009
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 71,698,504	$ 74,933,630
Short-term investments	1,995,000	4,736,730
Accounts receivable, net of allowance for doubtful accounts of $176,826 and $256,572	13,144,922	13,693,340
Inventories	7,979,356	8,844,492
Prepaid expenses and other	2,024,463	2,609,518
Total current assets	96,842,245	104,817,710
PROPERTY AND EQUIPMENT, net	19,890,223	20,014,466
PATENTS AND PRODUCT RIGHTS, net	3,976,252	809,252
OTHER ASSETS	801,043	1,349,319
	$ 121,509,763	$ 126,990,747
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	$ 7,916,680	$ 509,761
Accounts payable	2,794,787	3,370,604
Accrued expenses and other	7,685,762	11,502,802
Total current liabilities	18,397,229	15,383,167
LONG-TERM DEBT		7,791,679
OTHER LIABILITIES	462	8,911
STOCKHOLDERS EQUITY		
Preferred stock, par value $.000001, 25,000,000 shares authorized, none issued		
Common stock, par value $.000001, 120,000,000 shares authorized, 46,220,322 and 45,929,511 shares issued and outstanding	46	46
Additional paid-in capital	240,924,224	239,126,422
Accumulated other comprehensive loss	(249,486)	(230,992)
Accumulated deficit	(137,562,712)	(135,088,486)
Total stockholders equity	103,112,072	103,806,990

	$ 121,509,763	$ 126,990,747

The accompanying notes are an integral part of these statements.

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ORASURE TECHNOLOGIES, INC.

STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
REVENUES:				
Product	$ 18,399,281	$ 20,907,469	$ 52,675,838	$ 54,576,906
Licensing and product development	634,829	701,848	3,521,632	1,562,423
	19,034,110	21,609,317	56,197,470	56,139,329
COST OF PRODUCTS SOLD	7,220,383	7,705,653	20,802,046	21,383,689
Gross profit	11,813,727	13,903,664	35,395,424	34,755,640
OPERATING EXPENSES:				
Research and development	3,008,359	2,925,242	9,143,792	8,710,380
Sales and marketing	4,593,270	5,227,933	15,897,966	15,539,730
General and administrative	3,923,348	3,974,684	12,775,932	12,866,414
Impairment of patent and product rights				3,028,375
	11,524,977	12,127,859	37,817,690	40,144,899
Operating income (loss)	288,750	1,775,805	(2,422,266)	(5,389,259)
INTEREST EXPENSE	(77,562)	(89,890)	(231,312)	(269,839)
INTEREST INCOME	48,465	116,002	139,283	690,506
FOREIGN CURRENCY GAIN (LOSS)	(6,004)	(4,508)	22,922	(11,652)
OTHER INCOME	20,305	1,933	17,147	1,933
Income (loss) before income taxes	273,954	1,799,342	(2,474,226)	(4,978,311)
INCOME TAXES				
NET INCOME (LOSS)	$ 273,954	$ 1,799,342	$ (2,474,226)	$ (4,978,311)
EARNINGS (LOSS) PER SHARE:				
BASIC AND DILUTED	$ 0.01	$ 0.04	$ (0.05)	$ (0.11)
SHARES USED IN COMPUTING EARNINGS (LOSS) PER SHARE				
BASIC	46,213,539	45,879,576	46,176,118	45,862,788

DILUTED	46,566,386	46,024,101	46,176,118	45,862,788

The accompanying notes are an integral part of these statements.

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ORASURE TECHNOLOGIES, INC.

STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine Months Ended September 30, 2010	2009
OPERATING ACTIVITIES:		
Net loss	$ (2,474,226)	$ (4,978,311)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Impairment of patent and product rights		3,028,375
Stock-based compensation	2,478,653	3,087,303
Depreciation and amortization	2,100,788	2,359,625
Reserve for excess and obsolete inventories	(12,491)	(289,311)
Changes in assets and liabilities:		
Accounts receivable	543,131	(755,345)
Inventories	877,627	1,563,768
Prepaid expenses and other assets	1,133,331	(81,957)
Accounts payable	(588,573)	(930,738)
Accrued expenses and other liabilities	(3,817,040)	(314,916)
Net cash provided by operating activities	241,200	2,688,493
INVESTING ACTIVITIES:		
Purchases of short-term investments		(5,986,000)
Proceeds from maturities and redemptions of short-term investments	2,741,000	40,592,000
Payments for patents and product rights	(3,500,000)	
Purchases of property and equipment	(1,643,266)	(989,428)
Net cash (used in) provided by investing activities	(2,402,266)	33,616,572
FINANCING ACTIVITIES:		
Repayments of long-term debt	(384,760)	(418,315)
Proceeds from issuance of common stock	3,722	17,898
Withholding and retirement of common stock	(693,022)	(377,008)
Purchase and retirement of common stock		(308,605)
Net cash used in financing activities	(1,074,060)	(1,086,030)
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(3,235,126)	35,219,035
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	74,933,630	39,565,218
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 71,698,504	$ 74,784,253
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		

Cash paid (received) for:				
Interest	$	256,670	$	273,162
Income taxes	$	(585,893)	$	30,500

The accompanying notes are an integral part of these statements.

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ORASURE TECHNOLOGIES, INC.

Notes to Financial Statements

(Unaudited)

1. The Company

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

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

2. Summary of Significant Accounting Policies

Basis of Presentation. The accompanying financial statements are unaudited and, in the opinion of management, include all adjustments (consisting only of normal and recurring adjustments) necessary for a fair presentation of our financial position and results of operations for these interim periods. These financial statements should be read in conjunction with the financial statements and notes thereto included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2009. Results of operations for the three and nine months ended September 30, 2010 are not necessarily indicative of the results of operations expected for the full year.

Use of Estimates. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions about future events. These estimates and underlying assumptions affect the amounts of assets and liabilities reported, disclosures about contingent assets and liabilities, and reported amounts of revenues and expenses. Such estimates include the valuation of accounts receivable, inventories and intangible assets, as well as calculations related to contingencies, accruals and indemnifications, among others. These estimates and assumptions are based on management s best estimates and judgment. Management evaluates its estimates and assumptions on an ongoing basis, using historical experience and other factors, which management believes to be reasonable under the circumstances, including the current economic environment. We adjust such estimates and assumptions when facts and circumstances dictate. Illiquid credit markets, volatile equity, foreign currency, and energy markets, and declines in consumer spending have combined to increase the uncertainty inherent in such estimates and assumptions. 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 September 30, 2010 and December 31, 2009, cash equivalents consisted of money market accounts.

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

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

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
September 30, 2010				
Certificates of deposit	$ 1,995,000	$	$	$ 1,995,000
Total available-for-sale securities	$ 1,995,000	$	$	$ 1,995,000
December 31, 2009				
Certificates of deposit	$ 3,986,000	$	$	$ 3,986,000
Corporate bonds	750,278	452		750,730
Total available-for-sale securities	$ 4,736,278	$ 452	$	$ 4,736,730

At September 30, 2010, all of our available-for-sale securities mature within less than one year.

Fair Value of Financial Instruments. As of September 30, 2010, the carrying values of cash and cash equivalents, short-term investments, accounts receivable, accounts payable and accrued expenses approximate their respective fair values based on their short-term nature. In addition, we believe the carrying value of our debt instruments, which do not have readily ascertainable market values, approximate their fair values, given that the interest rates on outstanding borrowings approximate market rates.

Fair value measurements of all financial assets and liabilities that are being measured and reported on a fair value basis are required to be classified and disclosed in one of the following three categories:

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2: Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability; and

Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

All our available-for-sale securities were classified and measured as Level 1 instruments.

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Inventories. Inventories are stated at the lower of cost or market determined on a first-in, first-out basis and are comprised of the following:

	September 30, 2010	December 31, 2009
Raw materials	$ 4,766,573	$ 4,911,570
Work in process	280,683	334,452
Finished goods	2,932,100	3,598,470
	$ 7,979,356	$ 8,844,492

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 September 30, 2010 and December 31, 2009 was $19,465,882 and $17,764,364, respectively.

Patents and Product Rights. Patents and product rights consist of costs associated with the acquisition of patents, licenses and product distribution rights. Patents and product rights are amortized using the straight-line method over their estimated useful lives of three to ten years. Accumulated amortization of patents and product rights as of September 30, 2010 and December 31, 2009 was $5,472,368 and $5,139,368, respectively.

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

Revenue Recognition. We recognize product revenues when there is persuasive evidence that an arrangement exists, the price is fixed or determinable, title has passed and collection is reasonably assured. Product revenues are recorded net of allowances for any discounts or rebates. We do not grant price protection or product return rights to our customers, except for warranty returns and return rights granted to retail customers for our domestic cryosurgical wart removal product.

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

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

Up-front licensing fees are deferred and recognized ratably over the related license period. Product development revenues are recognized over the period in which the related product development efforts are performed. Amounts received prior to the performance of product development efforts are recorded as deferred revenues. Grant revenue is recognized as the related work is performed and costs are incurred. We record shipping and handling charges billed to our customers as product revenue and the related expense as cost of products sold. Taxes assessed by governmental authorities, such as sales or value-added taxes, are excluded from product revenues.

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Significant Customer Concentration. The Company had no significant concentrations (greater than 10%) in accounts receivable as of September 30, 2010 or in revenues for both the three and nine months ended September 30, 2010 and 2009. As of December 31, 2009, one of our customers, National Aids Control Program, accounted for 11% of our accounts receivable balance.

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

Earnings (Loss) Per Share. Basic and diluted earnings (loss) per share is computed by dividing net income (loss) by the weighted-average number of shares of common stock outstanding during the period. Diluted earnings (loss) per share is computed in a manner similar to basic earnings (loss) per share except that the weighted average number of shares outstanding is increased to include incremental shares from the assumed vesting or exercise of dilutive securities, such as common stock options, warrants and unvested restricted stock. The number of incremental shares is calculated by assuming that outstanding stock options and warrants were exercised and unvested restricted share were vested, and the proceeds from such exercises or vesting were used to acquire shares of common stock at the average market prices during the reporting period.

The computations of basic and diluted earnings (loss) per share are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Net income (loss)	$ 273,954	$ 1,799,342	$ (2,474,226)	$ (4,978,311)
Weighted average shares of common stock outstanding:				
Basic	46,213,539	45,879,576	46,176,118	45,862,788
Dilutive effect of stock options, warrants and restricted stock	352,847	144,525		
Diluted	46,566,386	46,024,101	46,176,118	45,862,788
Earnings (loss) per share:				
Basic and Diluted	$ 0.01	$ 0.04	$ (0.05)	$ (0.11)

For the three-month periods ended September 30, 2010 and 2009, outstanding common stock options, warrants and unvested restricted stock, representing 6,053,737 and 6,504,430 shares, respectively, were excluded from the computation of diluted earnings (loss) per share, as their inclusion would have been anti-dilutive. For the nine months ended September 30, 2010 and 2009, outstanding common stock options, warrants and unvested restricted stock, representing 5,593,988 and 6,249,498 shares, respectively, were excluded from the computation of diluted earnings (loss) per share, as their inclusion would have been anti-dilutive.

Other Comprehensive Income (Loss). We classify items of other comprehensive loss by their nature and disclose the accumulated balance of other comprehensive loss separately from accumulated deficit and additional paid-in capital in the stockholders equity section of our balance sheet. Accumulated other comprehensive loss at September 30,

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2010 and December 31, 2009 consisted of currency translation adjustments and net unrealized losses on short-term investments. Comprehensive income (loss) was $257,158 and $1,781,623 for the three months ended September 30, 2010 and 2009, respectively, and $(2,492,720) and $(4,947,946) for the nine months ended September 30, 2010 and 2009, respectively.

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

3. Patents and Product Rights

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

During the second quarter of 2010, we achieved another milestone under this agreement and have capitalized a $2,500,000 payment. Commencing in July 2010, we began amortizing this payment on a straight line basis over ten years, which represents the expected life of the product. Under the terms of the license agreement, we will also be required to pay an additional license fee of $1,000,000, upon the achievement of a specific commercial milestone.

4. Prepaid Expenses and Other Noncurrent Assets

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

5. Stock-Based Compensation

We grant stock-based awards under the OraSure Technologies, Inc. 2000 Stock Award Plan, as amended and restated (the 2000 Plan). The 2000 Plan permits stock-based awards to employees, outside directors and consultants or other third-party advisors. Awards which may be granted under the 2000 Plan include qualified incentive stock options, nonqualified stock options, stock appreciation rights, restricted awards, performance awards and other stock-based awards. We recognize compensation expense for stock option awards issued to employees and directors on a straight-line basis over the requisite service period of the award. To satisfy the exercise of options or to issue new restricted stock, we normally issue new shares rather than purchase shares on the open market.

The fair value of each stock option is estimated on the date of the grant using the Black-Scholes option-pricing model. The weighted average grant date fair value of stock options granted during the three months ended September 30, 2010 and 2009 was $1.47 and $1.20 per share, respectively. The weighted average grant date fair

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value of stock options granted during the nine months ended September 30, 2010 and 2009 was $2.24 and $1.19 per share, respectively.

Total compensation cost related to stock options for the three months ended September 30, 2010 and 2009 was $219,477 and $311,388, respectively, of which $8,897 and $8,827 was capitalized into inventory during the quarters ended September 30, 2010 and 2009, respectively. The amounts recognized in cost of products sold for amounts previously capitalized were $18,379 and $19,911 for the three months ended September 30, 2010 and 2009, respectively. Total compensation cost related to stock options for the nine months ended September 30, 2010 and 2009 was $695,096 and $1,009,193, respectively, of which $35,671 and $46,234 was capitalized into inventory during the nine months ended September 30, 2010 and 2009, respectively. The amounts recognized in cost of products sold for amounts previously capitalized were $50,366 and $113,913 for the nine months ended September 30, 2010 and 2009, respectively.

The following table summarizes the stock option activity for the nine months ended September 30, 2010:

	Options
Outstanding on January 1, 2010	5,431,665
Granted	699,230
Exercised	(1,327)
Forfeited	(263,281)
Outstanding on September 30, 2010	5,866,287

As of September 30, 2010, there was $2,057,041 of unrecognized compensation expense related to unvested option awards that is expected to be recognized over a weighted average period of 1.9 years.

Net cash proceeds from the exercise of stock options were $3,722 and $17,898 for the nine months ended September 30, 2010 and 2009, respectively. As a result of the Company s net operating loss carryforward position, no actual income tax benefit was realized from the stock option exercises during these periods.

As mentioned above, the 2000 Plan also permits us to grant restricted shares of our common stock to eligible employees, including officers and outside directors. Generally, these shares are nontransferable until vested and are subject to vesting requirements and/or forfeiture, as determined by the Compensation Committee of our Board of Directors. The market value of these shares at the date of grant is recognized on a straight-line basis over the period during which the restrictions lapse. During the nine months ended September 30, 2010, we granted 454,715 restricted shares of our common stock, with a weighted average grant date fair value of $5.19 per share, to certain key officers, members of management and outside directors. Compensation cost of $562,557 and $682,218 related to restricted shares was recognized during the three months ended September 30, 2010 and 2009, respectively. Compensation cost of $1,783,556 and $2,078,110 related to restricted shares was recognized during the nine months ended September 30, 2010 and 2009, respectively.

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

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	Shares
Issued and unvested, January 1, 2010	819,877
Granted	454,715
Vested	(422,829)
Forfeited	(53,127)
Issued and unvested, September 30, 2010	798,636

As of September 30, 2010, there was $2,834,844 of unrecognized compensation expense related to unvested restricted stock awards that is expected to be recognized over a weighted average period of 2.3 years. In connection with the vesting of restricted shares, during the nine months ended September 30, 2010 and 2009, 133,345 and 129,960 shares, respectively, with aggregate values of $693,022 and $377,008, respectively, were withheld and retired in satisfaction of minimum tax withholding obligations.

6. Share Repurchase Program

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

7. Accrued Expenses

	September 30, 2010	December 31, 2009
Payroll and related benefits	$ 3,377,537	$ 4,867,716
Royalties	1,673,860	3,394,991
Deferred revenue	1,192,611	1,618,798
Professional fees	127,726	290,208
Clinical research obligations	17,369	658,605
Other	1,296,659	672,484
	$ 7,685,762	$ 11,502,802

Deferred revenue at September 30, 2010 and December 31, 2009 included customer prepayments of $1,126,711 and $1,501,598, respectively.

8. Geographic Information

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
United States	$ 16,398	$ 17,664	$ 47,723	$ 46,350
Europe	1,598	1,560	4,792	4,932
Other regions	1,038	2,385	3,682	4,857
	$ 19,034	$ 21,609	$ 56,197	$ 56,139

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Item 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Statements below regarding future events or performance are forward-looking statements within the meaning of the Federal securities laws. These may include statements about our expected revenues, earnings/loss per share, net income (loss), expenses, cash flow or other financial performance or developments, clinical trial or development activities, expected regulatory filings and approvals, planned business transactions, views of future industry, competitive or market conditions, and other factors that could affect our future operations, results of operations or financial position. These statements often include the words believes, expects, anticipates, intends, plans, estimates, may, will, should, could, or similar expressions. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include, but are not limited to: ability to market and sell products, whether through an internal, direct sales force or third parties; ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements; changes in relationships, including disputes or disagreements, with strategic partners or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements; failure of distributors or other customers to meet purchase forecasts or minimum purchase requirements for the Company s products; impact of replacing distributors and success of direct sales efforts; inventory levels at distributors and other customers; impact of competitors, competing products and technology changes; impact of the economic downturn, high unemployment and poor credit conditions; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products; market acceptance of oral fluid testing or other products; changes in market acceptance of products based on product performance, extended shelf life or other factors; continued bulk purchases by customers, including governmental agencies, and the ability to fully deploy those purchases in a timely manner; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical product components; availability of related products produced by third parties or products required for use of our products; ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; ability to comply with applicable regulatory requirements; history of losses and ability to achieve sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of our stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; loss or impairment of sources of capital; ability to meet financial covenants in agreements with financial institutions; ability to retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; ability to identify, complete and realize the full benefits of potential acquisitions; and general political, business and economic conditions. These and other factors are discussed more fully in our Securities and Exchange Commission (SEC) filings, including our registration statements, Annual Report on Form 10-K for the year ended December 31, 2009, Quarterly Reports on Form 10-Q, and other filings with the SEC. Although forward-looking statements help to provide information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. The forward-looking statements are made as of the date of this Report and we undertake no duty to update these statements.

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

Overview

We operate primarily in the *in vitro* diagnostic business. Our business principally involves the development, manufacture, marketing and sale of oral fluid diagnostic products and specimen collection devices using our

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

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

We rely heavily on distributors to purchase and resell many of our products. For example, Genomma Labs (Genomma) has exclusive rights to our wart removal product in the OTC market in Mexico, Argentina, Brazil and various other Central and South American countries and SSL International plc (SSL) has similar rights to our wart removal product in the OTC footcare market in Europe, Australia and New Zealand. We have contracted with several distributors to sell our OraQuick *ADVANCE*® HIV-1/2 test to the U.S. physician office market and in certain international markets, 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.

Competitive and Economic Outlook

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

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

The current economic downturn, including disruptions in the capital and credit markets, may continue for the foreseeable future and intensify, and has adversely affected and could continue to adversely affect our financial performance and condition or those of our customers and suppliers. These circumstances could adversely affect our access to liquidity needed to conduct or expand our business or conduct acquisitions or make other discretionary

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

Current Financial Results

During the nine months ended September 30, 2010, our total revenues were $56.2 million, remaining relatively flat when compared to the same period in 2009. Our 2010 revenues include $2.0 million in milestone payments received under the terms of our collaboration agreement with Merck & Co., Inc. (formerly called Schering-Plough) (Merck) for the development and promotion of our OraQuick® rapid HCV test. Our net loss for the nine months ended September 30, 2010 was $2.5 million or $0.05 per share, compared to a net loss of $5.0 million or $0.11 per share for the nine months ended September 30, 2009. The net loss for the first nine months of 2009 included a $3.0 million pre-tax charge for the impairment of certain patent and product rights.

Cash flow provided by operating activities for the nine months ended September 30, 2010 was approximately $241,000, compared to the $2.7 million provided by operating activities for the nine months ended September 30, 2009. As of September 30, 2010, we had $73.7 million in cash, cash equivalents and short-term investments, compared to $79.7 million at December 31, 2009. During the third quarter of 2010, we paid $3.5 million in milestone payments pursuant to our HCV patent license agreement with certain third parties. These milestone payments were accrued and capitalized during the first half of the year.

Recent Developments

OraQuick® HCV Test

We have continued our efforts to obtain FDA approval of additional applications for our OraQuick® HCV test. As previously disclosed, the FDA required us to conduct additional clinical studies in support of a premarket approval (PMA) application for use of the OraQuick® HCV test with fingerstick whole blood and oral fluid specimens. We completed the studies and were prepared to submit a PMA supplement seeking approval of both claims after the venous whole blood claim was approved in June 2010. In advance of submitting the PMA supplement, and in conjunction with discussions related to the CLIA (Clinical Laboratory Improvement Amendments of 1988) waiver protocols for the product, we shared our additional clinical data for fingerstick whole blood and oral fluid with the FDA. The FDA provided us with comments primarily related to the lower sensitivity of the OraQuick® HCV test for oral fluid and fingerstick whole blood when compared to venous whole blood. As a result of these comments, we decided to separate the PMA submissions for the fingerstick whole blood and oral fluid claims.

A separate PMA supplement was filed with the FDA for fingerstick whole blood in July 2010. We believe this supplement is under active review by the agency.

We intend to pursue approval of an oral fluid claim for our OraQuick® HCV test. However, the filing of a PMA supplement for oral fluid has been delayed pending additional discussions with the FDA.

Our protocols for a CLIA waiver have been reviewed and approved by the FDA and our CLIA studies have started. We expect the studies to continue through the remainder of 2010. We intend to submit the results of our studies and request a CLIA waiver for fingerstick whole blood and venous whole blood once FDA approval of the fingerstick whole blood claim is received.

OraQuick® HIV Test

As previously disclosed, the automated manufacturing equipment we installed in our Bethlehem, Pennsylvania facility has been validated and approved by the FDA for use in the manufacture of our OraQuick *ADVANCE* ® HIV test. During the third quarter, we successfully manufactured several device lots using this equipment. Once we fully convert to an automated manufacturing process for our OraQuick *ADVANCE* ® HIV device, which we expect to

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occur during the fourth quarter of this year, we should be able to produce larger quantities of this product at a lower overall cost.

OraQuick® HIV OTV Test

As previously disclosed, we have conducted studies to validate the labeling for our OraQuick® HIV OTC test, and we have been developing, with input from the FDA, a protocol for the final phase of clinical studies for this product. This work has been completed, and in October 2010 we submitted to the FDA our final label validation data and a request for an investigational device exemption (IDE) for the final phase of clinical studies. We intend to commence the final phase of clinical testing as soon as possible after the FDA approves our IDE submission.

Results of Operations

Three months ended September 30, 2010 compared to September 30, 2009

Total revenues decreased 12% to $19.0 million in the third quarter of 2010 from $21.6 million in the comparable quarter of 2009. Increased sales in our cryosurgical and insurance risk assessment markets were offset by decreased sales in the infectious disease and substance abuse testing markets, as well as a decrease in licensing and product development revenues. Revenues derived from products sold to customers outside the U.S. were $2.6 million and $3.9 million, or 14% and 18% of total revenues, in the third quarters of 2010 and 2009, respectively. Because the majority of our international sales are denominated in U.S. dollars, the impact of fluctuating foreign currency exchange rates was not material to our operating results.

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

	Three Months Ended September 30,				
	Dollars		%	Percentage of Total Revenues	
Market	2010	2009	Change	2010	2009
Infectious disease testing	$ 10,843	$ 13,540	(20)%	57%	63%
Substance abuse testing	3,019	3,269	(8)	16	15
Cryosurgical systems	3,008	2,682	12	16	12
Insurance risk assessment	1,529	1,416	8	8	7
Product revenues	18,399	20,907	(12)	97	97
Licensing and product development	635	702	(10)	3	3
Total revenues	$ 19,034	$ 21,609	(12)%	100%	100%

Infectious Disease Testing Market

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

Sales to the infectious disease testing market decreased 20% to $10.8 million in the third quarter of 2010. OraQuick® HIV sales totaled $10.5 million and $13.2 million in the third quarters of 2010 and 2009, respectively.

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Sales of our OraSure® oral fluid collection device totaled $305,000 and $358,000 in the third quarters of 2010 and 2009, respectively.

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

	Three Months Ended September 30,		
Market	**2010**	**2009**	**% Change**
Domestic	$ 10,102	$ 11,767	(14)%
International	436	1,415	(69)
Total OraQuick® revenues	$ 10,538	$ 13,182	(20)%

During the three months ended September 30, 2010, sales of the OraQuick *ADVANCE*® HIV test in the U.S. market decreased 14%, or $1.7 million, when compared to the same period of 2009. In the second quarter of 2009, we experienced inventory shortages resulting from a manufacturing issue related to our OraQuick *ADVANCE*® test, which created a $2.2 million backlog of orders as of June 30, 2009. During the third quarter of 2009, our manufacturing issue was corrected and we filled the $2.2 million backlog. Had this revenue been recognized in the second quarter of 2009, we would have experienced an increase in domestic sales of our OraQuick *ADVANCE*® HIV test during the third quarter of 2010 when compared to the same period in 2009. Despite cautious spending in the first half of 2010 by our public health customers, we saw an increase in spending during the third quarter by certain of these customers as they approached the end of their fiscal year. As a result, during the three months ended September 30, 2010, we saw an increase in purchasing volume from certain public health customers. This increase in volume was partially offset by a lower average selling price experienced during this same period.

International sales of our OraQuick® HIV test decreased 69% to $436,000 for the three months ended September 30, 2010 from $1.4 million for the three months ended September 30, 2009. This decrease resulted from customer losses due to price competition, changes in the use of our test within government testing algorithms, and a decrease or elimination of funding for HIV testing initiatives. International sales are not expected to improve during the remainder of 2010.

Sales of our OraSure® oral fluid collection device decreased 15% from $358,000 in the third quarter of 2009 to $305,000 in the third quarter of 2010 due to reduced public health funding by state and local governments. In addition, some customers who have purchased our OraSure® device for laboratory HIV-1 testing in the past are now electing to purchase our OraQuick *ADVANCE*® test. We believe this is the result of customers recognizing the benefits of rapid HIV testing, especially with oral fluid. OraSure® sales are expected to continue to decline during the remainder of 2010.

Substance Abuse Testing Market

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

Substance abuse testing revenues decreased 8% from $3.3 million in the third quarter of 2009 to $3.0 million in the third quarter of 2010 as a result of decreased domestic sales of our Intercept® drug testing system and the absence of laboratory equipment sales.

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

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Market	Three Months Ended September 30, 2010	2009	% Change
Domestic	$ 1,913	$ 2,086	(8)%
International	562	479	17
Total Intercept® revenues	$ 2,475	$ 2,565	(4)%

Domestic Intercept® revenues decreased 8% from $2.1 million in the third quarter of 2009 to $1.9 million in the third quarter of 2010. This decrease is largely the result of the corporate acquisition of one of our larger customers by one of our competitors, as well as some of our laboratory customers moving away from rapid drug testing to other testing methods.

International Intercept® revenues for the third quarter of 2010 increased approximately $83,000, primarily due to variability in ordering patterns experienced with our largest distributor.

We do not expect renewed growth in Intercept® sales until employment conditions in the U.S. recover and overall economic conditions improve. In addition, the microplate oral fluid drug assays, which are sold for use with the Intercept® collection device, have come under increasing competitive pressure from home-brew assays developed internally by our laboratory customers and compete with urine-based homogeneous assays that are run on fully-automated, random access analyzers. We believe our competitors are developing oral fluid tests suitable for use on these fully automated homogeneous assay systems and these assays, if and when they are developed and commercialized, could represent a significant competitive threat to our oral fluid microplate business. Pursuant to a development agreement with Roche Diagnostics, homogenous fully-automated oral fluid drugs of abuse assays are being developed for use with our Intercept® collection device. Applications for 510(k) clearance of several of these assays for use with the Intercept® device are currently pending before the FDA. The assays use Roche s technology and will run on various automated analyzers to allow oral fluid samples to be processed with the same efficiency currently achieved with urine-based drug tests. We have also entered into a commercialization agreement with Roche pursuant to which a drug testing system comprised of our Intercept® device and the newly developed homogenous assays will be marketed and sold on a worldwide basis.

Cryosurgical Systems Market

Sales in the cryosurgical systems market (which includes both the physicians office and OTC markets) increased 12% to $3.0 million in the third quarter of 2010, compared to $2.7 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 third quarters of 2010 and 2009.

Market	Three Months Ended September 30, 2010	2009	% Change
Professional domestic	$ 1,690	$ 1,220	39%
Professional international	326	337	(3)
Over-the-counter	992	1,125	(12)
Total cryosurgical systems revenues	$ 3,008	$ 2,682	12%

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The overall increase in cryosurgical systems revenues was primarily the result of a $470,000 increase in sales into the domestic professional market due to the elimination of the diversion of less expensive international Histofreezer® product into the domestic market and the impact of our new manufacturer s sales representative organizations. As previously described, in early 2010, we signed agreements with two manufacturers sales representative organizations to support sales of our Histofreezer® product in the U.S. Under these arrangements, over 40 additional sales representatives have been working with our physicians office distributors throughout the United States, resulting in additional sales growth during the third quarter.

During the three months ended September 30, 2010, sales of Histofreezer® in the international market decreased 3% as compared to the third quarter of 2009. This decline was largely experienced in the European market as a result of variability in the ordering pattern of our largest distributor. In addition, in the European professional marketplace, healthcare reimbursement has been or may be reduced or eliminated for certain treatment types, including treatments for common warts. The reduction in or elimination of reimbursement for wart treatments has affected international sales of our Histofreezer® product and will continue to do so.

Sales of our cryosurgical OTC products during the third quarter of 2010 decreased 12% primarily due to lower sales to our Latin American OTC distributor, Genomma, largely due to their management of internal inventory levels. Sales to our European OTC distributor, SSL, remained flat when compared to the third quarter of 2009.

In July 2010, SSL announced that it had agreed to be acquired by Reckitt Benckiser Group PLC. Our distribution contract with SSL is subject to an annual renewal at the end of 2010 and we expect to negotiate a contract extension following the closing of the acquisition.

Insurance Risk Assessment Market

Sales to the insurance risk assessment market increased 8% to $1.5 million in the third quarter of 2010 from $1.4 million in the third quarter of 2009.

Licensing and Product Development

Licensing and product development revenues decreased 10% to $635,000 during the third quarter of 2010 from $702,000 during the third quarter of 2009. Our 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 third quarter of 2010 was 62% compared to 64% for the third quarter of 2009. Production during the third quarter of 2009 had increased significantly in order to fill the backlog of orders for our OraQuick® HIV test existing at June 30, 2009. This increased production allowed for a higher absorption of overhead costs and consequentially drove a higher gross margin for the prior year quarter. Gross margin in the third quarter of 2010 is more representative of normalized production levels and benefited from an improved product mix and lower scrap.

Operating Expenses

Research and development expenses increased 3% from $2.9 million in the third quarter of 2009 to $3.0 million in the same period in 2010, primarily as a result of increased laboratory supplies expense related to the development of new infectious disease products, and higher clinical trial costs related to the development of our OraQuick® HIV OTC test. These increases were partially offset by lower clinical trial costs related to the ongoing clinical development of our OraQuick® HCV test and decreased staffing costs. We expect our research and development costs will increase during the remaining three months of 2010 as a result of anticipated clinical work in support of our HIV OTC and OraQuick® HCV products, as well as the development of other new products.

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Sales and marketing expenses decreased 12% to $4.6 million in the third quarter of 2010 from $5.2 million in the third quarter of 2009, as a result of decreased staffing and consulting expenses, partially offset by increased advertising costs.

General and administrative expenses decreased slightly to $3.9 million in the third quarter of 2010 from $4.0 million in the same period in 2009. This decrease was primarily attributed to lower staffing expenses.

Interest Income/Expense

Interest expense decreased to $78,000 in the third quarter of 2010 from $90,000 in the third quarter of 2009 as a result of lower average debt balances. Interest income decreased to $48,000 in the third quarter of 2010 from $116,000 in the third quarter of 2009, primarily as a result of lower yields earned on our investment portfolio, lower investment balances and an overall conservative, shorter-term investment approach.

Income Taxes

In 2008, we established a full valuation allowance against our total net deferred tax asset. Management has continued to evaluate whether the full valuation is still appropriate. At September 30, 2010 and 2009, we concluded that the full valuation allowance remained appropriate as the facts and circumstances since establishing the allowance had not changed. As a result, no income tax benefit was recorded in the third quarters of 2010 or 2009.

Nine Months Ended September 30, 2010 Compared to September 30, 2009

Total revenues remained flat at $56.2 million for the first nine months of 2010 compared to $56.1 million in the comparable period of 2009. Increased sales in the cryosurgical systems market and higher licensing and product development revenues were offset by lower revenues from our infectious disease testing, substance abuse testing and insurance risk assessment businesses. Revenues derived from products sold to customers outside the U.S. were $8.5 million, or 15% of total revenues, during the first nine months of 2010, and $9.8 million, or 17% of total revenues, during the first nine months of 2009. Because the majority of our international sales are denominated in U.S. dollars, the impact of fluctuating foreign currency exchange rates was not material to our operating results.

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

	Nine Months Ended September 30,				
	Dollars		%	Percentage of Total Revenues	
Market	2010	2009	Change	2010	2009
Infectious disease testing	$ 30,297	$ 33,407	(9)%	54%	59%
Substance abuse testing	8,785	8,890	(1)	16	16
Cryosurgical systems	9,122	7,728	18	16	14
Insurance risk assessment	4,471	4,552	(2)	8	8
Product revenues	52,675	54,577	(3)	94	97
Licensing and product development	3,522	1,562	125	6	3
Total revenues	$ 56,197	$ 56,139	0%	100%	100%

Infectious Disease Testing Market

As previously disclosed, an increasing number of our public health customers are supplying hospitals with OraQuick *ADVANCE*® HIV tests purchased from us. This is a positive development as it indicates increased support of

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hospital testing initiatives by public health agencies. However, this overlap is making it more difficult to separately track OraQuick® sales into these markets. Since this trend is likely to continue, we are now reporting public health and hospital sales of our OraQuick *ADVANCE*® HIV-1/2 test in the U.S. on a combined basis. Prior year amounts have been reclassified to conform to the current presentation.

Sales to the infectious disease testing market decreased 9% to $30.3 million in the first nine months of 2010. OraQuick® sales totaled $29.2 million in the first nine months of 2010 and $31.7 million for the first nine months of 2009. Sales of our OraSure® oral fluid collection device totaled $1.1 million and $1.7 million in the first nine months of 2010 and 2009, respectively.

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

	Nine Months Ended September 30,		
Market	**2010**	**2009**	**% Change**
Domestic	$ 28,083	$ 29,358	(4)%
International	1,089	2,370	(54)
Total OraQuick® revenues	$ 29,172	$ 31,728	(8)%

During the first nine months of 2010, sales of the OraQuick *ADVANCE*® HIV test in the U.S. market decreased 4% or $1.3 million, when compared to the same period in 2009. This decrease in revenue reflects lower sales volumes resulting from reduced public health funding by state and local governments, as well as a lower average selling price.

International sales of our OraQuick® HIV test decreased 54% to $1.1 million for the nine months ended September 30, 2010 from $2.4 million for the nine months ended September 30, 2009. This decrease resulted from customer losses due to price competition, changes in the use of our test within government testing algorithms, and a decrease or elimination of funding for HIV testing initiatives. International sales are not expected to improve during the remainder of 2010.

Sales of our OraSure® oral fluid collection device decreased 33% from $1.7 million in the first nine months of 2009 to $1.1 million in the first nine months of 2010 due to reduced public health funding by state and local governments. In addition, some customers who have purchased our OraSure® device for laboratory HIV-1 testing in the past are now electing to purchase our OraQuick *ADVANCE*® test. We believe this is the result of customers recognizing the benefits of rapid HIV testing, especially with oral fluids. OraSure® sales are expected to continue to decline during the remainder of 2010.

Substance Abuse Testing Market

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

Substance abuse testing revenues remained relatively flat at $8.8 million in the first nine months of 2010 compared to $8.9 million in the first nine months of 2009.

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

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Market	Nine Months Ended September 30, 2010	2009	% Change
Domestic	$ 5,391	$ 5,434	(1)%
International	1,522	1,524	0
Total Intercept® revenues	$ 6,913	$ 6,958	(1)%

Domestic and international Intercept® revenues remained relatively flat when comparing the first nine months of 2010 to the same period in the prior year.

We do not expect renewed growth in Intercept® sales until employment conditions in the U.S. recover and overall economic conditions improve. In addition, the microplate oral fluid drug assays, which are sold for use with the Intercept® collection device, have come under increasing competitive pressure from home-brew assays developed internally by our laboratory customers and compete with urine-based homogeneous assays that are run on fully-automated, random access analyzers. We believe our competitors are developing oral fluid tests suitable for use on these fully automated homogeneous assay systems and these assays, if and when they are developed and commercialized, could represent a significant competitive threat to our oral fluid microplate business. Pursuant to a development agreement with Roche Diagnostics, homogenous fully-automated oral fluid drugs of abuse assays are being developed for use with our Intercept® collection device. Applications for 510(k) clearance of several of these assays for use with the Intercept® device are currently pending before the FDA. The assays use Roche s technology and will run on various automated analyzers to allow oral fluid samples to be processed with the same efficiency currently achieved with urine-based drug tests. We have also entered into a commercialization agreement with Roche pursuant to which a drug testing system comprised of our Intercept® device and the newly developed homogenous assays will be marketed and sold on a worldwide basis.

Cryosurgical Systems Market

Sales in the cryosurgical systems market (which includes both the physicians office and OTC markets) increased 18% to $9.1 million in the first nine months of 2010, compared to $7.7 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 nine months of 2010 and 2009.

Market	Nine Months Ended September 30, 2010	2009	% Change
Professional domestic	$ 4,476	$ 2,969	51%
Professional international	865	1,601	(46)
Over-the-counter	3,781	3,158	20
Total cryosurgical systems revenues	$ 9,122	$ 7,728	18%

Sales of our Histofreezer® product to physicians offices in the United States increased 51% to $4.5 million in the first nine months of 2010, compared to $3.0 million in 2009, largely due to the elimination of the diversion of less expensive international Histofreezer® product into the domestic market. In addition, 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

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distributors throughout the United States, resulting in additional domestic Histofreezer® sales growth during this year.

Sales of Histofreezer® in the international market decreased 46% in the first nine months of 2010, as compared to the first nine months of 2009. This decline was largely due to a discontinuance of sales to certain foreign distributors that we believe were diverting product to the U.S. market. The selling prices for our Histofreezer® product are lower in some foreign countries due to differences in the healthcare systems in those countries. During 2008 and early 2009, some distributors in these countries purchased English-labeled Histofreezer® product and resold it into the domestic distribution network to distributors who employ alternate sourcing programs.

We also experienced a decline in the European market as a result of the negative impact of changing European health regulations. In the European professional marketplace, healthcare reimbursement has been or may be reduced or eliminated for certain treatment types, including treatments for common warts. The reduction in or elimination of reimbursement for wart treatments has affected international sales of our Histofreezer® product and will continue to do so.

During the nine months ended September 30, 2010, our OTC cryosurgical sales increased 20% primarily due to increased sales to both our Latin American OTC distributor, Genomma, and our European OTC distributor, SSL. During the first nine months of 2010, Genomma s purchases increased by $510,000, largely representing product required to support Genomma s launch of our OTC cryosurgical wart removal product in Brazil. Sales to SSL were $2.1 million and $1.9 million in the first nine months of 2010 and 2009, respectively.

In July 2010, SSL announced that it had agreed to be acquired by Reckitt Benckiser Group PLC. Our distribution contract with SSL is subject to an annual renewal at the end of 2010 and we expect to negotiate a contract extension following the closing of the acquisition.

Insurance Risk Assessment Market

Sales to the insurance risk assessment market decreased 2% to $4.5 million in 2010 from $4.6 million in the first nine months of 2009.

Licensing and Product Development

Licensing and product development revenues increased to $3.5 million during the first nine months of 2010 from $1.6 million during the first nine months of 2009. This increase was primarily due to $2.0 million in milestone payments received as a result of our achievement of certain regulatory and commercial objectives pursuant to our collaboration agreement with Merck for the development and promotion of an OraQuick® rapid HCV test. The remaining licensing revenues for the first nine months of both 2010 and 2009 represent royalties received on domestic outsales of Merck s OTC cryosurgical wart removal product, pursuant to our license and settlement agreement executed in January 2008.

Gross Margin

Gross margin in the first nine months of 2010 was 63%, compared to 62% for the first nine months of 2009. Gross margin in 2010 benefitted from the higher licensing and product development revenues, a more favorable product revenue mix and an improvement in scrap and spoilage levels when compared to 2009. These benefits to gross margin were partially offset by additional severance costs related to a reduction in work-force during the second quarter of 2010.

Operating Expenses

Research and development expenses increased 5% from $8.7 million in the first nine months of 2009 to $9.1 million in the same period of 2010, primarily as a result of higher laboratory supplies expense related to the development of new infectious disease products and higher clinical trial costs related to the development of our OraQuick® HIV OTC test. Theses increases were partially offset by decreased validation, vendor qualification and clinical trial costs

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related to the development of our OraQuick® HCV test. We expect our research and development costs will increase during the remainder of 2010 as a result of our anticipated clinical work in support of our HIV OTC and OraQuick® HCV products, as well as the development of other new products.

Sales and marketing expenses increased 2% from $15.5 million in the first nine months of 2009 to $15.9 million in the first nine months of 2010. This increase was the result of increased consulting costs, additional market research activities, and the commissions paid to the two new manufacturers sales representative organizations that we retained during the first quarter of 2010 to support sales of our Histofreezer® product in the U.S. physician office market. These higher costs were partially offset by a decrease in staffing costs.

General and administrative expenses remained relatively flat at $12.8 million in the first nine months of 2010 compared to $12.9 million in the first nine months of 2009. Increases in consulting and staffing costs were offset by lower legal expenses.

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

Interest Income/Expense

Interest expense decreased to $231,000 in the first nine months of 2010 from $270,000 in the first nine months of 2009 as a result of lower average debt balances. Interest income decreased to $139,000 in the first nine months of 2010 from $691,000 in the first nine months of 2009, primarily as a result of lower yields earned on our investment portfolio, lower investment balances, and an overall conservative, shorter-term investment approach.

Income Taxes

In 2008, we established a full valuation allowance against our total net deferred tax asset. Management has continued to evaluate whether the full valuation is still appropriate. At September 30, 2010 and 2009, we concluded that the full valuation allowance remained appropriate as the facts and circumstances since the establishment of the allowance had not changed. As a result, no income tax benefit was recorded in the first nine months of 2010 or 2009.

Liquidity and Capital Resources

	September 30, 2010	December 31, 2009
	(In thousands)	
Cash and cash equivalents	$ 71,699	$ 74,934
Short-term investments	1,995	4,737
Working capital	78,445	89,435

Our cash, cash equivalents and short-term investments decreased $6.0 million from $79.7 million at December 31, 2009 to $73.7 million at September 30, 2010, primarily as a result of $3.5 million in payments for patents and product rights, $1.6 million in property and equipment purchases, $693,000 associated with the retirement of common stock to pay minimum tax withholding obligations on the vesting of restricted shares, and $385,000 for debt repayments. Our working capital declined as a result of the reduction in our cash, cash equivalents and short-term investments, as well as the reclassification of the remaining unpaid principal balance of our debt obligation to a current liability as a result of its maturity date in June 2011.

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During the first nine months of 2010, operating activities provided cash of $241,000. Cash provided by operating activities resulted from our net loss of $2.5 million and a reduction in our scrap and spoilage reserve of $12,000 offset by non-cash stock-based compensation expense of $2.5 million and depreciation and amortization of $2.1 million. Also contributing to the cash provided by operating activities were a $543,000 decrease in accounts receivable resulting from the timely collection of amounts due, a $878,000 decrease in inventories largely as a result of managing our OraQuick® inventory to lower levels, and a $1.1 million decrease in prepaid expense largely due to the collection of a federal tax refund of $673,000. Offsetting these cash contributions were a decrease in accounts payable of $589,000 and a $3.8 million decrease in accrued expenses and other liabilities associated with payment of our 2009 royalty obligations, management incentive bonuses and other accruals.

Net cash used in investing activities during the first nine months of 2010 was $2.4 million. Proceeds of $2.7 million from maturities and redemptions of short-term investments were offset by $1.6 million in purchases of property and equipment and $3.5 million in payments for patents and licenses related to the achievement of milestones pursuant to our HCV patent license agreement.

Net cash used in financing activities was $1.1 million for the nine months ended September 30, 2010, primarily as a result of $385,000 in loan principal repayments and $693,000 used for the withholding and retirement of common stock related to the vesting of restricted shares.

At December 31, 2009, we had in place a $10,000,000 credit advance with Comerica Bank (Comerica). Pursuant to the terms of the advance, principal, and interest fixed at 4.15%, are payable monthly through June 2011, at which time the remaining unpaid principal balance is payable. Accordingly, beginning on June 30, 2010, our remaining unpaid principal balance was classified as a current liability as it will be payable within the ensuing twelve months. As of September 30, 2010, we had $7.9 million in outstanding borrowings under this advance.

All borrowings from Comerica are collateralized by a first priority security interest in all of our assets, including present and future accounts receivable, chattel paper, contracts and contract rights, equipment and accessories, general intangibles, investments, instruments, inventories, and a mortgage on our three facilities in Bethlehem, Pennsylvania. The Comerica agreement contains certain covenants that set forth minimum requirements for our quick ratio, liquidity, and tangible net worth. We were in full compliance with all covenants at September 30, 2010. The agreement also restricts our ability to pay dividends, to make certain investments, to incur additional indebtedness, to sell or otherwise dispose of a substantial portion of assets, and to merge or consolidate operations with an unaffiliated entity, without the consent of Comerica.

At December 31, 2009, we had net operating loss (NOL) carryforwards of approximately $45.2 million for federal income tax purposes. In the fourth quarter of 2008, we recorded a full valuation allowance against the deferred tax asset generated by these NOLs. Establishment of this valuation allowance does not change our view of the Company s long-term financial outlook or the expected utilization of our NOL carryforwards.

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

Summary of Contractual Obligations

The following sets forth our approximate aggregate obligations at September 30, 2010 for future payments under contracts and other contingent commitments for 2010 and beyond:

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Contractual Obligations	Total	Payments due by December 31, 2010	2011	2012	2013	2014	Thereafter
Long-term debt[1]	$ 7,916,680	$ 125,000	$ 7,791,680	$	$	$	$
Operating leases[2]	36,568	36,568					
Employment contracts[3]	3,979,750	583,250	1,975,500	1,171,000	250,000		
Purchase obligations[4]	2,204,961	1,758,905	446,056				
Minimum commitments under contracts[5]	4,291,667	500,000	500,000	500,000	500,000	500,000	1,791,667
Total contractual obligations	$ 18,429,626	$ 3,003,723	$ 10,713,236	$ 1,671,000	$ 750,000	$ 500,000	$ 1,791,667

1 Represents principal repayments required under notes payable to our lender.
2 Represents payments required under our operating leases.
3 Represents salary payments payable under the terms of employment agreements executed by us with certain officers and employees.
4 Represents payments required by non-cancellable purchase orders related to inventory, capital expenditures and other goods or services.
5 Represents payments required pursuant to certain licensing agreements executed by the Company. These agreements are cancellable within a specified number of days after communication by the Company of its intent to terminate. An additional payment of $1,000,000 may be required pursuant to one of these licensing agreements for the achievement of specific commercial milestones.

Critical Accounting Policies and Estimates

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

A more detailed review of our critical accounting policies is contained in our 2009 Annual Report on Form 10-K filed with the SEC. During the first nine months of 2010, there were no material changes in our critical accounting policies.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

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

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

As of September 30, 2010, we did not have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. We have operations in Europe and Africa, which are subject to foreign currency fluctuations. As currency rates change, translation of revenues and expenses for these operations from foreign currencies to U.S. dollars affects year-to-year comparability of operating results. Sales denominated in a foreign currency were minimal compared to our total revenues for the nine months ended September 30, 2010. We do not expect the risk of foreign currency fluctuations to be material to us in the near future.

Item 4. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures. The Company s management, with the participation of the Company s Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company s disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) as of September 30, 2010. Based on that evaluation, the Company s management, including such officers, concluded that the Company s disclosure controls and procedures were adequate and effective as of September 30, 2010 to ensure that information required to be disclosed by the Company in the reports that we file or submit under the Securities Exchange Act of 1934 was accumulated and communicated to the Company s management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure and was recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC.

(b) Changes in Internal Control Over Financial Reporting. There was no change in the Company s internal control over financial reporting that occurred during the three months ended September 30, 2010 that has materially affected, or is reasonably likely to materially affect, the Company s internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1A. RISK FACTORS

There have been no material changes to the factors disclosed in Item 1A., entitled Risk Factors, in our Annual Report on Form 10-K for the year ended December 31, 2009.

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

During the quarter ended September 30, 2010, pursuant to our 2000 Stock Award Plan and in connection with the vesting of restricted shares, we retired 4,720 shares of our Common Stock to satisfy minimum tax withholding obligations at an average price paid per share of $3.71.

On August 4, 2008, our Board of Directors approved a share repurchase program pursuant to which we are permitted to acquire up to $25.0 million of outstanding shares. We did not purchase any shares under this program during the three months ended September 30, 2010. As of September 30, 2010, we had remaining authority to purchase up to $19,570,287 of shares under this share repurchase program. We have no commitments to purchase any additional shares and the share repurchase program may be discontinued at any time.

Item 6. EXHIBITS

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

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SIGNATURES

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

ORASURE TECHNOLOGIES, INC.

Date: November 9, 2010

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

Date: November 9, 2010

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

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EXHIBIT INDEX

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