ORASURE TECHNOLOGIES INC
Form 10-Q
May 06, 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 March 31, 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 May 3, 2010: 46,196,585

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Item 1. FINANCIAL STATEMENTS

ORASURE TECHNOLOGIES, INC.

BALANCE SHEETS

(Unaudited)

	MARCH 31, 2010	DECEMBER 31, 2009
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 69,374,434	$ 74,933,630
Short-term investments	3,986,000	4,736,730
Accounts receivable, net of allowance for doubtful accounts of $235,347 and $256,572	12,103,249	13,693,340
Inventories	9,309,287	8,844,492
Prepaid expenses and other	3,381,242	2,609,518
Total current assets	98,154,212	104,817,710
PROPERTY AND EQUIPMENT, net	19,970,948	20,014,466
PATENTS AND PRODUCT RIGHTS, net	1,735,752	809,252
OTHER ASSETS	1,250,237	1,349,319
	$ 121,111,149	$ 126,990,747
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	$ 500,000	$ 509,761
Accounts payable	3,115,643	3,370,604
Accrued expenses and other	7,955,217	11,502,802
Total current liabilities	11,570,860	15,383,167
LONG-TERM DEBT	7,666,680	7,791,679
OTHER LIABILITIES	9,205	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, 46,195,258 and 45,929,511 shares issued and outstanding	46	46
Additional paid-in capital	239,378,873	239,126,422
Accumulated other comprehensive loss	(230,655)	(230,992)
Accumulated deficit	(137,283,860)	(135,088,486)
Total stockholders equity	101,864,404	103,806,990
	$ 121,111,149	$ 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 March 31, 2010	2009
REVENUES:		
Product	$ 16,572,754	$ 16,921,202
Licensing and product development	1,372,770	335,249
	17,945,524	17,256,451
COST OF PRODUCTS SOLD	6,541,462	6,284,379
Gross profit	11,404,062	10,972,072
OPERATING EXPENSES:		
Research and development	3,106,775	3,352,498
Sales and marketing	5,694,344	5,022,765
General and administrative	4,778,643	4,457,051
	13,579,762	12,832,314
Operating loss	(2,175,700)	(1,860,242)
INTEREST EXPENSE	(75,795)	(89,664)
INTEREST INCOME	42,116	335,370
FOREIGN CURRENCY GAIN (LOSS)	14,005	(3,425)
Loss before income taxes	(2,195,374)	(1,617,961)
INCOME TAX BENEFIT		
NET LOSS	$ (2,195,374)	$ (1,617,961)
LOSS PER SHARE:		
BASIC AND DILUTED	$ (0.05)	$ (0.04)
SHARES USED IN COMPUTING LOSS PER SHARE		
BASIC AND DILUTED	46,112,061	45,837,606

The accompanying notes are an integral part of these statements.

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ORASURE TECHNOLOGIES, INC.

STATEMENTS OF CASH FLOWS

(Unaudited)

	Three Months Ended March 31, 2010	2009
OPERATING ACTIVITIES:		
Net loss	$ (2,195,374)	$ (1,617,961)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	891,373	1,137,105
Depreciation and amortization	649,538	847,992
Reserve for excess and obsolete inventories	(89,464)	(145,669)
Changes in assets and liabilities:		
Accounts receivable	1,589,712	338,526
Inventories	(375,331)	932,822
Prepaid expenses and other assets	(672,642)	(221,000)
Accounts payable	(253,794)	(1,328,309)
Accrued expenses and other liabilities	(4,547,585)	(2,593,715)
Net cash used in operating activities	(5,003,567)	(2,650,209)
INVESTING ACTIVITIES:		
Purchases of short-term investments		(2,000,000)
Proceeds from maturities and redemptions of short-term investments	750,000	18,675,000
Purchases of property and equipment	(532,241)	(453,399)
Net cash provided by investing activities	217,759	16,221,601
FINANCING ACTIVITIES:		
Repayments of long-term debt	(134,760)	(139,366)
Proceeds from issuance of common stock		16,402
Withholding and retirement of common stock	(638,628)	(314,881)
Purchase and retirement of common stock		(308,605)
Net cash used in financing activities	(773,388)	(746,450)
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(5,559,196)	12,824,942
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	74,933,630	39,565,218
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 69,374,434	$ 52,390,160
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for:		
Interest	$ 85,645	$ 92,123
Income taxes	$ 10,000	$ 27,000

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 months ended March 31, 2010 are not necessarily indicative of the results of operations expected for the full year.

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

Cash and Cash Equivalents. We consider all highly liquid investments with a purchased maturity of ninety days or less to be cash equivalents. As of March 31, 2010 and December 31, 2009, cash equivalents consisted of money market accounts.

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ORASURE TECHNOLOGIES, INC.

Notes to Financial Statements (Continued)

(Unaudited)

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 March 31, 2010 and December 31, 2009:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
March 31, 2010				
Certificates of deposit	$ 3,986,000	$	$	$ 3,986,000
Total available-for-sale securities	$ 3,986,000	$	$	$ 3,986,000
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 March 31, 2010, maturities of our available-for-sale securities were as follows:				
Less than one year	$ 1,991,000	$	$	$ 1,991,000
One to two years	1,995,000			1,995,000
Total available-for-sale securities	$ 3,986,000	$	$	$ 3,986,000

Fair Value of Financial Instruments. As of March 31, 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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ORASURE TECHNOLOGIES, INC.

Notes to Financial Statements (Continued)

(Unaudited)

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

	March 31, 2010	December 31, 2009
Raw materials	$ 4,960,670	$ 4,911,570
Work in process	405,177	334,452
Finished goods	3,943,440	3,598,470
	$ 9,309,287	$ 8,844,492

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.

Significant Customer Concentration. The Company had no significant concentrations in accounts receivable as of March 31, 2010 or in revenues for both quarters ended March 31, 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.

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ORASURE TECHNOLOGIES, INC.

Notes to Financial Statements (Continued)

(Unaudited)

Loss Per Share. Basic and diluted loss per share is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during the period. Diluted loss per share is generally computed assuming the exercise or vesting of all dilutive securities such as common stock options and unvested restricted stock. As a result of our net losses for the three month periods ended March 31, 2010 and 2009, outstanding common stock options and unvested restricted stock, representing 5,750,570 and 6,164,909 shares, respectively, were excluded from the computation of diluted loss per share, as their inclusion would have been anti-dilutive.

Other Comprehensive Loss. We classify items of other comprehensive loss by their nature and disclose the accumulated balance of other comprehensive loss separately from accumulated deficit and additional paid-in capital, in the stockholders equity section of our balance sheet. Accumulated other comprehensive loss at March 31, 2010 and December 31, 2009 consisted of currency translation adjustments and net unrealized losses on short-term investments. Comprehensive loss was $2,195,037 and $1,574,132 for the three months ended March 31, 2010 and 2009, respectively.

3. Patents and Product Rights

In August 2005, we entered into a license agreement with third parties, pursuant to which we have been granted a limited, personal, non-transferable, non-exclusive license related to certain Hepatitis C Virus (HCV) patents held by such parties. During the first quarter of 2010, we achieved a milestone under this agreement and have accrued and capitalized a $1,000,000 payment. Commencing in April 2010, this payment will be amortized on a straight-line basis over ten years, which represents management s estimate of the remaining useful life of the licensed patents. Under the terms of the license agreement, we may also be required to pay additional license fees of up to $3,500,000, upon the achievement of specific development and/or commercial milestones.

4. Prepaid Expenses and Other Noncurrent Assets

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

5. Stock-Based Compensation

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

The fair value of each stock option is estimated on the date of the grant using the Black-Scholes option-pricing model. The weighted average grant date fair value of stock options granted during the three months ended March 31, 2010 and 2009 was $2.26 and $1.16 per share, respectively.

Total compensation cost related to stock options for the three months ended March 31, 2010 and 2009 was $275,242 and $402,661, respectively, of which $13,807 and $32,019 was capitalized into inventory during the quarters ended March 31, 2010 and 2009, respectively. The amounts recognized in cost of products sold for amounts previously capitalized were $19,945 and $66,831 for the three months ended March 31, 2010 and 2009, respectively.

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ORASURE TECHNOLOGIES, INC.

Notes to Financial Statements (Continued)

(Unaudited)

The following table summarizes the stock option activity for the three months ended March 31, 2010:

	Options
Outstanding on January 1, 2010	5,431,665
Granted	662,230
Exercised	
Forfeited	(12,863)
Outstanding on March 31, 2010	6,081,032

As of March 31, 2010, there was $2,798,669 of unrecognized compensation expense related to unvested option awards that is expected to be recognized over a weighted average period of 2.1 years.

No options were exercised during the first quarter of 2010. Net cash proceeds from the exercise of stock options during the first quarter of 2009 were $16,402. As a result of the Company s net operating loss carryforward position, no actual income tax benefit was realized from the stock option exercises.

As mentioned above, the 2000 Plan also permits us to grant restricted shares of our common stock to eligible employees, including officers and outside directors. Generally, these shares are nontransferable until vested and are subject to vesting requirements and/or forfeiture, as determined by the Compensation Committee of our Board of Directors. The market value of these shares at the date of grant is recognized on a straight-line basis over the period during which the restrictions lapse. During the three months ended March 31, 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 $616,131 and $734,444 related to restricted shares was recognized during the three months ended March 31, 2010 and 2009, respectively.

The following table summarizes restricted stock award activity for the three months ended March 31, 2010:

	Shares
Issued and unvested, January 1, 2010	819,877
Granted	454,715
Vested	(387,276)
Forfeited	(2,223)
Issued and unvested, March 31, 2010	885,093

As of March 31, 2010, there was $4,267,142 of unrecognized compensation expense related to unvested restricted stock awards that is expected to be recognized over a weighted average period of 2.5 years. In connection with the vesting of restricted shares, during the three months ended March 31, 2010 and 2009, 121,529 and 108,619 shares, respectively, with aggregate values of $638,628 and $314,881, respectively, were withheld and retired in satisfaction of minimum tax withholding obligations.

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ORASURE TECHNOLOGIES, INC.

Notes to Financial Statements (Continued)

(Unaudited)

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 three months ended March 31, 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 three month period ended March 31, 2009. No such purchases were made in the quarter ended March 31, 2010.

7. Accrued Expenses

	March 31, 2010	December 31, 2009
Payroll and related benefits	$ 2,620,717	$ 4,867,716
Royalties	1,405,687	3,394,991
Deferred revenue	1,214,725	1,618,798
Licensing fee	1,000,000	
Professional fees	762,709	290,208
Clinical research obligations	218,715	658,605
Other	732,664	672,484
	$ 7,955,217	$ 11,502,802

Deferred revenue at March 31, 2010 and December 31, 2009 included customer prepayments of $1,134,824 and $1,501,598, respectively.

8. Geographic Information

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

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

	Three Months Ended March 31,	
	2010	2009
United States	$ 14,868	$ 14,837
Europe	1,342	1,500
Other regions	1,735	919
	$ 17,945	$ 17,256

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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, 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; 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 proprietary oral fluid technologies, as well as other diagnostic products including immunoassays and other *in vitro*

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

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

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

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

Competitive and Economic Outlook

Competition in the market for HIV testing is intense and is expected to increase. We believe that our principal competition will come from existing point-of-care rapid blood tests, laboratory-based blood tests, and urine assays or other oral fluid-based tests that may be developed. Our competitors include medical diagnostic companies and specialized biotechnology firms, as well as pharmaceutical companies with biotechnology divisions.

Our OraQuick® HCV test that is now available in Europe is expected to compete against laboratory-based HCV blood tests. In non-U.S. countries outside of Europe, we expect this product to compete against other rapid HCV blood tests in addition to the laboratory-based tests.

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 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.

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Current Financial Results

During the three months ended March 31, 2010, our total revenues were $17.9 million, which represents a 4% increase from the same period in 2009. Revenues include a $1.0 million milestone payment we 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 three months ended March 31, 2010 was $2.2 million or $0.05 per share, compared to a net loss of $1.6 million or $0.04 per share for the three months ended March 31, 2009.

Cash flow used in operating activities for the three months ended March 31, 2010 was $5.0 million compared to the $2.7 million used in operating activities for the three months ended March 31, 2009. As of March 31, 2010, we had $73.4 million in cash, cash equivalents and short-term investments, compared to $79.7 million at December 31, 2009.

Recent Developments

OraQuick® HCV Test

During the fourth quarter of 2009, we received approval to affix the CE mark to our OraQuick® rapid HCV test. CE mark approval is the first step required in order to allow us to sell our HCV test in the 27 countries that make up the European Union. Our HCV test is the first and only rapid HCV test bearing a CE mark that can be used with oral fluid. We are currently pursuing certain additional registrations in specific European countries where required.

In April 2010, we formally launched the commercialization of our OraQuick® HCV test in Europe at a meeting of the European Association for the Study of the Liver. Although we now can begin selling the OraQuick® HCV test internationally, our initial focus is on finding distributors and building awareness and acceptance for this product.

Results of Operations

Three months ended March 31, 2010 compared to March 31, 2009

Total revenues increased 4% to $17.9 million in the first quarter of 2010 from $17.3 million in the comparable quarter in 2009. Increased sales in the cryosurgical systems market and higher licensing and product development revenues were partially offset by lower revenues from our infectious disease testing and insurance risk assessment businesses. Revenues derived from products sold to customers outside the U.S. were $3.1 million and $2.4 million, or 17% and 14% of total revenues, in the first 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 (in thousands, except %) generated in each of our principal markets and by licensing and product development activities.

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	Three Months Ended March 31,				
	Dollars			Percentage of Total Revenues	
Market	2010	2009	% Change	2010	2009
Infectious disease testing	$ 9,481	$ 10,451	(9)%	53%	61%
Substance abuse testing	2,713	2,690	1	15	16
Cryosurgical systems	2,994	2,145	40	17	12
Insurance risk assessment	1,384	1,635	(15)	7	9
Product revenues	16,572	16,921	(2)	92	98
Licensing and product development	1,373	335	310	8	2
Total revenues	$ 17,945	$ 17,256	4%	100%	100%

Infectious Disease Testing Market

Sales to the infectious disease testing market decreased 9% to $9.5 million in the first quarter of 2010. OraQuick® sales totaled $9.1 million and $9.8 million in the first quarters of 2010 and 2009, respectively. Sales of our OraSure® oral fluid collection device totaled $412,000 and $693,000 in the first quarters of 2010 and 2009, respectively.

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

The table below shows a breakdown of our total OraQuick® HIV revenues (in thousands, except %) during the first quarters of 2010 and 2009.

	Three Months Ended March 31,		
Market	2010	2009	% Change
Domestic	$ 8,733	$ 9,299	(6)%
International	336	459	(27)
Total OraQuick® revenues	$ 9,069	$ 9,758	(7)%

During the three months ended March 31, 2010, sales of the OraQuick *ADVANCE*® HIV test in the U.S. market decreased 6%, or $566,000, when compared to the same period in 2009. This decrease is largely due to lower average selling prices, as well as slightly lower sales volume resulting from reduced public health funding by state and local governments.

International sales of our OraQuick® HIV test decreased 27% to $336,000 for the three months ended March 31, 2010 from $459,000 for the three months ended March 31, 2009. This decrease resulted from customer losses due to price competition and non-recurrence of customer orders from the prior year period.

Sales of our OraSure® oral fluid collection device decreased from $693,000 in the first quarter of 2009 to $412,000 in the first quarter of 2010 largely due to the ordering patterns of one of our largest OraSure® public health

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customers. 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 in 2010.

Substance Abuse Testing Market

Substance abuse testing revenues remained flat at $2.7 million in the first quarters of 2010 and 2009 as lower sales of our Intercept® drug testing system were offset by increased sales of the Q.E.D.® rapid point-of-care saliva alcohol test.

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

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

	Three Months Ended March 31,		
Market	**2010**	**2009**	**% Change**
Domestic	$ 1,528	$ 1,577	(3)%
International	517	523	(1)
Total Intercept® revenues	$ 2,045	$ 2,100	(3)%

Domestic Intercept® revenues decreased 3% from $1.6 million in the first quarter of 2009 to $1.5 million in the first quarter of 2010. During the first quarter of 2010, our primary drug testing laboratory customer changed its business model by bringing device inventory storage in-house. This change and the customer s reassessment of its inventory levels caused a temporary disruption to their ordering patterns during the first quarter of 2010.

International Intercept® revenues for the first quarter of 2010 remained flat when compared to the first quarter of 2009.

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. 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.

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Cryosurgical Systems Market

Sales in the cryosurgical systems market (which includes both the physicians office and OTC markets) increased 40% to $3.0 million in the first quarter of 2010, compared to $2.1 million in the same period of the prior year.

The table below shows a breakdown of our total cryosurgical systems revenues (in thousands, except %) generated in each market during the first quarters of 2010 and 2009.

	Three Months Ended March 31,		
Market	**2010**	**2009**	**% Change**
Professional domestic	$ 1,210	$ 942	28%
Professional international	270	629	(57)
OTC domestic	45	57	(21)
OTC international	1,469	517	184
Total cryosurgical systems revenues	$ 2,994	$ 2,145	40%

The overall increase in cryosurgical systems revenues was primarily the result of a $952,000 increase in sales of our international OTC products. During the three months ended March 31, 2010, we experienced increased sales to our Latin American OTC distributor, Genomma, which were partially offset by a decrease in sales to our European OTC distributor, SSL.

During 2008, Genomma reduced its purchases in response to an increase in product returns from retailers in Mexico who overstocked during the winter months of 2007. Throughout 2008 and early in 2009, Genomma worked through its excess inventory levels and resumed purchasing product during the second quarter of 2009 with no purchases made during the first quarter of 2009. During the first quarter of 2010, Genomma s purchases totaled $1.1 million. This increase represents product required to support Genomma s launch of our OTC cryosurgical wart removal product in Brazil.

Sales to SSL were $406,000 and $517,000 in the first quarter of 2010 and 2009, respectively. First quarter 2009 revenues were favorably impacted by product purchases to support SSL s expansion into the French mass merchandise market. Current quarter revenues reflect purchases made for multiple European markets and are more reflective of on-going business operations.

During the first quarter of 2009, we reentered the U.S. OTC cryosurgery marketplace through the launch of our own cryosurgical wart removal product under a new national brand, Freeze n Clear Skin Clinic , and shipped product to one major retailer. In accordance with U.S. generally accepted accounting principles, retail revenues are reduced by costs associated with promotional rebates, advertising, slotting and return allowances provided to the retail trade. Gross sales into the domestic OTC market were $55,000 in the first quarter of 2010 compared to $99,000 in the first quarter of 2009.

Sales of our Histofreezer® product to physicians offices in the United States increased 28% to $1.2 million in the first quarter of 2010, compared to $942,000 in 2009, largely due to increased purchases by our Canadian and U.S. distributors in anticipation of price increases implemented in January and April 2010, respectively. Sales of Histofreezer® in the international market decreased 57% in the first quarter of 2010, as compared to the first quarter 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. Although we aggressively tried to address this diversion issue, we believe it negatively impacted sales in the domestic physicians office market during the first quarter of 2010 and may continue to do so until the supply of diverted product is exhausted.

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In early 2010, we signed agreements with two manufacturer s sales representative organizations to support sales of our Histofreezer® product in the U.S. Under these arrangements, over 40 additional sales representatives will be working with our physicians office distributors throughout the United States. The addition of these sales representatives is expected to contribute to domestic Histofreezer® sales growth during 2010.

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 could negatively affect international sales of our Histofreezer® product. We are also seeing evidence that sales of OTC cryosurgical products may reduce the number of individuals that will seek to obtain treatment of their warts by a physician, which in turn could negatively affect sales of our Histofreezer® product in the domestic professional market. However, it is not possible at this time to estimate the likelihood or financial impact of these changes.

Insurance Risk Assessment Market

Sales to the insurance risk assessment market decreased 15% to $1.4 million in 2010 from $1.6 million in the first quarter of 2009, due to variations in laboratory ordering patterns and a decrease in the issuance of new insurance policies.

Licensing and Product Development

Licensing and product development revenues increased to $1.4 million during the first quarter of 2010 from $335,000 during the first quarter of 2009. This increase was primarily due to a $1.0 million milestone payment received as a result of our achievement of certain regulatory 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 quarters of both 2010 and 2009 represent royalties received on domestic outsales of Merck s OTC cryosurgical wart removal product, pursuant to our license and settlement agreement executed in January 2008.

Gross Margin

Gross margin in the first quarter of 2010 was 64%, which is essentially unchanged from the gross margin achieved in the first quarter of 2009. Gross margin in the current quarter benefitted from the increase in licensing and product development revenues and decrease in royalty and licensing expenses. Gross margin was negatively affected by an increase in unabsorbed overhead costs due to lower product production in light of existing inventory levels coupled with the lower selling price realized from our OraQuick *ADVANCE*® HIV product.

Operating Expenses

Research and development expenses decreased 7% from $3.4 million in the first quarter of 2009 to $3.1 million in the same period in 2010, primarily as a result of decreased validation, vendor qualification, and clinical trial costs related to the development of our OraQuick® HCV and HIV OTC tests. These decreases were partially offset by higher laboratory supplies expense related to the development of new infectious disease products. We expect our research and development costs will increase in 2010 as a result of clinical trials for the HIV OTC and OraQuick® HCV products and development of other new products.

Sales and marketing expenses increased 13% from $5.0 million in the first quarter of 2009 to $5.7 million in the first quarter of 2010. This increase was the result of additional market research activities, increased recruiting and consulting costs and the commissions paid to the two new manufacturer s sales representative organizations that we retained during the first quarter to support sales of our Histofreezer® product in the U.S. physician office market.

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General and administrative expenses increased 7% to $4.8 million in the first quarter of 2010 from $4.5 million in the same period in 2009. This increase was primarily attributed to an increase in consulting costs, partially offset by a decrease in legal expenses.

Interest Income/Expense

Interest expense decreased to $76,000 in the first quarter of 2010 from $90,000 in the first quarter of 2009 as a result of lower average debt balances. Interest income decreased to $42,000 in the first quarter of 2010 from $335,000 in the first quarter of 2009, primarily as a result of lower yields earned on our investment portfolio, lower investment balances, and an overall conservative, shorter-term investment approach.

Income Taxes

In 2008, we established a full valuation allowance against our total net deferred tax asset. Management has continued to evaluate whether the full valuation is still appropriate. At the end of the three-month period ended March 31, 2010, we concluded that the full valuation allowance still remains appropriate as the facts and circumstances during 2010 have not changed. As a result, no income tax benefit was recorded in the first quarters of 2010 or 2009.

Liquidity and Capital Resources

	March 31, 2010	December 31, 2009
	(In thousands)	
Cash and cash equivalents	$ 69,374	$ 74,934
Short-term investments	3,986	4,737
Working capital	86,583	89,435

Our cash, cash equivalents and short-term investments decreased $6.3 million to $73.4 million at March 31, 2010, primarily as a result of $5.0 million in net cash used in operations during the first quarter, $532,000 of cash used for property and equipment purchases, $639,000 associated with the retirement of common stock to pay minimum tax withholding obligations on the vesting of restricted shares, and $135,000 for debt repayments.

The $5.0 million of net cash used in operating activities in the first quarter of 2010 represented an increase of $2.4 million when compared to the same period in 2009. This increase resulted from our net loss of $2.2 million and reduced scrap and spoilage of $89,000, partially offset by non-cash stock-based compensation expense of $891,000 and depreciation and amortization of $650,000. Also contributing to the higher net cash used in operations were increases in inventory and prepaid expenses of $375,000 and $673,000, respectively. Inventory increased largely due to increased raw material purchases for our cryosurgical product line to take advantage of price discounts on bulk purchases. Prepaid expenses increased primarily as a result of $530,000 in prepaid royalties recorded in the first quarter of 2010 associated with the termination and buy-out of a license and supply agreement with our HIV peptide supplier. Additional uses of cash during the first quarter of 2010 resulted from a decrease in accounts payable of $254,000 and a $4.5 million decrease in accrued expenses and other liabilities associated with payment of our 2009 royalty obligations, management incentive bonuses and other accruals. Offsetting these uses of cash during the quarter was a $1.6 million decrease in accounts receivable, resulting from the timely collections of amounts due and the decrease in product revenues experienced in the first quarter of 2010 as compared to the fourth quarter of 2009.

Net cash provided by investing activities during the first three months of 2010 was $218,000. Proceeds of $750,000 from maturities and redemptions of short-term investments were partially offset by $532,000 in purchases of property and equipment.

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During the remainder of the year ending December 31, 2010, we expect to invest approximately $2.0 million in additional capital expenditures, primarily related to purchases of additional new equipment, and improvements to our facilities.

Net cash used in financing activities was $773,000 for the three months ended March 31, 2010, primarily as a result of $135,000 in loan principal repayments and $639,000 used for the withholding and retirement of common stock related to the vesting of restricted shares.

At December 31, 2009, we had in place a $10,000,000 credit advance with Comerica Bank (Comerica). Pursuant to the terms of the advance, principal, and interest fixed at 4.15%, are payable monthly through June 2011, at which time the remaining unpaid principal balance is payable. Accordingly, at June 30, 2010, our remaining unpaid principal balance will be classified as a current liability since it will be payable within the ensuing twelve months. As of March 31, 2010, we had $8.2 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 March 31, 2010. The agreement also restricts our ability to pay dividends, to make certain investments, to incur additional indebtedness, to sell or otherwise dispose of a substantial portion of assets, and to merge or consolidate operations with an unaffiliated entity, without the consent of Comerica.

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

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

Summary of Contractual Obligations

A summary of our obligations to make future payments under contracts existing at December 31, 2009 is included in Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations, of our Annual Report on Form 10-K for the year ended December 31, 2009. As of March 31, 2010, there were no significant changes to this information.

Critical Accounting Policies and Estimates

This Management s Discussion and Analysis of Financial Condition and Results of Operations discusses our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires that we make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. On an on-going basis, we evaluate our judgments and estimates, including those related to bad debts, inventories, investments, intangible assets, income taxes and realization of the related deferred tax assets,

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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 three months of 2010, there were no material changes in our critical accounting policies.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

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

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

As of March 31, 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 three months ended March 31, 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 March 31, 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 March 31, 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 March 31, 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 1. LEGAL PROCEEDINGS

Cryosurgical Patent Infringement Litigation

In December 2009, we filed legal proceedings in the Patents Court of the High Court of England and Wales against D.D.D. Limited, DioMed Developments Limited and Sixtem Life Srl, alleging that the import and/or sale of the Bazuka Sub-Zero OTC cryosurgical product by the defendants in the United Kingdom infringes our European Patent (UK) 0 608 954. We are seeking injunctive relief and damages, among other remedies, in this matter. The defendants have filed a response denying infringement and alleging that our patent is invalid. We have filed a further response denying the defendants allegations of invalidity.

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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 March 31, 2010, pursuant to our 2000 Stock Award Plan and in connection with the vesting of restricted shares, we retired 121,529 shares to satisfy minimum tax withholding obligations at an average price paid per share of $5.25.

On August 5, 2008, our Board of Directors approved a share repurchase program pursuant to which we are permitted to acquire up to $25.0 million of outstanding shares. We did not purchase any shares under this program during the three months ended March 31, 2010. As of March 31, 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.

/s/ RONALD H. SPAIR

Date: May 6, 2010

Ronald H. Spair
Chief Operating Officer and

Chief Financial Officer
(Principal Financial Officer)

/s/ MARK L. KUNA

Date: May 6, 2010

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.