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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2009.

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 ☒ No ☐

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

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

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐ Smaller reporting company ☐

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

Number of shares of Common Stock, par value $.000001 per share, outstanding as of May 5, 2009: 45,870,266

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PART I. FINANCIAL INFORMATION

PART II. OTHER INFORMATION

Item 1. FINANCIAL STATEMENTS

ORASURE TECHNOLOGIES, INC.
BALANCE SHEETS
(Unaudited)

	MARCH 31, 2009	DECEMBER 31, 2008
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 52,390,160	$ 39,565,218
Short-term investments	26,229,592	42,957,467
Accounts receivable, net of allowance for doubtful account of $261,630 and $163,100	11,237,255	11,571,048
Inventories	9,916,935	10,704,088
Prepaid expenses and other	1,642,408	1,418,171
Total current assets	101,416,350	106,215,992
PROPERTY AND EQUIPMENT, net	21,078,111	21,235,367
PATENTS AND PRODUCT RIGHTS, net	4,182,584	4,380,540
OTHER ASSETS	83,053	86,290
	$ 126,760,098	$ 131,918,189
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	$ 553,292	$ 557,897
Accounts payable	2,544,763	3,925,662
Accrued expenses and other	8,202,240	10,795,955
Total current liabilities	11,300,295	15,279,514
LONG-TERM DEBT	8,166,679	8,301,440
OTHER LIABILITIES	5,453	11,985
STOCKHOLDERS' EQUITY		
Preferred stock, par value $.000001, 25,000,000 shares authorized, none issued	—	—
Common stock, par value $.000001, 120,000,000 shares authorized, 45,870,266 and 45,769,221 shares issued and outstanding	46	46
Additional paid-in capital	236,399,552	235,862,999
Accumulated other comprehensive loss	(218,613)	(262,442)
Accumulated deficit	(128,893,314)	(127,275,353)
Total stockholders' equity	107,287,671	108,325,250
	$ 126,760,098	$ 131,918,189

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.
STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31,	
	2009	2008
REVENUES:		
Product	$16,921,202	$17,635,611
Licensing and product development	335,249	453,208
	17,256,451	18,088,819
COST OF PRODUCTS SOLD	6,284,379	7,445,851
Gross profit	10,972,072	10,642,968
OPERATING EXPENSES:		
Research and development	3,352,498	4,597,631
Sales and marketing	5,022,765	5,215,989
General and administrative	4,457,051	3,840,781
	12,832,314	13,654,401
Operating loss	(1,860,242)	(3,011,433)
INTEREST EXPENSE	(89,664)	(83,126)
INTEREST INCOME	335,370	1,017,805
OTHER INCOME	2,510	4,883,714
FOREIGN CURRENCY LOSS	(5,935)	(73,000)
Income (loss) before income taxes	(1,617,961)	2,733,960
INCOME TAX PROVISION	—	732,223
NET INCOME (LOSS)	$ (1,617,961)	$ 2,001,737
EARNINGS (LOSS) PER SHARE:		
BASIC AND DILUTED	$ (0.04)	$ 0.04
SHARES USED IN COMPUTING EARNINGS (LOSS) PER SHARE		
BASIC	45,837,606	46,783,527
DILUTED	45,837,606	47,267,643

The accompanying notes are an integral part of these statements.

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

	Three Months Ended March 31, 2009	2008
OPERATING ACTIVITIES:		
Net income (loss)	$ (1,617,961)	$ 2,001,737
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Stock-based compensation	1,137,105	1,385,668
Deferred income taxes	—	745,885
Depreciation and amortization	847,992	690,693
Net change in reserve for excess and obsolete inventories	(145,669)	133,952
Changes in assets and liabilities:		
Accounts receivable	338,526	(2,433,811)
Inventories	932,822	(653,696)
Prepaid expenses and other assets	(221,000)	34,009
Accounts payable	(1,328,309)	(1,896,228)
Accrued expenses and other liabilities	(2,593,715)	(3,717,595)
Net cash used in operating activities	(2,650,209)	(3,709,386)
INVESTING ACTIVITIES:		
Purchase of short-term investments	(2,000,000)	(36,608,135)
Proceeds from maturities and redemptions of short-term investments	18,675,000	22,204,837
Purchase of property and equipment	(453,399)	(755,312)
Net cash provided by (used in) investing activities	16,221,601	(15,158,610)
FINANCING ACTIVITIES:		
Repayments of long-term debt	(139,366)	(97,413)
Proceeds from issuance of common stock	16,402	92,517
Withholding and retirement of common stock	(314,881)	(839,956)
Purchase and retirement of common stock	(308,605)	—
Net cash used in financing activities	(746,450)	(844,852)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	12,824,942	(19,712,848)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	39,565,218	32,229,697
CASH AND CASH EQUIVALENTS, END OF PERIOD	$52,390,160	$ 12,516,849
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for:		
Interest	$ 92,123	$ 125,302
Income taxes	$ 27,000	$ 371,284

The accompanying notes are an integral part of these statements.

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

1. The Company

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

The current economic downturn, including disruptions in the capital and credit markets, may continue indefinitely and intensify, and could adversely affect our results of operations, cash flows and financial condition or those of our customers and suppliers. These circumstances could adversely affect our access to liquidity needed to conduct or expand our business or conduct acquisitions or make other discretionary investments. These circumstances could adversely affect our ability to draw on our existing revolving credit facility, which depends on the ability of the bank that is a party to that facility to meet its funding commitments to us. A bank may not be able to meet its funding commitments if it experiences shortages of capital and liquidity. These circumstances 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. In addition, demand for our products by consumers may also be adversely affected by the economic downturn. All of these factors could adversely affect our results of operations, cash flows and financial condition. A weakening 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 the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2008. Results of operations for the three months ended March 31, 2009 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, 2009 and December 31, 2008, cash equivalents consisted of money market accounts, commercial paper and U.S. government agency obligations.

Short-term Investments. We consider all short-term investments to be available-for-sale securities, in accordance with Statement of Financial Accounting Standards ("SFAS") No. 115, "Accounting for Certain Investments in Debt and Equity Securities." These securities are comprised of certificates of deposits, commercial paper, U.S. government and agency obligations, 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 income (loss).

The following is a summary of our available-for-sale securities at March 31, 2009 and December 31, 2008:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
March 31, 2009				
Certificates of deposit	$ 6,498,000	$ 3,743	$ —	$ 6,501,743
Government and agency bonds	5,270,559	32,189	—	5,302,748
Corporate bonds	14,443,934	13,970	(32,803)	14,425,101
Total available-for-sale securities	$26,212,493	$ 49,902	$ (32,803)	$26,229,592
December 31, 2008				
Certificates of deposit	$ 6,098,000	$ 8,401	$ —	$ 6,106,401
Commercial paper	2,894,609	4,425	—	2,899,034
Government and agency bonds	11,229,287	106,173	—	11,335,460
Corporate bonds	22,730,229	8,639	(122,296)	22,616,572
Total available-for-sale securities	$42,952,125	$127,638	$(122,296)	$42,957,467
At March 31, 2009, maturities of our available-for-sale securities were as follows:				
Less than one year	$24,963,800	$ 46,641	$ (32,803)	$24,977,638
One to two years	1,248,693	3,261	—	1,251,954
Total available-for-sale securities	$26,212,493	$ 49,902	$ (32,803)	$26,229,592

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, 2009	December 31, 2008
Raw materials	$ 6,067,214	$ 6,721,102
Work in process	549,187	390,259
Finished goods	3,300,534	3,592,727
	$ 9,916,935	$ 10,704,088

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 that the revenue is recognized. In addition, revenue from retail sales is also recorded net of promotional and slotting allowances granted.

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. Our distribution agreement with Abbott Laboratories terminated at the end of 2008. Effective January 1, 2009, we began selling the OraQuick *ADVANCE*® rapid HIV-1/2 antibody test directly to U.S. hospitals and other customers previously served by Abbott. As a result, we had no sales to Abbott during the first quarter of 2009. During the first quarter of 2008, sales to Abbott accounted for 11 percent of our total revenues.

The Company had the following significant concentrations in accounts receivable:

	Percentage of Accounts Receivable	
	March 31, 2009	December 31, 2008
Quest Diagnostics, Incorporated	10%	8%
SSL International plc	5	10
National Aids Control Program	—	15

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. We have presented basic and diluted earnings (loss) per share pursuant to SFAS No. 128, “Earnings per Share.” In accordance with SFAS No. 128, basic 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 per share is computed in a manner similar to basic earnings 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 shares 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 March 31,	
	2009	2008
Net income (loss)	$ (1,617,961)	$ 2,001,737
Weighted average shares of common stock outstanding:		
Basic	45,837,606	46,783,527
Dilutive effect of stock options, warrants and restricted stock	—	484,116
Diluted	45,837,606	47,267,643
Earnings (loss) per share:		
Basic	$ (0.04)	$ 0.04
Diluted	$ (0.04)	$ 0.04

For the three-month periods ended March 31, 2009 and 2008, outstanding common stock options and unvested restricted stock, representing 5,208,750 and 3,199,598 shares, respectively, were excluded from the computation of diluted earnings per share, as their inclusion would have been anti-dilutive.

Other Comprehensive Income (Loss). We follow SFAS No. 130, “Reporting Comprehensive Income.” This statement requires the classification of items of other comprehensive income (loss) by their nature and disclosure of the accumulated balance of other comprehensive income (loss), separately from accumulated deficit and additional paid-in capital, in the stockholders’ equity section of our balance sheet. Other comprehensive income (loss) at March 31, 2009 and December 31, 2008 consisted of currency translation adjustments and net unrealized gains or losses on short term investments. Comprehensive income (loss) was $(1,574,132) and $2,087,124 for the three months ended March 31, 2009 and 2008, respectively.

3. Stock-Based Compensation

We grant stock-based awards under the OraSure Technologies, Inc. 2000 Stock Award Plan, as amended and restated (the “2000 Plan”). The 2000 Plan permits stock-based awards to employees, outside directors and consultants or other third-party advisors. Awards which may be granted under the 2000 Plan include qualified 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, 2009 and 2008 was $1.16 and $3.14 per share, respectively.

Total compensation cost related to stock options for the three months ended March 31, 2009 and 2008 was $402,661 and $544,414 ($441,267, net of tax), respectively, of which $32,019 and $38,979 was capitalized into inventory during the quarters ended March 31, 2009 and 2008, respectively. The amounts recognized in cost of products sold for amounts previously capitalized were $66,831 and $56,672 for the three months ended March 31, 2009 and 2008, respectively.

The following table summarizes the stock option activity for the three months ended March 31, 2009:

	Options
Outstanding on January 1, 2009	5,130,707
Granted	547,158
Exercised	(20,438)
Forfeited	(7,035)
Outstanding on March 31, 2009	5,650,392

As of March 31, 2009, there was $2,512,033 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 $16,402 and $92,517 for the three months ended March 31, 2009 and 2008, respectively. As a result of the Company's net operating loss carryforward position, no actual income tax benefit was realized from stock option exercises during these periods.

As mentioned above, the 2000 Plan enables us to grant restricted shares of our common stock to eligible employees, including officers, and outside directors. Generally, these shares are nontransferable and are subject to vesting requirements 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, 2009, we granted 422,190 restricted shares of our common stock, with a weighted average grant date fair value of $2.81 per share, to certain key officers, members of management and outside directors. Compensation cost of $734,444 and $841,254 related to restricted shares was recognized during the three months ended March 31, 2009 and 2008, respectively.

The following table summarizes restricted stock award activity for the three months ended March 31, 2009:

	Shares
Issued and unvested, January 1, 2009	831,488
Granted	422,190
Vested	(297,519)
Forfeited	—
Issued and unvested, March 31, 2009	956,159

As of March 31, 2009, there was $4,773,116 of unrecognized compensation expense related to unvested restricted stock awards that is expected to be recognized over a weighted average period of 2.6 years. In connection with the vesting of restricted shares during the three months ended March 31, 2009 and 2008, 108,619 and 102,128 shares, respectively, with aggregate values of $314,881 and $839,956, respectively, were withheld and retired in satisfaction of minimum tax withholding obligations.

4. 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 this same period.

5. Accrued Expenses

	March 31, 2009	December 31, 2008
Payroll and related benefits	$ 3,137,302	$ 3,513,124
Royalties	1,974,430	2,481,466
Deferred revenue	1,064,715	1,951,921
Professional fees	839,552	472,969
Clinical research obligations	27,330	348,459
Advertising	25,000	365,313
Other	1,133,911	1,662,703
	$ 8,202,240	$ 10,795,955

Deferred revenue at March 31, 2009 and December 31, 2008 included customer prepayments of $983,216 and $1,824,721, respectively.

6. Other Income

On January 11, 2008, we entered into a settlement and license agreement with Schering-Plough Healthcare Products, Inc. (“Schering”) to resolve our patent infringement litigation against Schering. Under the terms of the agreement, Schering was required to make a payment of $4,883,714 to us. This payment was received during the first quarter of 2008 and recorded in other income.

7. Geographic Information

Based on guidance in SFAS No. 131, “Disclosures about Segments of an Enterprise and Related Information,” we believe 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,	
	2009	2008
United States	$14,837	$14,142
Europe	1,500	2,437
Other regions	919	1,510
	$17,256	$18,089

8. Fair Value of Financial Instruments

We follow SFAS No. 157, “Fair Value Measurements.” SFAS No. 157 applies to all financial assets and liabilities that are being measured and reported on a fair value basis. The statement requires that fair value measurements 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 described in Note 2 were classified and measured as Level 1 instruments.

9. Pending Litigation

On April 22, 2008, a complaint was filed against us in the United States District Court for the District of New Jersey by Inverness Medical Innovations, Inc., Inverness Medical Switzerland GmbH and Church & Dwight Co., Inc., alleging that we infringed U.S. Patent No. 6,485,982. The complaint specifically refers to our OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test. The complaint seeks injunctive relief, damages and an award of attorneys’ fees. We have filed our Answer responding to the allegations in the Complaint and asserting various defenses and counterclaims.

On October 10, 2008, the plaintiffs filed a motion for summary judgment of infringement in this case, pursuant to a schedule previously established by the Court. On May 1, 2009, the Court issued an order denying the plaintiff’s motion without prejudice, and granting the plaintiffs leave to reinstate the motion following completion of the Court’s Markman hearing. The Markman process is the part of this patent infringement lawsuit where the Court determines the construction of various claim terms in the patent being asserted. A Markham hearing in this case has been scheduled for August 12, 2009.

We continue to believe that none of our products, including the OraQuick *ADVANCE*® HIV test, infringes the patent asserted in this lawsuit or any other party’s intellectual property rights. We also believe that the patent asserted in this matter is invalid or unenforceable, and we intend to defend this lawsuit vigorously. We are unable at this time to determine the impact, if any, that this lawsuit may have on our business, prospects or results of operations.

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 development, 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 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; 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 and extended shelf life; 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 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 patent infringement, 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, 2008, Quarterly Reports on Form 10-Q, and other filings with the SEC. Although forward-looking statements help to provide information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. The forward-looking statements are made as of the date of this Report and we undertake no duty to update these statements.

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

Overview

We operate primarily in the *in vitro* diagnostic business. Our business principally involves the development, manufacture, marketing and sale of oral fluid diagnostic products and specimen collection devices using our proprietary oral fluid technologies, as well as other diagnostic products including immunoassays and other *in vitro* diagnostic tests that are used on other specimen types, 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 ("OTC") or consumer retail market in the United States, Canada, Europe, Mexico 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. *In vitro* diagnostic tests are performed outside the body, in contrast to *in vivo* tests, which are performed directly on or within the body. 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 space.

During the three months ended March 31, 2009, our total revenues were $17.3 million, which represents a 5% decrease from the same period in 2008. Our net loss for the three months ended March 31, 2009 was $1.6 million, compared to net income of $2.0 million for the three months ended March 31, 2008. Our net income during the first three months of 2008 included a $4.9 million payment received from Schering-Plough Healthcare Products, Inc. ("Schering-Plough") to resolve our patent infringement litigation against them, which was recorded as other income.

Cash flow used in operating activities for the three months ended March 31, 2009 was $2.7 million compared to $3.7 million for the three months ended March 31, 2008. The decrease in cash used in operating activities is primarily the result of the collection of a large outstanding balance from one of our international customers during the first quarter of 2009. In addition, decreases in accounts payable and accrued expenses, offset by non-cash charges for stock-based compensation, depreciation and amortization, contributed to the cash used in operations during the first quarter of 2009. As of March 31, 2009, we had $78.6 million in cash, cash equivalents and short-term investments, a $3.9 million decrease from December 31, 2008.

Sales into the infectious disease testing market increased by 10% in the first quarter of 2009 primarily as a result of our decision to sell OraQuick *ADVANCE*® directly to U.S. hospitals and reference laboratories starting on January 1, 2009. As previously disclosed, we terminated our distribution agreement with Abbott for the sale of OraQuick *ADVANCE*® at the end of 2008. As a result, revenues from direct sales into the hospital market during the first quarter of 2009 increased 41% over the comparable period in 2008. This increase is due to higher average selling prices realized under the direct sales model. Pursuant to the transition agreement with Abbott, we paid a one-time, lump sum termination fee to Abbott during the first quarter of 2009. We had accrued this termination fee at December 31, 2008. We have no royalty or other ongoing financial obligations to Abbott as a result of the termination of the distribution agreement.

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

Sales of our cryosurgical products decreased 36% during the first three months of 2009 compared to 2008. These results reflect sales of Histofreezer® into both the domestic and international physicians' office markets and sales of the OTC formulation of this product through international distributors and U.S. retailers. During the first quarter of 2009, we launched Freeze 'n Clear Skin Clinic™, our own nationally branded cryosurgical wart removal product in the U.S. OTC market. It is not possible to predict at this time how this new branded product will perform.

SSL International plc ("SSL") distributes our cryosurgical product under its Scholl's and Dr. Scholl trademarks in the OTC market in several European countries, Australia and New Zealand. Genomma Labs ("Genomma") also distributes a similar product to the OTC market in Mexico and has rights to Argentina, Brazil and various other Central and South American countries. Overall, our

international OTC cryosurgical sales decreased 67% in the first three months of 2009 compared to the same period in the prior year primarily due to a $646,000 decline in sales to SSL, resulting from lower unit selling prices and variability in their ordering patterns and product launches.

Sales to the substance abuse testing market decreased 18% during the first quarter of 2009, due primarily to declining employment in the United States. Our workplace testing business has been impacted by the decline in employment rates in some of the markets that use our Intercept® collection device and related assays. We do not expect renewed growth in the utilization of our Intercept® product line until employment conditions in the U.S. recover.

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*® 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 FDA approvals could disrupt our ability to sell the affected products.

In past years, BioMerieux ("BMX") manufactured and sold the only oral fluid HIV-1 screening test that had received FDA approval for use in detecting HIV-1 in an oral fluid specimen collected with our OraSure® collection device. BMX also supplied the HIV-1 antigen used to manufacture our oral fluid Western blot HIV-1 confirmatory test and was the exclusive world-wide distributor of that product. BMX discontinued manufacturing their HIV-1 EIA screening test during 2007. As a result, we intend to seek FDA approval of an alternative HIV-1 EIA screening test for use with our OraSure® collection device. BMX also elected not to renew our Western blot agreements beyond December 31, 2007, and we are now selling the Western blot oral fluid HIV-1 confirmatory test directly to our laboratory customers.

We rely heavily on distributors to purchase and resell many of our products. For example, SSL has exclusive rights to our wart removal product in the OTC footcare market in Europe, Australia and New Zealand and Genomma Labs has exclusive rights in Mexico, Argentina, Brazil, and various other Central and South American countries. 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 expect to enter into additional distribution agreements for new and future products, for distribution 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.

We generated 86% of our first quarter 2009 revenues in the U.S. marketplace, compared to 78% in 2008. We are continuously evaluating strategies to increase our sales penetration in markets outside the U.S. As our business in foreign countries increases, we could be exposed to other economic, political, exchange rate, regulatory and cultural risks.

The current economic downturn, including disruptions in the capital and credit markets, may continue indefinitely and intensify, and could 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. These circumstances 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. In addition, demand for our products by consumers may also be adversely affected by the economic downturn.

Results of Operations

Three months ended March 31, 2009 compared to March 31, 2008

Total revenues decreased 5% to $17.3 million in the first quarter of 2009 from $18.1 million in the comparable quarter in 2008. Increased sales of our OraQuick *ADVANCE*® rapid HIV-1/2 antibody test were more than offset by decreased sales of our cryosurgical and substance abuse testing products. Revenues derived from products sold to customers outside the U.S. were $2.4 million and $3.9 million, or 14% and 22% of total revenues, in the first quarters of 2009 and 2008, respectively. Because the majority of our international sales are transactions in U.S. dollars, the impact of fluctuating foreign currency exchange rates has not been 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.

	Three Months Ended March 31,				
	Dollars			Percentage of Total Revenues	
Market	2009	2008	% Change	2009	2008
Infectious disease testing	$10,451	$ 9,480	10%	61%	52%
Substance abuse testing	2,690	3,277	(18)	16	18
Cryosurgical systems	2,145	3,336	(36)	12	18
Insurance risk assessment	1,635	1,543	6	9	9
Product revenues	16,921	17,636	(4)	98	97
Licensing and product development	335	453	(26)	2	3
Total revenues	$17,256	$18,089	(5)%	100%	100%

Infectious Disease Testing Market

Sales to the infectious disease testing market increased 10% to $10.5 million in the first quarter of 2009, primarily as a result of the continued strong performance of our OraQuick *ADVANCE*® rapid HIV-1/2 antibody test in an increasingly competitive environment. OraQuick® sales totaled $9.8 million and $8.9 million in the first quarters of 2009 and 2008, respectively. Sales of our OraSure® oral fluid collection device totaled $693,000 and $627,000 in the first quarters of 2009 and 2008, respectively.

The table below shows a breakdown of our total OraQuick® revenues (in thousands, except %) during the first quarters of 2009 and 2008.

	Three Months Ended March 31,		
Customers	2009	2008	% Change
Direct to U.S. Public Health	$6,577	$6,282	5%
Hospital Market	2,722	1,925	41
International	459	646	(29)
Total OraQuick® revenues	$9,758	$8,853	10%

During the first quarter of 2009, OraQuick® revenue derived from direct sales to the U.S. public health market increased by 5% as compared to 2008 and continues to benefit from growth in our base business. Sales into the hospital market increased 41% to $2.7 million during the first quarter of 2009 as compared to $1.9 million in 2008. On January 1, 2009, we switched to a direct sales model for U.S. hospitals as a result of the termination of our distribution agreement with Abbott Laboratories at the end of 2008. The increase in revenues in the U.S. hospital market is due to higher average selling prices realized under our direct sales model.

We believe that our OraQuick ADVANCE® device, which is FDA-approved for detecting antibodies to both HIV-1 and HIV-2 in oral fluid, finger-stick and venous whole blood, and plasma samples, and is CLIA-waived for use with all sample types except plasma, provides a significant competitive advantage, thereby enabling us to fully implement a strategy for selling OraQuick® in the U.S. and internationally. We received CE mark approval for our OraQuick ADVANCE® test and we currently sell small quantities of this product in Europe. We have established distribution channels in several European countries and are pursuing other distributors elsewhere in the European Union and in other countries.

International sales of our OraQuick® HIV-1/2 test decreased to $459,000 for the three months ended March 31, 2009 from $646,000 for the three months ended March 31, 2008. This 29% decline was a result of lower sales into Africa.

We have continued to see evidence that sales of OraQuick *ADVANCE*® are negatively impacting sales of our OraSure® oral fluid collection device in the infectious disease testing market in the U.S. While our sales of OraSure® increased slightly from $627,000 in the first quarter of 2008 to $693,000 in the first quarter of 2009, 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, and the CDC's efforts to increase rapid HIV testing in healthcare settings. While it is not possible at this time to estimate the extent of such ongoing change in purchasing patterns, we expect OraSure® sales to decline.

Substance Abuse Testing Market

Substance abuse testing revenues decreased 18% to $2.7 million in the first quarter of 2009 from $3.3 million in the first quarter of 2008, as sales of our Intercept® product for workplace testing were impacted by the continuing adverse economic conditions and higher unemployment rates.

The table below shows a breakdown of our total Intercept® revenues (in thousands, except %) generated in each market during the first quarters of 2009 and 2008.

	Three Months Ended March 31,		
Market	**2009**	**2008**	**% Change**
Workplace testing	$ 857	$1,016	(16)%
Criminal justice	552	619	(11)
International	523	525	0
Direct	168	271	(38)
Total Intercept® revenues	$2,100	$2,431	(14)%

Our workplace testing business decreased 16% from $1.0 million in the first quarter of 2008 to $857,000 in the first quarter of 2009. Pre-employment drug screening represents over 50% of our workplace testing business and the current decline in the domestic economy and rising unemployment have had a direct impact on this part of our business.

We do not expect renewed growth in Intercept® sales until employment conditions in the U.S. recover and overall economic conditions improve. In addition, our 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. Our oral fluid microplate assays also 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. In order to meet this competition, we are jointly developing and intend to commercialize fully-automated homogeneous oral fluid drugs of abuse assays with Roche Diagnostics for use with our Intercept® device.

Cryosurgical Systems Market

Sales of our products in the cryosurgical systems market (which includes both the physicians' office and OTC markets) decreased 36% to $2.1 million in the first quarter of 2009, compared to $3.3 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 2009 and 2008.

	Three Months Ended March 31,		
Market	2009	2008	% Change
Professional domestic	$ 942	$1,034	(9)%
Professional international	629	737	(15)
OTC domestic	57	—	100
OTC international	517	1,565	(67)
Total cryosurgical systems revenues	$2,145	$3,336	(36)%

The overall decrease in cryosurgical systems revenues was primarily the result of a 55% decrease in sales to our international OTC distributor, SSL. We have an agreement with SSL under which we manufacture and supply, and SSL distributes on an exclusive basis, our cryosurgical wart removal product in the OTC market in Europe, Australia and New Zealand under SSL's Scholl and Dr. Scholl trademarks. Sales to SSL were $517,000 and $1.2 million in the first quarters of 2009 and 2008, respectively. The decrease in revenues from SSL during the first quarter of 2009 resulted from lower unit selling prices and variability in SSL's ordering patterns and because during the first quarter of 2009, SSL purchased product primarily for one European market, while product was purchased for four European markets during the comparable period in 2008.

We also have granted Genomma Labs exclusive distribution rights to our cryosurgical wart removal product in the OTC markets in Mexico, Argentina, Brazil, and various other Central and South American countries. First quarter of 2008 international revenues included approximately $400,000 of sales to Genomma. This compares to no sales during the first quarter of 2009. During 2008, Genomma Labs reduced its purchases from us, in response to an increase in product returns from retailers in Mexico who overstocked during the winter months of 2007. Throughout 2008, Genomma worked to reduce its excess inventory position, and accordingly did not purchase additional product from us. Genomma has currently worked through their excess inventory levels and we expect to record sales to Genomma beginning in the second quarter of 2009.

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 our new national brand, Freeze 'n Clear Skin Clinic™. In February 2009, we shipped product to one major retailer and we plan to expand distribution to other retailers in the future. It is not possible to predict at this time how successful our new brand will be in the domestic OTC marketplace.

Sales of our Histofreezer® product to physicians' offices in the United States decreased 9% to $942,000 in the first quarter of 2009, as compared to $1.0 million in 2008. Sales of Histofreezer® in the international market decreased 15% to $629,000 in the first quarter of 2009, as compared to $737,000 in 2008. 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, 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 aggressively addressed this diversion issue in 2008. The residual impact of the 2008 diversion issue has been minimal in the domestic physicians' office market during the first quarter of 2009 and we do not expect it to have a material impact on 2009 revenues. The decline in revenues in the international market reflects the correction of this diversion issue.

We are beginning to see some 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. Furthermore, in the European professional marketplace, there is increasing pressure to change or exclude healthcare reimbursement 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. However it is not possible at this time to estimate the financial impact of those changes.

Insurance Risk Assessment Market

Sales to the insurance risk assessment market increased 6% to $1.6 million in 2009 from $1.5 million in the first quarter of 2008, primarily due to laboratory ordering patterns.

License and Product Development

During the first quarter of 2009, licensing and product development revenues decreased to $335,000 from $453,000 during 2008. Licensing revenue included royalties from Schering-Plough pursuant to our license and settlement agreement executed in January 2008.

Gross Margin

Gross margin in the first quarter of 2009 was 64%, compared to 59% for the first quarter of 2008. This improvement resulted from a decrease in scrap and spoilage charges and also reflected the higher gross margin associated with switching to a direct sales model for the OraQuick *ADVANCE*® HIV-1/2 test in the U.S. hospital market. While scrap and spoilage levels were lower in the first quarter of 2009, we expect there will be volatility in this expense from quarter to quarter throughout the remainder of 2009.

Operating Expenses

Research and development expenses decreased 27% from $4.6 million in the first quarter of 2008 to $3.4 million in the same period in 2009, primarily as a result of decreased clinical trial spending associated with the development of our OraQuick® HCV test and OraQuick® HIV OTC test. The majority of product development and clinical costs associated with the OraQuick® HCV device were incurred during 2008. A decrease in staffing costs resulting from organizational changes made during the fourth quarter of 2008 also contributed to the current period decline. We expect clinical trial expenses to increase above first quarter levels later in 2009.

Sales and marketing expenses decreased 4% to $5.0 million in the first quarter of 2009 from $5.2 million in the same period in 2008. This decrease was the result of reduced spending in many categories, partially offset by an expected increase in staffing costs required to implement the direct sales model for the U.S. hospital market. For the remainder of 2009, sales and marketing expenses are expected to increase above first quarter levels.

General and administrative expenses increased 16% to $4.5 million in the first quarter of 2009 from $3.8 million in the same period in 2008. This increase was primarily attributable to an increase in legal costs associated with the patent infringement lawsuit filed against us by Inverness Medical and Church & Dwight.

Other Income/Expense

Interest expense increased slightly to $90,000 in the first quarter of 2009 from $83,000 in the first quarter of 2008. Interest income decreased to $335,000 in the first quarter of 2009 from $1.0 million in the first quarter of 2008, primarily as a result of lower yields earned on our investment portfolio and an overall conservative, shorter-term investment approach.

As a result of the license and settlement agreement we entered into with Schering-Plough to resolve our patent infringement litigation, we received a payment of $4.9 million during the first quarter of 2008, which was recorded as other income.

Income Taxes

During the fourth quarter of 2008, as global economic conditions worsened, we re-evaluated whether or not we would realize the benefits associated with our total net deferred tax asset in the future. Given the uncertainty surrounding the magnitude and length of the current economic recession, our loss in 2008, and our projection of a loss in 2009, we determined that it was more likely than not that we would not realize the benefits associated with our net deferred tax assets in the immediate future. Accordingly, in accordance with SFAS 109, “Accounting for Income Taxes”, we recorded a full valuation allowance against our net deferred tax asset at December 31, 2008. As a result, we did not record a federal or state income tax benefit for our pre-tax loss during the first quarter of 2009. During the three months ended March 31, 2008, we incurred federal and state income tax expense of $732,000.

Liquidity and Capital Resources

	March 31, 2009	December 31, 2008
	(In thousands)	
Cash and cash equivalents	$ 52,390	$ 39,565
Short-term investments	26,230	42,957
Working capital	90,116	90,936

Our cash, cash equivalents and short-term investments decreased $3.9 million to $78.6 million at March 31, 2009, primarily as a result of the use of $2.7 million in cash to fund operations, $453,000 for property and equipment purchases, $315,000 associated with the retirement of common stock to pay minimum tax withholding obligations on the vesting of restricted shares, $309,000 to buy back shares under our stock repurchase plan and $139,000 for debt repayments.

Net cash used in operating activities was $2.7 million in the first quarter of 2009, resulting from our net loss of $1.6 million for the quarter offset by non-cash charges for depreciation and amortization of $848,000, non-cash stock-based compensation expense of $1.1 million, and a provision for scrap and spoilage of $146,000. Also contributing to the use of cash were decreases in accounts payable of $1.3 million and accrued expenses of $2.6 million, largely due to payments of our 2008 year-end royalty obligations, Abbott termination fee, advertising, severance and other accruals, and the utilization of $842,000 of customer prepayments previously recorded as deferred revenue. Prepaid expense increased $221,000 as a result of prepayments to contract research organizations (“CROs”) for clinical work to be performed in 2009. Offsetting these uses of cash were decreases in accounts receivable of $339,000 and inventory of $933,000.

Net cash provided by investing activities during the first quarter of 2009 was $16.2 million. Payments of $453,000 for purchases of property and equipment were offset by $16.7 million of net proceeds from maturities and redemptions of short-term investments.

During the remainder of the year ending December 31, 2009, we expect to invest an additional $3 million in capital expenditures, primarily to purchase additional equipment, upgrade certain older equipment and make improvements to our facilities.

Net cash used in financing activities was $746,000 for the quarter ended March 31, 2009, primarily as a result of the purchase of 108,293 shares of common stock under our stock repurchase plan at an aggregate cost of $309,000. Additional uses of cash for financing activities were $139,000 in loan principal repayments and $315,000 used for the withholding and retirement of common stock, partially offset by $16,000 in cash proceeds from the exercise of stock options.

At March 31, 2009, we had in place a $14,000,000 credit facility (the “Credit Facility”) with Comerica Bank (“Comerica”), which is comprised of a $10,000,000 facilities advance and a $4,000,000 revolving working capital line of credit. Pursuant to the terms of the facilities advance, principal and interest, fixed at 4.15%, are payable monthly through June 2011, at which time the remaining unpaid principal balance is payable. Interest on any advances under the revolving working capital line of credit is payable at either the U.S. prime rate less 0.25% or 30-day LIBOR plus 2.55%, in each case determined at the time of funding. As of March 31, 2009, we had $8,666,679 in outstanding borrowings under the facilities advance and no outstanding borrowings under the $4,000,000 revolving working capital line of credit, which has a maturity date of June 29, 2009.

All borrowings under the Credit Facility are collateralized by a first priority security interest in all of our assets, including present and future accounts receivable, chattel paper, contracts and contract rights, equipment and accessories, general intangibles, investments, instruments, inventories, and a mortgage on our three facilities in Bethlehem, Pennsylvania. Borrowings under the revolving working capital line of credit are limited to commercially standard percentages of accounts receivable. The Credit Facility 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, 2009. The Credit Facility also restricts our ability to pay dividends, to make certain investments, to incur additional indebtedness, to sell or otherwise dispose of a substantial portion of assets, and to merge or consolidate operations with an unaffiliated entity, without the consent of Comerica.

At December 31, 2008, we had NOL carryforwards of $49.5 million for federal income tax purposes. During the fourth quarter of 2005, the Company retained independent tax specialists to perform an ownership change study and analysis to determine the annual limitation amount applicable to utilization of the NOL carryforwards due to past ownership changes, as defined in Section 382 of the Internal Revenue Code. We continue to review ownership changes on an annual basis. We do not believe that ownership change limitations would impair our ability to utilize our NOLs against taxable income that we may generate in the future. 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, short-term investments, and available borrowings under our Credit Facility, is expected to be more than sufficient to fund our operating and capital needs throughout the remainder of 2009. 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 pending or 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 and other factors.

Summary of Contractual Obligations

A summary of our obligations to make future payments under contracts existing at December 31, 2008 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, 2008. As of March 31, 2009, there were no significant changes to this information.

Critical Accounting Policies and Estimates

This Management's Discussion and Analysis of Financial Condition and Results of Operations discusses our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires that we make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. On an on-going basis, we evaluate our judgments and estimates, including those related to bad debts, inventories, investments, intangible assets, income taxes and realization of the related deferred tax assets, revenue recognition, restructuring costs, contingencies and litigation. We base our judgments and estimates on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not 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 2008 Annual Report on Form 10-K filed with the SEC. During the first quarter of 2009, there have been 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.

A significant portion of our assets is comprised of certificates of deposit, U.S. government and agency obligations, and U.S. corporate bonds. All such instruments are classified as available-for-sale securities. The primary objective of our investment policy is to preserve principal while maximizing the related income without significantly increasing risk. Even so, some of the securities in which we invest may be subject to market risk. Market risk is the risk that a change in prevailing interest rates may cause the fair value of an investment to fluctuate. As interest rates increase, the fair value of a debt instrument would be expected to decrease. Correspondingly, if interest rates decrease the fair value of a debt instrument would be expected to increase. To minimize market risk, we have the ability to hold such debt instruments to maturity, at which time the debt instrument would be redeemed at its stated or face value. To further mitigate market risk, we also typically invest in the shorter end of the maturity spectrum. As such, we do not believe that we have a material exposure to market risk.

Our long-term debt bears interest at a fixed rate. As a result, we have no exposure to interest rate changes.

As of March 31, 2009, we did not have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. Our operations in Europe and Africa 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 quarter ended March 31, 2009. We do not expect the risk of foreign currency fluctuations to be material 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, 2009. 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, 2009 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, 2009 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

On April 22, 2008, a complaint was filed against us in the United States District Court for the District of New Jersey by Inverness Medical Innovations, Inc., Inverness Medical Switzerland GmbH and Church & Dwight Co., Inc., alleging that we infringed U.S. Patent No. 6,485,982. The complaint specifically refers to our OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test. The complaint seeks injunctive relief, damages and an award of attorneys' fees. We have filed our Answer responding to the allegations in the Complaint and asserting various defenses and counterclaims.

On October 10, 2008, the plaintiffs filed a motion for summary judgment of infringement in this case, pursuant to a schedule previously established by the Court. On May 1, 2009, the Court issued an order denying the plaintiff's motion without prejudice, and granting the plaintiffs leave to reinstate the motion following completion of the Court's Markman hearing. The Markman process is the part of this patent infringement lawsuit where the Court determines the construction of various claim terms in the patent being asserted. A Markham hearing in this case has been scheduled for August 12, 2009.

We continue to believe that none of our products, including the OraQuick *ADVANCE*® HIV test, infringes the patent asserted in this lawsuit or any other party's intellectual property rights. We also believe that the patent asserted in this matter is invalid or unenforceable, and we intend to defend this lawsuit vigorously. We are unable at this time to determine the impact, if any, that this lawsuit may have on our business, prospects or results of operations.

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, 2008.

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

Pursuant to our 2000 Stock Award Plan and in connection with the vesting of restricted shares, we retired 108,619 shares to satisfy minimum tax withholding obligations.

In addition, 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. The following is a summary of share repurchase activity during the three months ended March 31, 2009.

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as part of a publicly Announced Plan or Program [1]	Maximum Dollar Value of Shares that may yet be Purchased Under the Plan or Program [2]
January 1, 2009 - January 31, 2009	73,457	$ 2.90	41,728	$19,754,562
February 1, 2009 - February 28, 2009	141,031	2.86	66,565	19,570,287
March 1, 2009 - March 31, 2009	2,424	2.56	—	19,570,287
Total	216,912	$ 2.87	108,293	

1 These shares were purchased under our $25.0 million stock repurchase program, which was approved by the Board of Directors on August 5, 2008.

2 Under our stock repurchase program, we are authorized to spend up to an aggregate of $25.0 million for stock repurchases. This column represents the amount that remains available under the $25.0 million stock repurchase program, as of the end of the period indicated. We have made no commitment to purchase any shares, and purchases 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: May 7, 2009

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

Date: May 7, 2009

/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.

Exhibit 31.1

Certification

I, Douglas A. Michels, certify that:

1. I have reviewed this report on Form 10-Q of OraSure Technologies, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within the entity, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors:

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2009

/s/ Douglas A. Michels
Douglas A. Michels
President and Chief Executive Officer
(*Principal Executive Officer*)

Exhibit 31.2

Certification

I, Ronald H. Spair, certify that:

1. I have reviewed this report on Form 10-Q of OraSure Technologies, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within the entity, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors:

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2009

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

Exhibit 32.1

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

In connection with the Quarterly Report of OraSure Technologies, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2009 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Douglas A. Michels, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Douglas A. Michels
Douglas A. Michels
President and Chief Executive Officer

May 7, 2009

Exhibit 32.2

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

In connection with the Quarterly Report of OraSure Technologies, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2009 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ronald H. Spair, Chief Operating Officer and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Ronald H. Spair
Ronald H. Spair
Chief Operating Officer and
Chief Financial Officer

May 7, 2009