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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 June 30, 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 Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☐

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

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

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

Number of shares of Common Stock, par value $.000001 per share, outstanding as of August 5, 2009: 45,876,186

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Item 1. FINANCIAL STATEMENTS

ORASURE TECHNOLOGIES, INC.
BALANCE SHEETS
(Unaudited)

	JUNE 30, 2009	DECEMBER 31, 2008
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 63,019,261	$ 39,565,218
Short-term investments	16,143,003	42,957,467
Accounts receivable, net of allowance for doubtful account of $334,038 and $163,100	11,071,032	11,571,048
Inventories	8,662,672	10,704,088
Prepaid expenses and other	1,272,738	1,418,171
Total current assets	100,168,706	106,215,992
PROPERTY AND EQUIPMENT, net	20,774,959	21,235,367
PATENTS AND PRODUCT RIGHTS, net	956,252	4,380,540
OTHER ASSETS	79,816	86,290
	$ 121,979,733	$ 131,918,189
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	$ 538,854	$ 557,897
Accounts payable	2,086,258	3,925,662
Accrued expenses and other	8,223,191	10,795,955
Total current liabilities	10,848,303	15,279,514
LONG-TERM DEBT	8,041,679	8,301,440
OTHER LIABILITIES	5,008	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, 45,876,186 and 45,769,221 shares issued and outstanding	46	46
Additional paid-in capital	237,352,061	235,862,999
Accumulated other comprehensive loss	(214,358)	(262,442)
Accumulated deficit	(134,053,006)	(127,275,353)
Total stockholders' equity	103,084,743	108,325,250
	$ 121,979,733	$ 131,918,189

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.
STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
REVENUES:				
Product	$16,748,235	$18,141,842	$33,669,437	$35,777,453
Licensing and product development	525,326	804,356	860,575	1,257,564
	17,273,561	18,946,198	34,530,012	37,035,017
COST OF PRODUCTS SOLD	7,393,657	7,802,893	13,678,036	15,248,744
Gross profit	9,879,904	11,143,305	20,851,976	21,786,273
OPERATING EXPENSES:				
Research and development	2,432,640	6,099,501	5,785,138	10,697,132
Sales and marketing	5,289,032	4,961,853	10,311,797	10,177,842
General and administrative	4,434,679	3,889,960	8,891,730	7,730,741
Impairment of patent and product rights	3,028,375	—	3,028,375	—
	15,184,726	14,951,314	28,017,040	28,605,715
Operating loss	(5,304,822)	(3,808,009)	(7,165,064)	(6,819,442)
INTEREST EXPENSE	(90,285)	(72,074)	(179,949)	(155,200)
INTEREST INCOME	236,624	822,639	574,504	1,840,444
OTHER INCOME	—	—	—	4,883,714
FOREIGN CURRENCY LOSS	(1,209)	(6,344)	(7,144)	(79,344)
Loss before income taxes	(5,159,692)	(3,063,788)	(6,777,653)	(329,828)
INCOME TAX BENEFIT	—	(820,494)	—	(88,271)
NET LOSS	$ (5,159,692)	$ (2,243,294)	$ (6,777,653)	$ (241,557)
LOSS PER SHARE:				
BASIC AND DILUTED	$ (0.11)	$ (0.05)	$ (0.15)	$ (0.01)
SHARES USED IN COMPUTING LOSS PER SHARE				
BASIC AND DILUTED	45,870,720	46,847,027	45,854,255	46,815,277

The accompanying notes are an integral part of these statements.

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

	Six Months Ended June 30,	
	2009	2008
OPERATING ACTIVITIES:		
Net loss	$ (6,777,653)	$ (241,557)
Adjustments to reconcile net loss to net cash used in operating activities:		
Impairment of patent and product rights	3,028,375	—
Stock-based compensation	2,093,697	2,838,190
Deferred income taxes	—	(81,723)
Depreciation and amortization	1,672,784	1,386,854
Reserve for excess and obsolete inventories	(220,971)	(263,972)
Changes in assets and liabilities:		
Accounts receivable	507,273	(1,485,580)
Inventories	2,262,387	(611,992)
Prepaid expenses and other assets	151,907	753,110
Accounts payable	(1,786,392)	(1,340,127)
Accrued expenses and other liabilities	(2,572,764)	(2,867,795)
Net cash used in operating activities	(1,641,357)	(1,914,592)
INVESTING ACTIVITIES:		
Purchase of short-term investments	(5,986,000)	(59,396,670)
Proceeds from maturities and redemptions of short-term investments	32,713,000	51,829,880
Purchase of property and equipment	(741,184)	(1,314,472)
Payments of patents and licenses	—	(200,000)
Net cash provided by (used in) investing activities	25,985,816	(9,081,262)
FINANCING ACTIVITIES:		
Repayments of long-term debt	(278,804)	(236,566)
Proceeds from issuance of common stock	17,898	92,517
Withholding and retirement of common stock	(320,905)	(849,311)
Purchase and retirement of common stock	(308,605)	—
Net cash used in financing activities	(890,416)	(993,360)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	23,454,043	(11,989,214)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	39,565,218	32,229,697
CASH AND CASH EQUIVALENTS, END OF PERIOD	$63,019,261	$ 20,240,483
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for:		
Interest	$ 182,840	$ 221,539
Income taxes	$ 32,500	$ 386,284

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 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, Central and South America, 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 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 our Annual Report on Form 10-K for the fiscal year ended December 31, 2008. Results of operations for the three months and six months ended June 30, 2009 are not necessarily indicative of the results of operations expected for the full year. We have evaluated all subsequent events through the date that we filed our financial statements with the SEC on August 6, 2009.

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

Cash and Cash Equivalents. We consider all highly liquid investments with a purchased maturity of ninety days or less to be cash equivalents. As of June 30, 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 June 30, 2009 and December 31, 2008:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
June 30, 2009				
Certificates of deposit	$ 9,684,000	$ —	$ —	$ 9,684,000
Government and agency bonds	3,259,033	7,480	—	3,266,513
Corporate bonds	3,181,562	10,953	(25)	3,192,490
Total available-for-sale securities	$16,124,595	$ 18,433	$ (25)	$16,143,003
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 June 30, 2009, maturities of our available-for-sale securities were as follows:				
Less than one year	$14,129,595	$ 18,433	$ (25)	$14,148,003
One to two years	1,995,000	—	—	1,995,000
Total available-for-sale securities	$16,124,595	$ 18,433	$ (25)	$16,143,003

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:

	June 30, 2009	December 31, 2008
Raw materials	$5,345,943	$ 6,721,102
Work in process	391,612	390,259
Finished goods	2,925,117	3,592,727
	$8,662,672	$10,704,088

Impairment of Long-Lived Assets In accordance with SFAS No. 144, "Accounting for the Impairment or Disposal 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 asset. 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 asset.

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 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 three months and six months ended June 30, 2009. During the three months and six months ended June 30, 2008, sales to Abbott accounted for 9 percent and 10 percent of our total revenues, respectively.

The Company had the following significant concentrations in accounts receivable:

	Percentage of Accounts Receivable	
	June 30, 2009	December 31, 2008
Quest Diagnostics, Incorporated	11%	8%
SSL International plc	6	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.

Loss Per Share. We have presented basic and diluted loss per share pursuant to SFAS No. 128, “Earnings per Share.” In accordance with SFAS No. 128, basic 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 computed in a manner similar to basic loss per share except that the weighted average number of shares outstanding is increased to include incremental shares from the assumed vesting or exercise of dilutive securities, such as common stock options, warrants and unvested restricted stock. The number of incremental shares is calculated by assuming that outstanding stock options and warrants were exercised and unvested restricted 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.

For the three month periods ended June 30, 2009 and 2008, outstanding common stock options and unvested restricted stock, representing 6,079,154 and 5,552,330 shares, respectively, were excluded from the computation of diluted earnings per share, as their inclusion would have been anti-dilutive. For the six month periods ended June 30, 2009 and 2008, outstanding common stock options and unvested restricted stock, representing 6,122,032 and 4,866,588 shares, respectively, were excluded from the computation of diluted earnings per share, as their inclusion would have been anti-dilutive.

Other Comprehensive 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 loss at June 30, 2009 and December 31, 2008 consisted of currency translation adjustments and net unrealized gains or losses on short term investments. Comprehensive loss was $5,155,437 and $2,390,293 for the three months ended June 30, 2009 and 2008, respectively, and $6,729,569 and $303,169 for the six months ended June 30, 2009 and 2008, respectively.

Recent Accounting Pronouncements. In May 2009, the Financial Accounting Standards Board ("FASB") released SFAS No. 165, "Subsequent Events," which establishes the accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. It requires the disclosure of the date through which an entity has evaluated subsequent events and the basis for that date, that is, whether that date represents the date the financial statements were issued or were available to be issued. See "Basis of Presentation" for the related disclosures. The adoption of SFAS No. 165 did not have a material impact on our financial statements.

In April 2009, the FASB released FASB Staff Position (FSP) 107-1 and Accounting Principles Board ("APB") Opinion No. 28-1, "Interim Disclosures about Fair Value of Financial Instruments." This pronouncement amends FASB Statement No. 107, "Disclosures about Fair Values of Financial Instruments," to require disclosures about fair value of financial instruments in interim financial statements as well as in annual financial statements and is effective for interim reporting periods ending after June 15, 2009. FSP SFAS 107-1 and APB 28-1 also amends APB Opinion No. 28, "Interim Financial Reporting," to require those disclosures in summarized financial information at interim financial statements. The adoption of these pronouncements did not have a material impact on our financial statements.

3. Impairment of 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. The agreement required us to pay the third parties a one-time non-refundable license fee of $1,500,000, which was paid in August 2005. In December 2006, the first milestone was achieved and $3,000,000 was paid in 2007.

Our intent in executing the HCV license agreement was to provide for various alternative uses of the licensed patents, one of which was the marketing and sale of an existing rapid HCV test supplied by a third party manufacturer in certain developing countries. Based on our estimate of the cash flows to be received from future product sales in these international markets, we capitalized both of the $1,500,000 and $3,000,000 payments. We were amortizing these amounts to cost of products sold on a straight-line basis over ten years, which represented our estimate of the remaining useful life of the licensed patents.

We have been unable to penetrate the international marketplace with this third-party's rapid HCV test. In addition, given the impact of the current global recession and the deteriorating status of certain third-world economies, we no longer believe that we will be successful in selling a third-party's rapid HCV test in the foreseeable future. As a result, during the second quarter of 2009, we recorded an impairment charge of $3,028,375 which represented the remaining net book value of the HCV license, patents and product rights.

4. Stock-Based Compensation

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

The fair value of each stock option is estimated on the date of the grant using the Black-Scholes option-pricing model. The weighted average grant date fair value of stock options granted during the three months ended June 30, 2009 and 2008 was $1.55 and $2.72 per share, respectively. The weighted average grant date fair value of stock options granted during the six months ended June 30, 2009 and 2008 was $1.19 and $3.13 per share, respectively.

Total compensation cost related to stock options for the three months ended June 30, 2009 and 2008 was $295,144 and $553,417 ($369,832, net of tax), respectively, of which $5,388 and $39,607 was capitalized into inventory during the quarters ended June 30, 2009 and 2008, respectively. The amounts recognized in cost of products sold for amounts previously capitalized were $27,171 and $63,510 for the three months ended June 30, 2009 and 2008, respectively. Total compensation cost related to stock options for the six months ended June 30, 2009 and 2008 was $697,805 and $1,097,830 ($731,878, net of tax), respectively, of which $37,407 and $128,282 was capitalized into inventory during the six month periods ended June 30, 2009 and 2008, respectively. The amounts recognized in cost of products sold for amounts previously capitalized were $94,002 and $120,182 for the six months periods ended June 30, 2009 and 2008, respectively.

The following table summarizes the stock option activity for the six months ended June 30, 2009:

	Options
Outstanding on January 1, 2009	5,130,707
Granted	586,708
Exercised	(22,302)
Forfeited	(93,925)
Outstanding on June 30, 2009	5,601,188

As of June 30, 2009, there was $2,261,089 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 $17,898 and $92,517 for the six months ended June 30, 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 six months ended June 30, 2009, we granted 429,870 restricted shares of our common stock, with a weighted average grant date fair value of $2.82 per share, to certain key officers, members of management and outside directors. Compensation cost of $661,448 and $899,106 related to restricted shares was recognized during the three months ended June 30, 2009 and 2008, respectively. Compensation cost of $1,395,892 and $1,740,360 related to restricted shares was recognized during the six months ended June 30, 2009 and 2008, respectively.

The following table summarizes restricted stock award activity for the six months ended June 30, 2009:

	Shares
Issued and unvested, January 1, 2009	831,488
Granted	429,870
Vested	(303,999)
Forfeited	(46,440)
Issued and unvested, June 30, 2009	910,919

As of June 30, 2009, there was $3,877,747 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 six months ended June 30, 2009 and 2008, 111,043 and 104,552 shares, respectively, with aggregate values of $320,905 and $849,311, respectively, were withheld and retired in satisfaction of minimum tax withholding obligations.

5. Share Repurchase Program

On August 5, 2008, our Board of Directors approved a share repurchase program pursuant to which we are permitted to acquire up to $25 million of our outstanding common shares. During the six months ended June 30, 2009, we purchased and retired 108,293 shares of our common stock at an average price of $2.85 per share. Accordingly, we recorded a $308,605 reduction to additional paid-in capital during the six month period ended June 30, 2009.

6. Accrued Expenses

	June 30, 2009	December 31, 2008
Payroll and related benefits	$2,604,791	$ 3,513,124
Royalties	2,598,587	2,481,466
Deferred revenue	1,355,521	1,951,921
Professional fees	617,866	472,969
Clinical research obligations	3,773	348,459
Advertising	—	365,313
Other	1,042,653	1,662,703
	$8,223,191	$10,795,955

Deferred revenue at June 30, 2009 and December 31, 2008 included customer prepayments of $1,249,721 and $1,824,721, respectively.

7. 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.

8. 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 June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
United States	$13,848	$15,692	$28,686	$29,833
Europe	1,872	1,915	3,372	4,353
Other regions	1,554	1,339	2,472	2,849
	$17,274	$18,946	$34,530	$37,035

9. 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.

10. 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 a 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 rescheduled for October 5, 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 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 credit crisis; 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 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 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 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. *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.

We rely heavily on distributors to purchase and resell many of our products. For example, SSL International plc ("SSL") has exclusive rights to our wart removal product in the OTC footcare market in Europe, Australia and New Zealand and Genomma Labs ("Genomma") 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.

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 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 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.

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.

Current Financial Results

During the six months ended June 30, 2009, our total revenues were $34.5 million, which represents a 7% decline from the same period in 2008. Our net loss for the six months ended June 30, 2009 was $6.8 million or $0.15 per share compared to a net loss of $242,000 or $0.01 per share for the six months ended June 30, 2008. Our net loss for the first six months of 2009 includes a $3.0

million pre-tax charge for the impairment of patents and product rights and our net loss for the first six months of 2008 includes a $4.9 million payment received from Schering-Plough Healthcare Products, Inc. (“Schering-Plough”) to resolve a patent infringement lawsuit, which was recorded as other income.

Cash flows used in operating activities for the six months ended June 30, 2009 was $1.6 million, compared to $1.9 million for the six months ended June 30, 2008. As of June 30, 2009, we had $79.2 million in cash, cash equivalents and short-term investments, compared to $82.5 million at December 31, 2008.

Recent Developments

OraQuick® HCV Test

During the fourth quarter of 2008, we filed a premarket approval application (“PMA”) with the U.S. Food and Drug Administration (“FDA”) for our OraQuick® Hepatitis C (“HCV”) test for use in the professional market. The application sought approval for use of the product with multiple specimen types, including venous whole blood, fingerstick whole blood, oral fluid and other sample types. The clinical study data submitted in the PMA showed a high degree of correlation to a comparator assay conducted at a central laboratory.

Since filing the PMA, we have been in frequent communications with the FDA and have received a number of questions and requests for additional information from the agency. During its review of the PMA, the FDA indicated that our clinical data could potentially have been affected by bias because the same operators performed the test and interpreted the results on multiple specimen types derived from the same patient. The FDA had previously reviewed and concurred with our original clinical trial protocol, which had stated that the study would not be blinded to prevent an operator from seeing the results of multiple devices used on the same patient, but would be blinded as to central laboratory results using the FDA-approved comparator assay.

However, late in the second quarter of 2009 the FDA concluded that additional clinical testing will be required to obtain approval of the PMA for a venous whole blood claim, and that a new clinical study will be required for approval of claims for oral fluid and other sample types. Although we believe the clinical data originally submitted to the FDA is sufficient to support approval of our PMA, we have agreed to conduct the additional clinical testing and study mandated by the FDA in order to obtain approved claims for oral fluid, venous whole blood, and fingerstick whole blood. The exact timing and costs associated with this work will not be fully determined until after the clinical protocols are reviewed by the FDA, which should occur in the near future.

OraQuick® HIV OTC Test

In August 2008, we submitted the results of our observed use study to the FDA as part of our efforts to obtain approval for an OraQuick® rapid HIV OTC test. The observed use study was designed to assess an individual’s ability to interact with the product packaging, comprehend the instructions for use, take the test and interpret the results while a trained professional observed those activities. The observed use study was stopped after testing was completed for the first 1,000 subjects, because data from the study met the success criteria initially established in the study protocol for this phase of the trials.

The FDA recently reviewed the data from the observed use study at a meeting of its senior management. Following this meeting, the FDA contacted us and indicated that both the results of the observed use study and our remaining clinical activities should also be reviewed and approved by the Blood Products Advisory Committee (“BPAC”), an advisory committee to the FDA, before proceeding.

We are discussing plans for the upcoming BPAC meeting with the FDA and intend to gain alignment with the agency on the next steps required to complete and file a PMA application, before presenting a proposal at the BPAC’s meeting scheduled for November 2009.

OraQuick® HIV Manufacturing

During the quarter ended June 30, 2009, we began experiencing difficulty manufacturing a component for our OraQuick® rapid HIV-1/2 antibody test that met our internal quality requirements. A multi-functional team was immediately organized and began working aggressively with the assistance of outside consultants to resolve this manufacturing issue. While this issue initially resulted in lower production yields, we were still able to meet existing customer demand by supplementing production levels with existing finished goods inventories. As the quarter progressed, however, this manufacturing issue remained unresolved. As a result, inventory levels depleted rapidly and we began allocating available product across our customer base. We also provided some customers with free OraSure® oral fluid collection devices in order to help them meet their HIV testing needs.

Our revenues for the second quarter of 2009 were negatively impacted by this manufacturing issue which was largely responsible for the 16% decrease in OraQuick® sales to the U.S. public health market during this period. In addition, gross margin for the second quarter was negatively impacted by the decline in revenues and an increase in product support costs. Gross margin for the second quarter ended June 30, 2009 declined to 57% compared to 64% during the first quarter ended March 31, 2009.

Early in the third quarter, we identified the root cause for the manufacturing issue and implemented corrective action. As a result, we have resumed full scale production of the OraQuick® HIV product. We expect to eliminate the backlog in product orders resulting from the reduced production and return to normal inventory levels over the next several months.

Results of Operations

Three months ended June 30, 2009 compared to June 30, 2008

Total revenues decreased 9% to $17.3 million in the second quarter of 2009 from $18.9 million in the comparable quarter in 2008. Increased sales of our OTC cryosurgical products were more than offset by decreased sales of our OraQuick *ADVANCE*® rapid HIV-1/2 antibody test, our professional cryosurgical products and our substance abuse testing products. We also experienced a decrease in revenue from sales into the insurance risk assessment market, as well as a decrease in licensing and product development revenues. Revenues derived from products sold to customers outside the U.S. were $3.4 million and $3.3 million, or 20% and 17% of total revenues, in the second quarters of 2009 and 2008, respectively. Because the majority of our international sales are denominated 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 June 30,				
	Dollars			Percentage of Total Revenues	
Market	2009	2008	% Change	2009	2008
Infectious disease testing	$ 9,417	$10,033	(6)%	54%	53%
Substance abuse testing	2,932	3,697	(21)	17	20
Cryosurgical systems	2,901	2,719	7	17	14
Insurance risk assessment	1,499	1,693	(11)	9	9
Product revenues	16,749	18,142	(8)	97	96
Licensing and product development	525	804	(35)	3	4
Total revenues	$17,274	$18,946	(9)%	100%	100%

Infectious Disease Testing Market

Sales to the infectious disease testing market decreased 6% to $9.4 million in the second quarter of 2009. OraQuick® sales totaled $8.8 million and $9.3 million in the second quarters of 2009 and 2008, respectively. Sales of our OraSure® oral fluid collection device totaled $630,000 and $735,000 in the second quarters of 2009 and 2008, respectively.

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

	Three Months Ended June 30,		
Customers	2009	2008	% Change
Direct to U.S. Public Health	$5,790	$6,899	(16)%
Hospital Market	2,501	1,698	47
International	496	701	(29)
Total OraQuick® revenues	$8,787	$9,298	(5)%

During the second quarter of 2009, OraQuick® revenue derived from direct sales to the U.S. public health market decreased by 16% as compared to 2008. This decrease is directly related to inventory shortages we experienced in the current quarter as a result of an issue related to manufacturing a component required for our OraQuick® Rapid HIV-1/2 antibody test. As the quarter progressed, the manufacturing issue remained unresolved, inventory levels were depleted rapidly and we began allocating available product across our customer base. We also provided some customers with free OraSure® oral fluid collection devices during the quarter in order to help them meet their HIV testing needs. As a result of this issue, as of June 30, 2009 we had a $1.8 million backlog of orders for our OraQuick ADVANCE® test from our public health customers.

Sales into the hospital market increased 47% to $2.5 million during the second quarter of 2009 as compared to $1.7 million in 2008. On January 1, 2009, we switched to a direct sales model for the U.S. hospital market 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 during the current period is due to higher average selling prices realized under our direct sales model. As a result of the OraQuick® manufacturing issue described above, as of June 30, 2009 we had a $400,000 backlog of orders from our hospital customers for our OraQuick *ADVANCE*® Rapid HIV-1/2 antibody test.

Early in the third quarter, we identified the root cause for the manufacturing issue and implemented corrective action. As a result, we have resumed full scale production of the OraQuick® HIV product. We expect to eliminate the backlog in product orders resulting from the reduced production and return to normal inventory levels over the next several months.

International sales of our OraQuick® test decreased to $496,000 for the three months ended June 30, 2009 from $701,000 for the three months ended June 30, 2008. This 29% decline reflects decreased sales into Africa, primarily due to the timing of certain testing initiatives and placement of the related OraQuick® product orders. We expect sales in Africa to improve from current levels during the remaining six months of 2009.

We continue to believe 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. Our sales of OraSure® decreased from $735,000 in the second quarter of 2008 to $630,000 in the second 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 this ongoing change in purchasing patterns, we expect OraSure® sales will continue to decline in the future.

Substance Abuse Testing Market

Substance abuse testing revenues decreased 21% to $2.9 million in the second quarter of 2009 from $3.7 million in the second quarter of 2008, as sales of our Intercept® product for workplace testing were impacted by the continuing adverse economic conditions and high unemployment rates.

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

	Three Months Ended June 30,		
Market	2009	2008	% Change
Workplace testing	$ 946	$1,272	(26)%
Criminal justice	630	708	(11)
International	523	564	(7)
Direct	195	330	(41)
Total Intercept® revenues	$2,294	$2,874	(20)%

Our workplace testing business decreased 26% from $1.3 million in the second quarter of 2008 to $946,000 in the second quarter of 2009. Pre-employment drug screening represents over 50% of our workplace testing business and the current decline in the domestic economy and high unemployment levels have had a significant impact on this part of our business, as well as our direct sales results. We are also seeing a negative impact in our criminal justice market as a result of funding reductions at the state and local levels.

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) increased 7% to $2.9 million in the second quarter of 2009, compared to $2.7 million in the same period of the prior year.

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

Market	Three Months Ended June 30, 2009	2008	% Change
Professional domestic	$ 807	$1,004	(20)%
Professional international	636	665	(4)
OTC domestic	122	—	100
OTC international	1,336	1,050	27
Total cryosurgical systems revenues	$2,901	$2,719	7%

The overall increase in cryosurgical systems revenues was primarily the result of a 27% increase in sales of our international OTC products. Increased sales to our Latin American OTC distributor, Genomma, were partially offset by a decrease in sales to our European OTC distributor, SSL, during the current three-month period.

Genomma distributes our cryosurgical wart removal product in the OTC markets in Mexico, Argentina, Brazil, and various other Central and South American countries. During the second quarter of 2008, Genomma did not purchase any product from us, as they were working through a higher-than-expected level of returns from their retail customers experienced during the first quarter of 2008. Throughout the remainder of 2008 and the first quarter of 2009, Genomma worked to reduce its excess inventory position and did not purchase additional product. Genomma has worked through its excess inventory and purchased $596,000 of product during the second quarter of 2009. In addition, Genomma recently registered our OTC cryosurgical wart removal product in Brazil, which we believe will support continuing sales to Genomma during the remaining half of this year.

SSL distributes 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 $740,000 and $1.1 million in the second quarters of 2009 and 2008, respectively. The decrease in SSL revenues during the second quarter of 2009 resulted from a reduction in our per unit selling price to SSL and a volume decrease in SSL outsales due to increased competition from lower-priced products in the highly competitive European marketplace.

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™. Commencing in February 2009, we shipped product to one major retailer and we plan to expand distribution to other retailers in the future. During the three months ended June 30, 2009, we recorded $122,000 in revenues from Freeze 'n Clear Skin Clinic™, net of $314,000 in returns, rebates, advertising and slotting allowances provided to the retail trade. 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 20% to $807,000 in the second quarter of 2009, as compared to $1.0 million in 2008 largely due to differences in distributor ordering patterns and the residual impact of the international product diversion issues described below. Sales of Histofreezer® in the international market remained flat at $636,000 in the second quarter of 2009, as compared to $665,000 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 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 addressed this diversion issue, we believe it negatively impacted sales in the domestic physicians' office market during the second quarter of 2009 and it may continue to do so until the supply of diverted product is exhausted.

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 decreased 11% to $1.5 million in 2009 from $1.7 million in the second quarter of 2008, primarily due to laboratory ordering patterns and the issuance of fewer life insurance policies as a result of the impact of current economic conditions on the underwriting industry.

Licensing and Product Development

During the second quarter of 2009, licensing and product development revenues decreased to $525,000 from $804,000 during 2008. Licensing revenue represents royalties received on outsales of Schering-Plough's OTC cryosurgical wart removal product, pursuant to our license and settlement agreement executed in January 2008.

Gross Margin

Gross margin in the second quarter of 2009 was 57%, compared to 59% for the second quarter of 2008. Gross margin was favorably impacted in the current quarter by our switch in January 2009 to a direct sales model for our OraQuick *ADVANCE*® HIV-1/2 test in the U.S. hospital market. This favorable impact, however, was more than offset by the impact of a less favorable revenue mix and increased product support costs during the current quarter, as we worked to resolve the manufacturing issue related to our OraQuick® HIV-1/2 test. We believe the resolution of our manufacturing challenge and return to full-scale production will positively impact our gross margin in future periods.

Operating Expenses

Research and development expenses decreased 60% from $6.1 million in the second quarter of 2008 to $2.4 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 the initial product development and clinical costs associated with our OraQuick® HCV device PMA submission occurred during 2008. A decrease in staffing costs resulting from organizational changes made during the fourth quarter of 2008 also contributed to the current period decrease. We expect clinical trial expenses will increase during the remaining six months of 2009, as we begin to conduct the additional clinical testing and studies recently mandated by the FDA in order to obtain approved claims for use of our OraQuick® HCV test with oral fluid, venous whole blood, and fingerstick whole blood specimen types.

Sales and marketing expenses increased 7% to $5.3 million in the second quarter of 2009 from $5.0 million in the same period in 2008. This overall increase was the result of an expected increase in staffing costs associated with implementing the direct sales model for the U.S. hospital market; hiring, compensation, and relocation costs associated with new senior-level marketing personnel; and increased marketing research and consulting costs related to our domestic and international OTC cryosurgical products. During the third quarter of 2009, sales and marketing expenses are expected to increase as a result of certain customer retention incentives offered in response to our OraQuick® manufacturing issue and expenses associated with hiring additional marketing personnel.

General and administrative expenses increased 14% to $4.4 million in the second quarter of 2009 from $3.9 million in the same period in 2008. This increase was primarily attributed to an increase in legal costs associated with the patent infringement lawsuit filed against us by Inverness Medical and Church & Dwight described in Item 1 of Part II of this Quarterly Report.

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

Interest Income/Expense

Interest expense increased to $90,000 in the second quarter of 2009 from $72,000 in the second quarter of 2008. Interest income decreased to $237,000 in the second quarter of 2009 from $823,000 in the second quarter of 2008, 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

During the fourth quarter of 2008, 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 second quarter of 2009. During the three months ended June 30, 2008, we recorded a federal and state income tax benefit of $820,000.

Six months ended June 30, 2009 compared to June 30, 2008

Total revenues decreased 7% to $34.5 million for the first six months of 2009 from $37.0 million in the comparable period in 2008. Higher revenues derived from the direct sale of our OraQuick *ADVANCE*® rapid HIV-1/2 antibody test into the hospital market were more than offset by decreased sales of OraQuick® into the international and U.S. public health markets and decreased sales of our cryosurgical and substance abuse testing products. We also experienced a decrease in revenue from sales into the insurance risk assessment market as well as a decrease in licensing and product development revenues. Revenues derived from products sold to customers outside the U.S. were $5.8 million and $7.2 million, or 17% and 19% of total revenues, during the first six months of 2009 and 2008, respectively. Because the majority of our international sales are denominated 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.

	Six Months Ended June 30,				
	Dollars			Percentage of Total Revenues	
Market	2009	2008	% Change	2009	2008
Infectious disease testing	$19,867	$19,512	2%	58%	53%
Substance abuse testing	5,622	6,974	(19)	16	19
Cryosurgical systems	5,046	6,055	(17)	15	16
Insurance risk assessment	3,134	3,236	(3)	9	9
Product revenues	33,669	35,777	(6)	98	97
Licensing and product development	861	1,258	(32)	2	3
Total revenues	$34,530	$37,035	(7)%	100%	100%

Infectious Disease Testing Market

Sales to the infectious disease testing market increased 2% to $19.9 million in the first six months of 2009, primarily as a result of the switch to a direct sales model for our OraQuick *ADVANCE*® rapid HIV 1/2 test into the U.S. hospital market. OraQuick® sales totaled $18.5 million and $18.2 million in the first six months of 2009 and 2008, respectively. Sales of our OraSure® oral fluid collection device totaled $1.3 million and $1.4 million in the first six months of 2009 and 2008, respectively.

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

	Six Months Ended June 30,		
Customers	2009	2008	% Change
Direct to U.S. Public Health	$12,346	$13,183	(6)%
Hospital Market	5,245	3,622	45
International	953	1,347	(29)
Total OraQuick® revenues	$18,544	$18,152	2%

During the first half of 2009, OraQuick® revenue derived from direct sales to the U.S. public health market decreased 6% as compared to 2008, primarily due to inventory shortages experienced during the second quarter of 2009 as a result of an issue related to manufacturing a component required for our OraQuick® Rapid HIV-1/2 antibody test. As the second quarter progressed, the manufacturing issue remained unresolved, inventory levels were depleted rapidly and we began allocating available product across our customer base. We also provided some customers with free OraSure® oral fluid collection devices during the second quarter in order to help them meet their HIV testing needs. As a result of this issue, as of June 30, 2009 we had a $1.8 million backlog of orders for our OraQuick *ADVANCE* ® test from our public health customers.

Sales into the hospital market increased 45% to $5.2 million during the first six months of 2009 as compared to $3.6 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. As a result of the OraQuick® manufacturing issue described above, as of June 30, 2009 we had a $400,000 backlog of orders from our hospital customers for our OraQuick *ADVANCE*® Rapid HIV-1/2 test.

Early in the third quarter, we identified the root cause for the manufacturing issue and implemented corrective action. As a result, we have resumed full scale production of the OraQuick® HIV product. We expect to eliminate the backlog in product orders resulting from the reduced production and return to normal inventory levels over the next several months.

International sales of our OraQuick® HIV-1/2 test decreased to $953,000 for the six months ended June 30, 2009 from $1.3 million for the six months ended June 30, 2008. This 29% decline reflects decreased sales into Africa, primarily due to the timing of certain testing initiatives and placement of the related OraQuick® product orders. Partially offsetting this decrease were increased sales into Asia, Latin America and Europe. We expect sales in Africa to improve from current levels during the remaining six months of 2009.

We continue to believe 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. Sales of OraSure® decreased slightly from $1.4 million for the first six months of 2008 to $1.3 million in the first six months 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 19% to $5.6 million in the first half of 2009 from $7.0 million in the first half of 2008, as sales of our Intercept® product for workplace testing were impacted by the continuing adverse economic conditions and high unemployment rates.

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

	Six Months Ended June 30,		
Market	2009	2008	% Change
Workplace testing	$1,803	$2,287	(21)%
Criminal justice	1,182	1,327	(11)
International	1,045	1,089	(4)
Direct	363	601	(40)
Total Intercept® revenues	$4,393	$5,304	(17)%

Our workplace testing business decreased 21% from $2.3 million in the first half of 2008 to $1.8 million in the first half of 2009. Pre-employment drug screening represents over 50% of our workplace testing business and the current decline in the domestic economy and high unemployment levels have had a significant impact on this part of our business, as well as our direct sales results. We are also seeing a negative impact in our criminal justice market, as a result of funding reductions at the state and local levels.

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 17% to $5.0 million in the first six months of 2009, compared to $6.1 million in the same period of the prior year.

The table below shows a breakdown of our total cryosurgical systems revenues (in thousands, except %) generated in each market in the first six months of 2009 and 2008.

Market	Six Months Ended June 30, 2009	2008	% Change
Professional domestic	$1,749	$2,037	(14)%
Professional international	1,265	1,404	(10)
OTC domestic	179	—	100
OTC international	1,853	2,614	(29)
Total cryosurgical systems revenues	$5,046	$6,055	(17)%

The overall decrease in cryosurgical systems revenues was primarily the result of a 43% decrease in sales to our European OTC distributor, SSL. 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 $1.3 million and $2.2 million in the first six months of 2009 and 2008, respectively. The decrease in revenues from SSL during the first half of 2009 resulted from lower per unit selling prices to SSL and a volume decrease in SSL outsales due to increased competition from lower priced products in the highly competitive European marketplace.

Our Latin American distributor, Genomma, distributes our cryosurgical wart removal product in the OTC markets in Mexico, Argentina, Brazil, and various other Central and South American countries. Sales to Genomma for the six months ended June 30, 2009 were $596,000, compared to $401,000 during the six months ended June 30, 2008. 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 the first quarter of 2009, Genomma worked to reduce its excess inventory position, and accordingly did not purchase additional product from us. Genomma has worked through its excess inventory levels and resumed purchasing product during the second quarter of 2009. In addition, Genomma recently registered our cryosurgical wart removal product in Brazil, which we believe will support continuing sales to Genomma during the remaining half of this year.

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™. Commencing in February 2009, we shipped product to one major retailer and we plan to expand distribution to other retailers in the future. During the six months ended June 30, 2009, we recorded $179,000 in revenues from Freeze 'n Clear Skin Clinic™, net of $346,000 in returns, rebates, advertising and slotting allowances provided to the retail trade. 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 14% to $1.7 million in the first six months of 2009, as compared to $2.0 million in 2008 largely due to differences in distributor ordering patterns and the residual impact of the international product diversion issues described below. Sales of Histofreezer® in the international market decreased 10% to $1.3 million in the first six months of 2009, as compared to $1.4 million 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 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 addressed this diversion issue, we believe it negatively impacted sales in the domestic physicians' office market during the six-month period ended June 30, 2009 and may continue to do so until the supply of diverted product is exhausted. 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 remained relatively flat at $3.1 million during the first half of 2009 compared to $3.2 million during the first half of 2008.

Licensing and Product Development

During the first six months of 2009, licensing and product development revenues decreased to $861,000 from $1.3 million during 2008. Licensing revenue represents royalties received on outsales of Schering-Plough's OTC cryosurgical wart removal product, pursuant to our license and settlement agreement executed in January 2008.

Gross Margin

Gross margin in the first six months of 2009 was 60%, compared to 59% for the first six months of 2008. Gross margin was favorably impacted during the first six months of 2009 by our switch in January 2009 to a direct sales model for our OraQuick *ADVANCE*® HIV-1/2 test in the U.S. hospital market. This favorable impact, however, was partially offset by the impact of a less favorable revenue mix and increased product support costs experienced during the first six months of 2009, as we worked to resolve the manufacturing issue related to our OraQuick® HIV-1/2 test. We believe the resolution of our manufacturing challenge and return to full-scale production will positively impact our gross margins in future periods.

Operating Expenses

Research and development expenses decreased 46% from $10.7 million in the first half of 2008 to $5.8 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 the initial product development and clinical costs associated with the OraQuick® HCV device PMA submission was 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 decrease. We expect clinical trial expenses will increase during the remaining six months of 2009, as we begin to conduct the additional clinical testing and studies recently mandated by the FDA in order to obtain approved claims for use of our OraQuick® HCV test with oral fluid, venous whole blood, and fingerstick whole blood specimen types.

Sales and marketing expenses increased 1% to $10.3 million in the first six months of 2009 from $10.2 million in the same period in 2008. This increase was the result of an expected increase in staffing costs associated with implementing the direct sales model for the U.S. hospital market; hiring, compensation, and relocation costs associated with new senior-level marketing personnel; and increased marketing research and consulting costs related to our OTC cryosurgical products offset by reduced spending across many other categories. During the third quarter of 2009, sales and marketing expenses are expected to increase as a result of certain customer retention incentives offered in response to our OraQuick® manufacturing issues and expenses associated with hiring additional marketing personnel.

General and administrative expenses increased 15% to $8.9 million in the first six months of 2009 from $7.7 million in the same period in 2008. This increase was primarily attributed to an increase in legal costs associated with the patent infringement lawsuit filed against us by Inverness Medical and Church & Dwight described in Item 1 of Part II of this Quarterly Report.

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

Other Income/Expense

Interest expense increased to $180,000 in the first half of 2009 from $155,000 in the first half of 2008. Interest income decreased to $575,000 in the first half of 2009 from $1.8 million in the first half of 2008, primarily as a result of lower yields earned on our investment portfolio, lower investment balances, 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, 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 in the first six months of 2009. During the six months ended June 30, 2008, we recorded a federal and state income income tax benefit of $88,000.

Liquidity and Capital Resources

	June 30, 2009	December 31, 2008
	(In thousands)	
Cash and cash equivalents	$63,019	$ 39,565
Short-term investments	16,143	42,957
Working capital	89,320	90,936

Our cash, cash equivalents and short-term investments decreased $3.4 million to $79.2 million at June 30, 2009, primarily as a result of the use of $1.6 million in cash to fund operations, $741,000 for property and equipment purchases, $321,000 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 $279,000 for debt repayments.

Net cash used in operating activities was $1.6 million in the first half of 2009, resulting from our net loss of $6.8 million offset by a non-cash charge of $3.0 million associated with the impairment of patent and product rights, depreciation and amortization of $1.7 million, non-cash stock-based compensation expense of $2.1 million, and a reduced provision for scrap and spoilage of $221,000. Also contributing to the use of cash during the current six months were decreases in accounts payable and accrued expenses of $1.8 and $2.6 million, respectively, largely due to payment of our 2008 year-end royalty obligations, a termination fee paid to Abbott, advertising, severance and other accruals, and the recognition of $596,000 of customer prepayments previously recorded as deferred revenue. Offsetting these uses of cash were decreases in inventory of $2.3 million, directly related to our OraQuick® manufacturing issues experienced in the second quarter of 2009, along with the utilization of a significant amount of cryosurgery raw material inventory in the same period and decreases in accounts receivable of $507,000 and prepaid expenses of $152,000.

Net cash provided by investing activities during the first half of 2009 was $26.0 million. Payments of $741,000 for purchases of property and equipment were offset by $26.7 million of net proceeds from maturities, redemptions and purchases of short-term investments.

During the remainder of the year ending December 31, 2009, we expect to invest an additional $1.2 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 $890,000 for the six months ended June 30, 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 $279,000 in loan principal repayments and $321,000 used for the withholding and retirement of common stock, partially offset by $18,000 in cash proceeds from the exercise of stock options.

At December 31, 2008, we had in place a $14,000,000 credit facility (the “Credit Facility”) with Comerica Bank (“Comerica”), which was 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 June 30, 2009, we had $8.5 million in outstanding borrowings under the facilities advance.

On June 29, 2009, our $4,000,000 working capital line of credit expired. We elected not to renew this working capital line of credit, given our Credit Facility matures in June 2011 and we had in excess of $79.0 million of cash, cash equivalents and short-term investments available as of June 30, 2009 to fund our ongoing operations and capital needs.

All borrowings under the Credit Facility are collateralized by a first priority security interest in all of our assets, including present and future accounts receivable, chattel paper, contracts and contract rights, equipment and accessories, general intangibles, investments, instruments, inventories, and a mortgage on our three facilities in Bethlehem, Pennsylvania. The Credit Facility contains certain covenants that set forth minimum requirements for our quick ratio, liquidity, and tangible net worth. We were in full compliance with all covenants at June 30, 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.

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 the end of 2010. 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, 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, 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 June 30, 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 six months 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 June 30, 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 six months ended June 30, 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 June 30, 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 June 30, 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 June 30, 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 a patent infringement lawsuit where the Court determines the construction of various claim terms in the patent being asserted. Due to a recent scheduling change, the Markham hearing in this case has been rescheduled for October 5, 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

On June 30, 2009, pursuant to our 2000 Stock Award Plan and in connection with the vesting of restricted shares, we retired 2,424 shares to satisfy minimum tax withholding obligations at an average price paid per share of $2.49.

On August 5, 2008, our Board of Directors approved a share repurchase program pursuant to which we are permitted to acquire up to $25.0 million of outstanding shares. We did not purchase any shares under this program during the three months ended June 30, 2009. As of June 30, 2009, we had remaining authority to purchase up to $19,570,287 of shares under this share repurchase program. We have no commitment to purchase any additional shares and purchases may be discontinued at any time.

Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

At our 2009 Annual Meeting of Stockholders ("Annual Meeting") held on May 12, 2009, the following individuals were elected by the votes indicated as Class III directors of the Company for terms expiring at the 2012 Annual Meeting of Stockholders:

Nominee	Votes For	Votes Withheld
Michael Celano	39,164,359	3,872,203
Douglas A. Michels	39,279,948	3,756,614
Charles W. Patrick	39,384,607	3,651,955

The terms of the following directors continued after the Annual Meeting: Jack Goldstein, Douglas G. Watson, Ronny B. Lancaster, Roger L. Pringle, and Ronald H. Spair.

At the Annual Meeting, stockholders also ratified the appointment of KPMG LLP as our independent registered public accounting firm for 2009. Voting results on this matter were as follows: 42,483,024 shares were voted for ratification; 409,893 shares were voted against ratification; and 143,645 shares abstained. There were no broker non-votes.

Lastly, stockholders considered a stockholder proposal to modify the Company's Management Incentive Plan pursuant to which annual incentive cash bonuses may be paid to senior management. Results of the vote were as follows: 2,727,503 shares were voted for modification of the Management Incentive Plan; 28,143,954 shares were voted against modification; and 50,069 shares abstained. There were 12,115,036 broker non-votes.

Item 6. EXHIBITS

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

SIGNATURES

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

ORASURE TECHNOLOGIES, INC.

/s/ Ronald H. Spair

Date: August 6, 2009

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

/s/ Mark L. Kuna

Date: August 6, 2009

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

EXHIBIT INDEX

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

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 the registrant's board of directors:

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

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

Date: August 6, 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 the registrant's board of directors:

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

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

Date: August 6, 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 June 30, 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

August 6, 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 June 30, 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

August 6, 2009