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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 September 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 November 2, 2009: 45,918,465

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Item 1. FINANCIAL STATEMENTS

ORASURE TECHNOLOGIES, INC.

BALANCE SHEETS
(Unaudited)

	SEPTEMBER 30, 2009	DECEMBER 31, 2008
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 74,784,253	$ 39,565,218
Short-term investments	8,243,207	42,957,467
Accounts receivable, net of allowance for doubtful accounts of $336,695 and $163,100	12,328,632	11,571,048
Inventories	9,429,631	10,704,088
Prepaid expenses and other	1,233,473	1,418,171
Total current assets	106,019,196	106,215,992
PROPERTY AND EQUIPMENT, net	20,419,352	21,235,367
PATENTS AND PRODUCT RIGHTS, net	882,752	4,380,540
OTHER ASSETS	352,945	86,290
	$ 127,674,245	$ 131,918,189
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	$ 524,343	$ 557,897
Accounts payable	2,943,307	3,925,662
Accrued expenses and other	10,481,039	10,795,955
Total current liabilities	13,948,689	15,279,514
LONG-TERM DEBT	7,916,679	8,301,440
OTHER LIABILITIES	2,268	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, 45,917,247 and 45,769,221 shares issued and outstanding	46	46
Additional paid-in capital	238,292,304	235,862,999
Accumulated other comprehensive loss	(232,077)	(262,442)
Accumulated deficit	(132,253,664)	(127,275,353)
Total stockholders' equity	105,806,609	108,325,250
	$ 127,674,245	$ 131,918,189

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.

STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
REVENUES:				
Product	$ 20,907,469	$ 16,157,670	$ 54,576,906	$ 51,935,123
Licensing and product development	701,848	702,512	1,562,423	1,960,076
	21,609,317	16,860,182	56,139,329	53,895,199
COST OF PRODUCTS SOLD	7,705,653	7,144,718	21,383,689	22,393,462
Gross profit	13,903,664	9,715,464	34,755,640	31,501,737
OPERATING EXPENSES:				
Research and development	2,925,242	4,166,646	8,710,380	14,863,778
Sales and marketing	5,227,933	5,327,224	15,539,730	15,505,066
General and administrative	3,974,684	3,561,780	12,866,414	11,292,521
Litigation settlement	—	—	—	(4,883,714)
Impairment of patent and product rights	—	—	3,028,375	—
	12,127,859	13,055,650	40,144,899	36,777,651
Operating income (loss)	1,775,805	(3,340,186)	(5,389,259)	(5,275,914)
INTEREST EXPENSE	(89,890)	(95,475)	(269,839)	(250,675)
INTEREST INCOME	117,935	666,598	692,439	2,507,042
FOREIGN CURRENCY GAIN (LOSS)	(4,508)	16,230	(11,652)	(63,114)
Income (loss) before income taxes	1,799,342	(2,752,833)	(4,978,311)	(3,082,661)
INCOME TAX BENEFIT	—	(991,181)	—	(1,079,452)
NET INCOME (LOSS)	$ 1,799,342	$ (1,761,652)	$ (4,978,311)	$ (2,003,209)
EARNINGS (LOSS) PER SHARE:				
BASIC AND DILUTED	$ 0.04	$ (0.04)	$ (0.11)	$ (0.04)
SHARES USED IN COMPUTING EARNINGS (LOSS) PER SHARE				
BASIC	45,879,576	46,691,600	45,862,788	46,773,750
DILUTED	46,024,101	46,691,600	45,862,788	46,773,750

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.

STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine Months Ended September 30,	
	2009	2008
OPERATING ACTIVITIES:		
Net loss	$ (4,978,311)	$ (2,003,209)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Impairment of patent and product rights	3,028,375	—
Stock-based compensation	3,087,303	4,315,681
Deferred income taxes	—	(1,270,888)
Depreciation and amortization	2,359,625	2,122,187
Reserve for excess and obsolete inventories	(289,311)	(806,445)
Changes in assets and liabilities:		
Accounts receivable	(755,345)	(1,085,773)
Inventories	1,563,768	(21,462)
Prepaid expenses and other assets	(81,957)	1,280,605
Accounts payable	(930,738)	(3,016,189)
Accrued expenses and other liabilities	(314,916)	(3,257,549)
Net cash provided by (used in) operating activities	2,688,493	(3,743,042)
INVESTING ACTIVITIES:		
Purchase of short-term investments	(5,986,000)	(65,921,172)
Proceeds from maturities and redemptions of short-term investments	40,592,000	75,193,426
Purchase of property and equipment	(989,428)	(1,949,520)
Payments of patents and licenses	—	(200,000)
Net cash provided by investing activities	33,616,572	7,122,734
FINANCING ACTIVITIES:		
Repayments of long-term debt	(418,315)	(375,789)
Proceeds from issuance of common stock	17,898	92,517
Withholding and retirement of common stock	(377,008)	(983,834)
Purchase and retirement of common stock	(308,605)	(2,524,111)
Net cash used in financing activities	(1,086,030)	(3,791,217)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	35,219,035	(411,525)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	39,565,218	32,229,697
CASH AND CASH EQUIVALENTS, END OF PERIOD	$74,784,253	$ 31,818,172
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for:		
Interest	$ 273,162	$ 269,969
Income taxes	$ 30,500	$ 399,350

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 for the foreseeable future and intensify, and could adversely affect our results of operations, cash flows and financial condition or those of our customers and suppliers. These circumstances could adversely affect our access to liquidity needed to conduct or expand our business or conduct acquisitions or make other discretionary investments. 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 nine months ended September 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 Securities Exchange Commission ("SEC") on November 5, 2009.

Reclassification. In response to a comment letter received from the SEC dated August 31, 2009, we reclassified our patent litigation settlement of $4.9 million received in January 2008 from Other Income in the Statement of Operations to a reduction of operating expenses.

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.

ORASURE TECHNOLOGIES, INC.

Notes to Financial Statements—Continued
(Unaudited)

Cash and Cash Equivalents. We consider all highly liquid investments with a purchased maturity of ninety days or less to be cash equivalents. As of September 30, 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 Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 320-10-25, "Investments—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 September 30, 2009 and December 31, 2008:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
September 30, 2009				
Certificates of deposit	$ 7,484,000			$ 7,484,000
Corporate bonds	752,106	7,101	—	759,207
Total available-for-sale securities	$ 8,236,106	$ 7,101	$ —	$ 8,243,207
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 September 30, 2009, maturities of our available-for-sale securities were as follows:				
Less than one year	$ 6,241,106	$ 7,101	$ —	$ 6,248,207
One to two years	1,995,000	—	—	1,995,000
Total available-for-sale securities	$ 8,236,106	$ 7,101	$ —	$ 8,243,207

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

	September 30, 2009	December 31, 2008
Raw materials	$ 5,151,630	$ 6,721,102
Work in process	451,274	390,259
Finished goods	3,826,727	3,592,727
	$ 9,429,631	$10,704,088

Impairment of Long-Lived Assets. If indicators of impairment exist, we assess the recoverability of the affected long-lived assets, which include property and equipment and patents and product rights, by determining whether the carrying value of such assets can be recovered through the sum of the undiscounted future cash flows from the use and eventual disposition of the 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.

ORASURE TECHNOLOGIES, INC.

Notes to Financial Statements—Continued
(Unaudited)

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

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

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

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

Significant Customer Concentration. 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 nine months ended September 30, 2009.

The Company had the following significant concentrations in revenue and accounts receivable:

	Percentage of Total Revenues			
	Three Months Ended September 30,		Nine Months Ended September 30,	
Customer	2009	2008	2009	2008
Quest Diagnostics, Incorporated	8%	11%	9%	10%
Abbott Laboratories	—	10	—	10

	Percentage of Accounts Receivable	
	September 30, 2009	December 31, 2008
SSL International plc	4%	10%
National Aids Control Program	6	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

ORASURE TECHNOLOGIES, INC.

Notes to Financial Statements—Continued
(Unaudited)

CROs based on purchase order estimates provided by the CROs. Differences between actual and estimated clinical trial expenses recorded are generally not material and would be adjusted for in the period in which they become known.

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Net income (loss)	$ 1,799,342	$ (1,761,652)	$ (4,978,311)	$ (2,003,209)
Weighted average shares of common stock outstanding:				
Basic	45,879,576	46,691,600	45,862,788	46,773,750
Dilutive effect of stock options, warrants and restricted stock	144,525	—	—	—
Diluted	46,024,101	46,691,600	45,862,788	46,773,750
Earnings (loss) per share:				
Basic and Diluted	$ 0.04	$ (0.04)	$ (0.11)	$ (0.04)

For the three month periods ended September 30, 2009 and 2008, outstanding common stock options and unvested restricted stock, representing 6,504,430 and 5,825,981 shares, respectively, were excluded from the computation of diluted earnings per share, as their inclusion would have been anti-dilutive. For the nine month periods ended September 30, 2009 and 2008, outstanding common stock options and unvested restricted stock, representing 6,249,498 and 5,186,392 shares, respectively, were excluded from the computation of diluted earnings per share, as their inclusion would have been anti-dilutive.

Other Comprehensive Income (Loss). We follow FASB ASC 220-10, “Comprehensive Income.” This topic requires the classification of items of other comprehensive income (loss) by their nature and disclosure of the accumulated balance of other comprehensive income (loss), separately from accumulated deficit and additional paid-in capital, in the stockholders’ equity section of our balance sheet. Other comprehensive income (loss) at September 30, 2009 and December 31, 2008 consisted of currency translation adjustments and net unrealized gains or losses on short-term investments. Comprehensive income (loss) was $1,781,623 and $(2,015,409) for the three months ended September 30, 2009 and 2008, respectively, and $(4,947,946) and $(2,318,578) for the nine months ended September 30, 2009 and 2008, respectively.

Recent Accounting Pronouncements. In May 2009, the FASB issued a new disclosure requirement under FASB ASC 855-10-50-1, “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,” above, for the related disclosures. The adoption of this new disclosure requirement did not have a material impact on our financial statements.

ORASURE TECHNOLOGIES, INC.

Notes to Financial Statements—Continued
(Unaudited)

In April 2009, the FASB added additional disclosures requirements under FASB ASC 825-10-65 "Financial Instruments," to require disclosures about fair value of financial instruments in interim financial statements as well as in annual financial statements, effective for interim reporting periods ending after June 15, 2009. FASB ASC 825-10-65 also requires those disclosures in summarized financial information in interim financial statements. These additional disclosure requirements did not have a material impact on our financial statements.

3. Patents and Product Rights

Impairment. In August 2005, we entered into a license agreement with third parties, pursuant to which we have been granted a limited, 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 we paid $3,000,000 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.

Termination of Royalty Agreement. On July 13, 2009, we entered into a termination and release agreement with the third party from whom we purchased certain patents, trademarks, copyrights and technology related to our Histofreezer® product line. Pursuant to this termination and release agreement, we made a one-time payment of $643,050 to this third party in full consideration of the termination of the original asset purchase agreement we executed with this third party in June 1998, and its related royalty obligations, which extended until December 2011. We recorded this payment, net of the royalties previously accrued, as prepaid royalties, which will be expensed in relation to Histofreezer® revenues through December 31, 2011.

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 September 30, 2009 and 2008 was $1.20 and $1.87 per share, respectively. The weighted average grant date fair value of stock options granted during the nine months ended September 30, 2009 and 2008 was $1.19 and $3.03 per share, respectively.

ORASURE TECHNOLOGIES, INC.

Notes to Financial Statements—Continued
(Unaudited)

Total compensation cost related to stock options for the three months ended September 30, 2009 and 2008 was $311,388 and $559,905 ($392,465, net of tax), respectively, of which $8,827 and $13,615 was capitalized into inventory during the quarters ended September 30, 2009 and 2008, respectively. The amounts recognized in cost of products sold for amounts previously capitalized were $19,911 and $40,023 for the three months ended September 30, 2009 and 2008, respectively. Total compensation cost related to stock options for the nine months ended September 30, 2009 and 2008 was $1,009,193 and $1,657,736 ($1,124,342, net of tax), respectively, of which $46,234 and $92,201 was capitalized into inventory during the nine month periods ended September 30, 2009 and 2008, respectively. The amounts recognized in cost of products sold for amounts previously capitalized were $113,913 and $160,205 for the nine months periods ended September 30, 2009 and 2008, respectively.

The following table summarizes the stock option activity for the nine months ended September 30, 2009:

	Options
Outstanding on January 1, 2009	5,130,707
Granted	631,708
Exercised	(22,302)
Forfeited	(165,484)
Outstanding on September 30, 2009	5,574,629

As of September 30, 2009, there was $1,918,078 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 nine months ended September 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 and/or forfeiture, as determined by the Compensation Committee of our Board of Directors. The market value of these shares at the date of grant is recognized on a straight-line basis over the period during which the restrictions lapse. During the nine months ended September 30, 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 $682,218 and $917,584 related to restricted shares was recognized during the three months ended September 30, 2009 and 2008, respectively. Compensation cost of $2,078,110 and $2,657,945 related to restricted shares was recognized during the nine months ended September 30, 2009 and 2008, respectively.

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

	Shares
Issued and unvested, January 1, 2009	831,488
Granted	429,870
Vested	(363,977)
Forfeited	(53,345)
Issued and unvested, September 30, 2009	844,036

As of September 30, 2009, there was $3,171,563 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 nine months ended September 30, 2009 and 2008, 129,960 and 132,302 shares, respectively, with aggregate values of $377,008 and $983,834, respectively, were withheld and retired in satisfaction of minimum tax withholding obligations.

ORASURE TECHNOLOGIES, INC.

Notes to Financial Statements—Continued
(Unaudited)

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 nine months ended September 30, 2009, we purchased and retired 108,293 shares of our common stock at an average price of $2.85 per share. Accordingly, we recorded a $308,605 reduction to additional paid-in capital during the nine month period ended September 30, 2009.

6. Accrued Expenses

	September 30, 2009	December 31, 2008
Payroll and related benefits	$ 3,868,706	$ 3,513,124
Royalties	3,548,603	2,481,466
Deferred revenue	2,063,244	1,951,921
Professional fees	379,229	472,969
Clinical research obligations	96,930	348,459
Advertising	—	365,313
Other	524,327	1,662,703
	$10,481,039	$10,795,955

Deferred revenue at September 30, 2009 and December 31, 2008 included customer prepayments of $1,965,244 and $1,824,721, respectively.

7. Litigation Settlement

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 operating income.

8. Geographic Information

Based on guidance in FASB ASC 280-10, “Segment Reporting,” 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.

ORASURE TECHNOLOGIES, INC.

Notes to Financial Statements—Continued
(Unaudited)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
United States	$17,664	$14,226	$46,350	$44,059
Europe	1,560	1,175	4,932	5,527
Other regions	2,385	1,459	4,857	4,309
	$21,609	$16,860	$56,139	$53,895

9. Fair Value of Financial Instruments

We follow FASB ASC 820-10-50, "Fair Value Measurements and Disclosures," which applies to all financial assets and liabilities that are being measured and reported on a fair value basis. The topic 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. Due to recent scheduling changes, the scheduling of the Markman hearing is expected to be considered by the Court in December of this year.

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, as well. 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 U.S. Food and Drug Administration ("FDA") approvals could disrupt our ability to sell the affected products.

Competitive and Economic Outlook

Competition in the market for HIV testing is intense and is expected to increase. We believe that our principal competition will come from existing 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 for the foreseeable future 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 nine months ended September 30, 2009, our total revenues were $56.1 million, which represents a 4% increase from the same period in 2008. Our net loss for the nine months ended September 30, 2009 was $5.0 million or $0.11 per share, compared to a net loss of $2.0 million or $0.04 per share for the nine months ended September 30, 2008. Our net loss for the first nine 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 nine months of 2008 includes a $4.9 million pre-tax payment received from Schering-Plough Healthcare Products, Inc. ("Schering-Plough") to resolve a patent infringement lawsuit.

Cash flow provided by operating activities for the nine months ended September 30, 2009 was $2.7 million, an improvement of $6.4 million compared to the $3.7 million used in operating activities for the nine months ended September 30, 2008. As of September 30, 2009, we had $83.0 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 FDA for our OraQuick® rapid 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.

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 new clinical studies 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 studies mandated by the FDA in order to obtain approved claims for oral fluid, venous whole blood, and fingerstick whole blood. In September 2009, we commenced the additional clinical testing required in support of these claims. We expect these clinical studies to be completed during the first half of 2010.

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.

During the quarter ended June 30, 2009, the FDA 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 intend to present a proposal regarding this clinical program at the BPAC's meeting scheduled for November 2009.

OraQuick® HIV Manufacturing

During the quarter ended June 30, 2009, we experienced difficulty manufacturing a component for our OraQuick® rapid HIV-1/2 antibody test in accordance with 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 second 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.

Early in the third quarter, we identified the root cause of the manufacturing issue and implemented corrective action. As a result, during the three months ended September 30, 2009, we resumed full-scale production of our OraQuick® rapid HIV-1/2 antibody test, fulfilled the $2.2 million backlog which existed at June 30, 2009, and restored our supply of finished goods inventories for this product.

Our revenues for the third quarter of 2009 included the elimination of the $2.2 million backlog, which was largely responsible for the 40% increase in OraQuick® sales to the U.S. public health market during this period. Our gross margin for the quarter ended September 30, 2009 increased to 64%, as compared to 58% experienced during the second quarter of 2009. Gross margin for the third quarter of 2009 benefited from the higher revenues and increased absorption of our fixed costs as a result of resuming full-scale production of our OraQuick® HIV product.

Availability of HIV-1 Antigen and Screening Test

In past years, bioMérieux, Inc. (“BMX”) manufactured and sold the only oral fluid HIV-1 enzyme immunoassay screening test (“EIA”) that had received FDA approval for use in detecting HIV-1 in an oral fluid specimen collected with our OraSure® collection device. BMX also supplied the HIV-1 antigen used to manufacture our oral fluid Western blot HIV-1 confirmatory test and was the exclusive world-wide distributor of that product. BMX discontinued manufacturing their HIV-1 EIA screening test during 2007 and our agreement with BMX for the supply of HIV-1 antigen terminated on December 31, 2007. As a result, we purchased a two-year supply of the antigen from BMX as permitted under the agreement.

During the third quarter of 2009, we made arrangements to purchase additional HIV-1 antigen from a third party subcontractor that had historically been used by BMX to manufacture this product for resale to us by BMX. We believe this subcontractor can supply our future requirements for the HIV-1 antigen, and we intend to negotiate a long-term supply contract with this party in the near future.

As previously disclosed, we had initially planned to conduct clinical trials and seek FDA approval of an alternate HIV-1 EIA for use in testing oral fluid samples collected with our OraSure® collection device. However, we recently learned that a third party called Avioq Inc., who had acquired a license from BMX to produce a new HIV-1 EIA test originally developed by BMX, recently obtained FDA approval of this product for use with our OraSure® collection device. As a result, we now believe that we will not need to conduct our own clinical trials or seek FDA approval for an alternate HIV-1 EIA, as originally planned.

Termination of Royalty Agreement

In July 2009, we entered into a termination and release agreement with the third party from whom we purchased certain patents, trademarks, copyrights and technology related to our Histofreezer® product line. Pursuant to this agreement, we made a one-time payment of $643,050 to this third party in full consideration of the termination of the original asset purchase agreement we executed with this third party in June 1998, and its related royalty obligations, which would have extended until December 2011. We recorded this payment, net of the royalties previously accrued, as prepaid royalties, which will be expensed in relation to Histofreezer® revenues through December 31, 2011.

Results of Operations

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

Total revenues increased 28% to $21.6 million in the third quarter of 2009 from $16.9 million in the comparable quarter in 2008. We experienced double digit revenue increases for all of our product lines, with the exception of our substance abuse testing products, which declined 9%. Licensing and product development revenues remained flat when compared to the third quarter of 2008.

Revenues derived from products sold to customers outside the U.S. were $3.9 million and $2.6 million, or 18% and 16% of total revenues, in the third 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 September 30,				
	Dollars			Percentage of Total Revenues	
Market	2009	2008	% Change	2009	2008
Infectious disease testing	$13,540	$ 9,743	39%	63%	58%
Substance abuse testing	3,269	3,581	(9)	15	21
Cryosurgical systems	2,682	1,671	61	12	10
Insurance risk assessment	1,416	1,163	22	7	7
Product revenues	20,907	16,158	29	97	96
Licensing and product development	702	702	0	3	4
Total revenues	$21,609	$16,860	28%	100%	100%

Infectious Disease Testing Market

Sales to the infectious disease testing market increased 39% to $13.5 million in the third quarter of 2009. OraQuick® sales totaled $13.2 million and $8.9 million in the third quarters of 2009 and 2008, respectively. Sales of our OraSure® oral fluid collection device totaled $358,000 and $830,000 in the third quarters of 2009 and 2008, respectively.

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

	Three Months Ended September 30,		
Customers	2009	2008	% Change
Direct to U.S. Public Health	$ 8,611	$ 6,157	40%
Hospital Market	3,156	1,799	75
International	1,415	957	48
Total OraQuick® revenues	$ 13,182	$ 8,913	48%

Early in the third quarter, we identified the root cause of the manufacturing issues we had experienced with our OraQuick® rapid HIV-1/2 antibody test during the second quarter of 2009. We implemented corrective action and as a result, we resumed full-scale production of the OraQuick® HIV product during the third quarter and eliminated the backlog in product orders that existed at June 30, 2009.

During the three months ended September 30, 2009, direct sales of OraQuick® to the U.S. public health market increased by 40%, or $2.5 million, when compared to the same period in 2008. This increase is largely due to the elimination of the $1.8 million backlog of public health orders for our OraQuick ADVANCE® Rapid HIV-1/2 antibody test which existed at June 30, 2009. The remaining balance of the current period increase is the result of growth in our base business as certain of our public health customers have expanded their HIV testing programs.

Sales into the hospital market increased 75% to $3.2 million during the third quarter of 2009 as compared to $1.8 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 hospital market during the current period is primarily due to higher average selling prices realized under our direct sales model and the elimination of a $400,000 backlog of hospital orders for our OraQuick *ADVANCE*® Rapid HIV-1/2 antibody test, which existed at June 30, 2009.

International sales of our OraQuick® HIV-1/2 test increased 48% to $1.4 million for the three months ended September 30, 2009 from $957,000 for the three months ended September 30, 2008. This increase reflects a 28% increase in sales to Africa, as well as increased sales activity in various countries in Europe and Latin America.

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 from $830,000 in the third quarter of 2008 to $358,000 in the third 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 efforts of the Centers for Disease Control and Prevention ("CDC") to increase rapid HIV testing in healthcare settings. However, it is not possible at this time to estimate the full extent or impact of this change in purchasing patterns.

Substance Abuse Testing Market

Substance abuse testing revenues decreased 9% to $3.3 million in the third quarter of 2009 from $3.6 million in the third quarter of 2008, as lower sales in the forensics toxicology market and reduced sales of our Intercept® product for workplace testing caused by the continuing adverse economic conditions and high unemployment rates, offset higher sales in the U.S. criminal justice and international markets.

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

	Three Months Ended September 30,		
Market	**2009**	**2008**	**% Change**
Workplace testing	$ 1,068	$ 1,193	(10)%
Criminal justice	736	637	16
International	479	481	0
Direct	282	303	(7)
Total Intercept® revenues	$ 2,565	$ 2,614	(2)%

Our workplace testing business decreased 10% from $1.2 million in the third quarter of 2008 to $1.1 million in the third quarter of 2009. Pre-employment drug screening represents over 50% of our workplace testing business and the recession experienced in the domestic economy and high unemployment levels have had a significant negative impact on this part of our business, as well as on our direct sales. During the third quarter of 2009, our primary drug testing lab customer reported a decrease in the number of oral fluid drug tests processed compared to the same period in 2008. Our direct sales of Intercept® products were also negatively impacted during the third quarter as a result of a reduction in drug testing by our small business customers. Criminal justice sales increased 16% primarily due to the variable ordering patterns of our criminal justice customers.

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 in the cryosurgical systems market (which includes both the physicians' office and OTC markets) increased 61% to $2.7 million in the third quarter of 2009, compared to $1.7 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 third quarters of 2009 and 2008.

	Three Months Ended September 30,		
Market	2009	2008	% Change
Professional domestic	$ 1,220	$ 903	35%
Professional international	337	401	(16)
OTC domestic	(122)	—	N/A
OTC international	1,247	367	240
Total cryosurgical systems revenues	$ 2,682	$ 1,671	61%

The overall increase in cryosurgical systems revenues was primarily the result of an $880,000 increase in sales of our international OTC products. During the three months ended September 30, 2009, we experienced increased sales to our Latin American OTC distributor, Genomma, and to our European OTC distributor, SSL.

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 third 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 through its excess inventory and resumed purchasing product from us during the second quarter of 2009. We shipped $564,000 of product to Genomma during the third quarter of 2009. Genomma recently registered our OTC cryosurgical wart removal product in Brazil, and in September 2009 we completed our first shipment to the Brazilian market. We believe that the commercial launch of our OTC product in Brazil will support continued sales to Genomma during the remainder of 2009.

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 $683,000 and $367,000 in the third quarter of 2009 and 2008, respectively. During the first half of 2009, we experienced a decline in purchasing volume from SSL due to a combination of excess inventory levels built at the end of 2008 and slower then expected outsales in the European market. The increase in SSL revenues during the third quarter of 2009 is a result of SSL having worked through its excess inventory. This increase in purchases was partially offset by a reduction in our per unit selling price to SSL in 2009.

During the first quarter of 2009, we reentered the U.S. OTC cryosurgery marketplace through the launch of our own cryosurgical wart removal product under our new national brand, Freeze 'n Clear Skin Clinic™. 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 September 30, 2009, we recorded $467,000 in revenues from Freeze ‘n Clear Skin Clinic™. These revenues were offset by $589,000 in promotional rebates, advertising and slotting, and return allowances provided to the retail trade, which we netted against the revenues in accordance with U.S. GAAP. We believe our participation in these promotional and advertising programs, which were executed and controlled by the retail trade, was necessary in order to create initial awareness and implement the launch of our product within the OTC marketplace. It is not possible to predict at this time how successful our new brand will perform in the domestic OTC marketplace or whether we will need to participate in future retail promotional and advertising programs at comparable levels.

Sales of our Histofreezer® product to physicians’ offices in the United States increased 35% to $1.2 million in the third quarter of 2009, as compared to $903,000 in 2008 largely due to fluctuations in distributor ordering patterns, a pricing increase enacted in certain distributor contract renewals, and a decrease in product diversion from international sources as described below when compared to the same period in 2008. Sales of Histofreezer® in the international market decreased 16% or $64,000 in the third quarter of 2009, as compared to the third quarter of 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. The decrease in sales in the international market in the third quarter of 2009 is largely due to the discontinuance of sales to one of these foreign distributors.

We see 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 likelihood or financial impact of these changes.

Insurance Risk Assessment Market

Sales to the insurance risk assessment market increased 22% to $1.4 million in 2009 from $1.2 million in the third quarter of 2008, primarily due to variations in laboratory ordering patterns.

Licensing and Product Development

Licensing and product development revenues remained flat at $702,000 during the third quarter of 2009 and 2008. Licensing revenue represents royalties received on domestic 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 third quarter of 2009 was 64%, compared to 58% for the third quarter of 2008. Gross margin was favorably impacted primarily by increased absorption of our fixed costs resulting from the increased number of units manufactured as we returned to full-scale production of our OraQuick® rapid HIV-1/2 antibody test and replenished our finished goods inventories. Gross margin also benefited 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.

Operating Expenses

Research and development expenses decreased 30% from $4.2 million in the third quarter of 2008 to $2.9 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 and related 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. In September 2009, we began conducting the additional clinical testing and studies recently required 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. We expect clinical trial expenses will increase during the remaining three months of 2009 and into 2010, as we continue to conduct these additional clinical studies.

Sales and marketing expenses decreased slightly from $5.3 million in the third quarter of 2008 to $5.2 million in the third quarter of 2009. This decrease was the result of a decrease in staffing costs for the quarter as prior year expenses included severance and sign-on bonus accruals for terminated and new senior-level sales and marketing personnel, respectively. During the fourth quarter of 2009, sales and marketing expenses are expected to increase due to costs associated with launching OraQuick® HCV in Europe and additional market research studies to be completed in the same period.

General and administrative expenses increased 12% to $4.0 million in the third quarter of 2009 from $3.6 million in the same period in 2008. This increase was primarily attributed to an increase in personnel and compensation costs.

Interest Income/Expense

Interest expense decreased to $90,000 in the third quarter of 2009 from $95,000 in the third quarter of 2008. Interest income decreased to $118,000 in the third quarter of 2009 from $667,000 in the third 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 FASB ASC 740-10-30, “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 provision on our pre-tax income during the third quarter of 2009. During the three months ended September 30, 2008, we recorded a federal and state income tax benefit of $991,000.

Nine months ended September 30, 2009 compared to September 30, 2008

Total revenues increased 4% to $56.1 million for the first nine months of 2009 from $53.9 million in the comparable period in 2008. Higher sales of our OraQuick *ADVANCE*® rapid HIV-1/2 antibody test and insurance risk assessment products were partially offset by decreased sales of our substance abuse testing products and a decrease in licensing and product development revenues. Revenues derived from products sold to customers outside the U.S. were $9.8 million during the first nine months of 2009 and 2008, or 17% and 18% of total revenues, 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.

Market	Nine Months Ended September 30, Dollars 2009	2008	% Change	Percentage of Total Revenues 2009	2008
Infectious disease testing	$33,407	$29,260	14%	59%	54%
Substance abuse testing	8,890	10,554	(16)	16	20
Cryosurgical systems	7,728	7,726	0	14	14
Insurance risk assessment	4,552	4,395	4	8	8
Product revenues	54,577	51,935	5	97	96
Licensing and product development	1,562	1,960	(20)	3	4
Total revenues	$56,139	$53,895	4%	100%	100%

Infectious Disease Testing Market

Sales to the infectious disease testing market increased 14% to $33.4 million in the first nine months of 2009, compared to the comparable period of 2008. OraQuick® sales totaled $31.7 million and $27.1 million in the first nine months of 2009 and 2008, respectively. Sales of our OraSure® oral fluid collection device totaled $1.7 million and $2.2 million in the first nine months of 2009 and 2008, respectively.

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

Customers	Nine Months Ended September 30, 2009	2008	% Change
Direct to U.S. Public Health	$20,957	$19,273	9%
Hospital Market	8,401	5,489	53
International	2,370	2,303	3
Total OraQuick® revenues	$31,728	$27,065	17%

During the first nine months of 2009, direct sales of OraQuick® to the U.S. public health market increased 9% as compared to 2008, primarily as a result of growth in our base business as certain of our public health customers expanded their HIV testing programs.

Sales into the hospital market increased 53% to $8.4 million during the first nine months of 2009 as compared to $5.5 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 hospital market is primarily due to higher average selling prices realized under our direct sales model.

International sales of our OraQuick® HIV-1/2 test increased to $2.4 million for the nine months ended September 30, 2009 from $2.3 million for the nine months ended September 30, 2008. This 3% increase reflects increased sales into Latin America, Europe and Asia. Partially offsetting this increase were decreased sales into Africa, primarily due to the timing of certain testing initiatives and placement of the related OraQuick® product orders.

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 from $2.2 million for the first nine months of 2008 to $1.7 million in the first nine 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 efforts of the CDC to increase rapid HIV testing in healthcare settings. However, it is not possible at this time to estimate the full extent or impact of such change in purchasing patterns.

Substance Abuse Testing Market

Substance abuse testing revenues decreased 16% to $8.9 million in the first nine months of 2009 from $10.6 million in the first nine months of 2008, as lower sales of Intercept® for workplace testing and direct sales of this product resulted from 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 nine months of 2009 and 2008.

	Nine Months Ended September 30,		
Market	**2009**	**2008**	**% Change**
Workplace testing	$ 2,871	$ 3,480	(18)%
Criminal justice	1,918	1,965	(2)
International	1,524	1,570	(3)
Direct	645	904	(29)
Total Intercept® revenues	$ 6,958	$ 7,919	(12)%

Our workplace testing business decreased 18% from $3.5 million in the first nine months of 2008 to $2.9 million in the first nine months of 2009. Pre-employment drug screening represents over 50% of our workplace testing business and the current recession in the domestic economy and high unemployment levels have had a significant negative impact on this part of our business, as well as on our direct sales results. During the first nine months of 2009, our primary drug testing lab customer reported a decrease in the number of oral fluid drug tests processed when compared to the first nine months of 2008. Sales to the criminal justice market in the current nine-month period were also negatively affected by the availability of competing lower priced drug testing products.

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 in the cryosurgical systems market (which includes both the physicians’ office and OTC markets) remained flat at $7.7 million in the first nine months of 2009 and 2008.

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

Market	Nine Months Ended September 30, 2009	2008	% Change
Professional domestic	$2,969	$2,942	1%
Professional international	1,601	1,802	(11)
OTC domestic	57	—	N/A
OTC international	3,101	2,982	4
Total cryosurgical systems revenues	$7,728	$7,726	0%

The 4% increase in international OTC cryosurgical systems revenues was primarily the result of increased sales into Latin America. Sales to our Latin American distributor, Genomma, for the nine months ended September 30, 2009 were $1.2 million, compared to $401,000 during the nine months ended September 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 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 and we completed our first shipment to Brazil in September 2009. We believe that the commercial launch of our OTC product in Brazil will support continuing sales to Genomma during the remainder of 2009.

The increase in sales to Latin America were partially offset by a decrease in sales to our European OTC distributor, SSL. Sales to SSL were $1.9 million and $2.6 million in the first nine months of 2009 and 2008, respectively. The decrease in revenues from SSL resulted from a lower per unit selling price to SSL and a decrease in 2009 purchases during the first half of the year as a result of excess inventory levels built at the end of 2008.

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 nine months ended September 30, 2009, we recorded $1.2 million in revenues from Freeze ‘n Clear Skin Clinic™. These revenues were offset by $1.1 million in promotional rebates, advertising and slotting, and return allowances provided to the retail trade, which we netted against the revenues in accordance with U.S. GAAP. We believe our participation in these promotional and advertising programs, which were executed and controlled by the retail trade, was necessary in order to increase initial awareness and implement the launch of our product within the OTC market. It is not possible to predict at this time how successful our new brand will perform in the domestic OTC marketplace or whether we will need to participate in future retail promotional and advertising programs at comparable levels.

Sales of our Histofreezer® product to physicians’ offices in the United States increased 1% to $3.0 million in the first nine months of 2009, as compared to $2.9 million in 2008. Sales of Histofreezer® in the international market decreased 11% to $1.6 million in the first nine months of 2009, as compared to $1.8 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 nine month period ended September 30, 2009 and may continue to do so until the supply of diverted product is exhausted. The decline in Histofreezer® revenues in the international market in 2009 is largely due to the discontinuance of sales to one of these foreign distributors.

We see 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 likelihood or financial impact of those changes.

Insurance Risk Assessment Market

Sales to the insurance risk assessment market increased 4% from $4.4 million during the first nine months of 2008 to $4.6 million during the first nine months of 2009, primarily due to variations in laboratory ordering patterns.

Licensing and Product Development

During the first nine months of 2009, licensing and product development revenues decreased to $1.6 million from $2.0 million during 2008. Licensing revenue represents royalties received on domestic 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 nine months of 2009 was 62%, compared to 58% for the first nine months of 2008. Gross margin was favorably impacted during the first nine months of 2009 primarily 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.

Operating Expenses

Research and development expenses decreased 41% from $14.9 million in the first nine months of 2008 to $8.7 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 and related 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. In September 2009, we began conducting the additional clinical testing and studies recently required 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. We expect clinical trial expenses will increase during the remaining three months of 2009 and into 2010, as we continue to conduct these additional clinical studies.

Sales and marketing expenses remained flat at $15.5 million for the first nine months of 2009 and 2008. The increase in staffing costs associated with implementing the direct sales model for the U.S. hospital market, and the hiring, compensation, and relocation costs associated with new senior-level sales and marketing personnel, were offset by a decrease in reimbursement of distributor advertising expenses. During the fourth quarter of 2009, sales and marketing expenses are expected to increase due to costs associated with launching OraQuick® HCV in Europe and additional market research studies to be completed in the same period.

General and administrative expenses increased 14% to $12.9 million in the first nine months of 2009 from $11.3 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.

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.

Other Income/Expense

Interest expense increased to $270,000 in the first nine months of 2009 from $251,000 in the first nine months of 2008. Interest income decreased to $692,000 in the first nine months of 2009 from $2.5 million in the first nine months 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 FASB ASC 740-10-30, “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 nine months of 2009. During the nine months ended September 30, 2008, we recorded a federal and state income tax benefit of $1.1 million.

Liquidity and Capital Resources

	September 30, 2009	December 31, 2008
	(In thousands)	
Cash and cash equivalents	$ 74,784	$ 39,565
Short-term investments	8,243	42,957
Working capital	92,071	90,936

Our cash, cash equivalents and short-term investments increased $505,000 to $83.0 million at September 30, 2009, primarily as a result of $2.7 million in cash provided by operations, partially offset by $989,000 of cash used for property and equipment purchases, $377,000 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 $418,000 for debt repayments.

Net cash provided by operating activities was $2.7 million in the first nine months of 2009, resulting from our net loss of $5.0 million and a reduced provision for scrap and spoilage of $289,000, offset by a non-cash charges of $3.0 million associated with the impairment of patent and product rights, depreciation and amortization of $2.4 million, and stock-based compensation expense of $3.1 million. Also contributing to net cash provided by operations was a decrease in inventory of $1.6 million, related to the utilization of a significant amount of cryosurgical raw material inventory. Offsetting these increases to cash during the nine months were decreases in accounts payable and accrued expenses of $930,000 and $315,000, respectively, largely due to payment of a termination fee to Abbott. Additional uses of cash included increases in accounts receivable and prepaid expenses of $755,000 and $82,000, respectively.

Net cash provided by investing activities during the first nine months of 2009 was $33.6 million. Net proceeds of $34.6 million from maturities, redemptions and purchases of short-term investments were partially offset by $989,000 in purchases of property and equipment.

During the remainder of the year ending December 31, 2009, we expect to invest approximately $1.0 million in additional capital expenditures, primarily to purchase additional new equipment, upgrade certain older equipment and make improvements to our facilities.

Net cash used in financing activities was $1.1 million for the nine months ended September 30, 2009, primarily as a result of $418,000 in loan principal repayments and $377,000 used for the withholding and retirement of common stock. During the first nine months of 2009, we also used $309,000 to purchase 108,293 shares of common stock under our stock repurchase plan and we received $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 September 30, 2009, we had $8.4 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, since 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 September 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 $49.9 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 at least 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

The following sets forth our approximate aggregate obligations at September 30, 2009 for future payments under contracts and other contingent commitments for 2009 and beyond:

Contractual Obligations	Total	Payments due by December 31, 2009	2010	2011	2012	2013	Thereafter
Long-term debt[1]	$ 8,441,022	$ 139,583	$ 509,761	$7,791,678	$ —	$ —	$ —
Operating leases[2]	14,713	14,713	—	—	—	—	—
Employment contracts[3]	2,204,750	556,500	1,395,875	252,375	—	—	—
Purchase obligations[4]	3,767,060	3,021,508	745,552				
Minimum commitments under contracts[5]	4,791,667	500,000	500,000	500,000	500,000	500,000	2,291,667
Total contractual obligations	$19,219,212	$4,232,304	$3,151,188	$8,544,053	$ 500,000	$ 500,000	$ 2,291,667

1 Represents principal repayments required under notes payable to our lenders.

2 Represents payments required under our operating leases.

3 Represents salary payments payable under the terms of employment agreements executed by us with certain officers and employees.

4 Represents payments required by non-cancellable purchase orders related to inventory, capital expenditures and other goods or services.

5 Represents payments required pursuant to certain, licensing agreements executed by the Company. These agreements are cancellable within a specified number of days after communication by the Company of its intent to terminate. Additional payments of up to $4,500,000 may be required pursuant to one of these licensing agreements for the achievement of specific development and/or commercial milestones.

Critical Accounting Policies and Estimates

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

A more detailed review of our critical accounting policies is contained in our 2008 Annual Report on Form 10-K filed with the SEC. During the first nine months of 2009, there were no material changes in our critical accounting policies.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

A significant portion of our assets is comprised of certificates of deposit, U.S. government 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 September 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 nine months ended September 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 September 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 September 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 September 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 recent scheduling changes, the scheduling of the Markman hearing is expected to be considered by the Court in December of this year.

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

During the quarter ended September 30, 2009, pursuant to our 2000 Stock Award Plan and in connection with the vesting of restricted shares, we retired 18,917 shares to satisfy minimum tax withholding obligations at an average price paid per share of $2.97.

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 September 30, 2009. As of September 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 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: November 5, 2009

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

/S/ MARK L. KUNA

Date: November 5, 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: November 5, 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: November 5, 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 September 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

November 5, 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 September 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

November 5, 2009