Table of Contents

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, 2008.

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 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	☐ (Do not check if a smaller reporting company)	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 4, 2008: 45,878,291

Table of Contents

Item 1. FINANCIAL STATEMENTS

ORASURE TECHNOLOGIES, INC.
BALANCE SHEETS
(Unaudited)

	SEPTEMBER 30, 2008	DECEMBER 31, 2007
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 31,818,172	$ 32,229,697
Short-term investments	53,563,643	63,336,408
Accounts receivable, net of allowance for doubtful account of $104,373 and $186,468	12,380,682	11,296,355
Inventories	10,237,650	9,409,743
Deferred income taxes	2,675,643	5,060,974
Prepaid expenses and other	1,192,988	2,455,534
Total current assets	111,868,778	123,788,711
PROPERTY AND EQUIPMENT, net	21,373,411	20,911,157
PATENTS AND PRODUCT RIGHTS, net	4,578,497	5,279,471
DEFERRED INCOME TAXES	21,108,602	17,265,591
OTHER ASSETS	89,527	107,586
	$ 159,018,815	$ 167,352,516
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	$ 557,608	$ 556,751
Accounts payable	2,533,960	5,615,998
Accrued expenses and other	9,228,431	11,995,710
Total current liabilities	12,319,999	18,168,459
LONG-TERM DEBT	8,441,023	8,817,669
OTHER LIABILITIES	11,035	311,799
STOCKHOLDERS' EQUITY		
Preferred stock, par value $.000001, 25,000,000 shares authorized, none issued	—	—
Common stock, par value $.000001, 120,000,000 shares authorized, 46,286,216 and 46,644,046 shares issued and outstanding	46	47
Additional paid-in capital	236,804,237	236,293,489
Accumulated other comprehensive loss	(554,265)	(238,896)
Accumulated deficit	(98,003,260)	(96,000,051)
Total stockholders' equity	138,246,758	140,054,589
	$ 159,018,815	$ 167,352,516

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,	
	2008	2007	2008	2007
REVENUES:				
Product	$ 16,157,670	$ 20,661,204	$ 51,935,123	$ 60,794,834
Licensing and product development	702,512	754,127	1,960,076	2,081,940
	16,860,182	21,415,331	53,895,199	62,876,774
COST OF PRODUCTS SOLD	7,144,718	8,647,522	22,393,462	24,121,646
Gross profit	9,715,464	12,767,809	31,501,737	38,755,128
OPERATING EXPENSES:				
Research and development	4,166,646	3,672,087	14,863,778	9,896,379
Sales and marketing	5,327,224	4,978,795	15,505,066	14,998,637
General and administrative	3,561,780	5,074,670	11,292,521	13,636,810
	13,055,650	13,725,552	41,661,365	38,531,826
Operating income (loss)	(3,340,186)	(957,743)	(10,159,628)	223,302
INTEREST EXPENSE	(95,475)	(168,490)	(250,675)	(499,302)
INTEREST INCOME	666,598	1,244,158	2,507,042	3,521,490
OTHER INCOME	—	—	4,883,714	1,428,691
FOREIGN CURRENCY GAIN (LOSS)	16,230	9,752	(63,114)	(7,513)
Income (loss) before income taxes	(2,752,833)	127,677	(3,082,661)	4,666,668
INCOME TAX PROVISION (BENEFIT)	(991,181)	123,618	(1,079,452)	2,221,531
NET INCOME (LOSS)	$ (1,761,652)	$ 4,059	$ (2,003,209)	$ 2,445,137
EARNINGS (LOSS) PER SHARE:				
BASIC AND DILUTED	$ (0.04)	$ —	$ (0.04)	$ 0.05
SHARES USED IN COMPUTING EARNINGS (LOSS) PER SHARE:				
BASIC	46,691,600	46,340,646	46,773,750	46,392,692
DILUTED	46,691,600	46,988,171	46,773,750	46,892,924

The accompanying notes are an integral part of these statements.

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

	Nine Months Ended September 30, 2008	2007
OPERATING ACTIVITIES:		
Net income (loss)	$ (2,003,209)	$ 2,445,137
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Gain on sale of investment in nonaffiliated company	—	(1,428,691)
Stock-based compensation	4,315,681	4,459,520
Deferred income taxes	(1,270,888)	1,557,785
Depreciation and amortization	2,122,187	1,996,736
Provision for excess and obsolete inventories	1,118,113	771,592
Changes in assets and liabilities:		
Accounts receivable	(1,085,773)	(1,657,083)
Inventories	(1,946,020)	(3,005,429)
Prepaid expenses and other assets	1,280,605	666,554
Accounts payable, accrued expenses, and other liabilities	(6,273,738)	1,981,186
Net cash provided by (used in) operating activities	(3,743,042)	7,787,307
INVESTING ACTIVITIES:		
Purchase of short-term investments	(65,921,172)	(77,787,229)
Proceeds from maturities and redemptions of short-term investments	75,193,426	75,283,513
Purchase of property and equipment	(1,949,520)	(4,280,934)
Payments for patents or licenses	(200,000)	(4,000,000)
Proceeds from sale of investment in nonaffiliated company	—	1,765,943
Net cash provided by (used in) investing activities	7,122,734	(9,018,707)
FINANCING ACTIVITIES:		
Repayments of long-term debt	(375,789)	(750,711)
Proceeds from issuance of common stock	92,517	1,742,999
Withholding and retirement of common stock	(983,834)	(760,856)
Purchase and retirement of common stock	(2,524,111)	—
Net cash provided by (used in) financing activities	(3,791,217)	231,432
NET DECREASE IN CASH AND CASH EQUIVALENTS	(411,525)	(999,968)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	32,229,697	19,949,821
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 31,818,172	$ 18,949,853
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for:		
Interest	$ 269,969	$ 514,532
Income taxes	$ 399,350	$ 395,284

The accompanying notes are an integral part of these statements.

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

1. The Company

We develop, manufacture and market oral specimen collection devices using our proprietary oral fluid technologies, diagnostic products, including *in vitro* diagnostic tests, and other medical devices. 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 also sold in the over-the-counter or consumer retail markets in Europe and Mexico.

2. Summary of Significant Accounting Policies

Basis of Presentation. The accompanying financial statements are unaudited and, in the opinion of management, include all adjustments (consisting only of normal and recurring adjustments) necessary for a fair presentation of our financial position and results of operations for these interim periods. These financial statements should be read in conjunction with the financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2007. Results of operations for the three-month and nine-month periods ended September 30, 2008 are not necessarily indicative of the results of operations expected for the full year.

Use of Estimates. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and 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. Actual results could differ from those estimates.

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, 2008, cash equivalents consisted of commercial paper. As of December 31, 2007, cash equivalents consisted of commercial paper, U.S. government obligations, corporate bonds, and certificates of deposit.

Short-term Investments. We consider all short-term investments to be available-for-sale securities, in accordance with Statement of Financial Accounting Standards ("SFAS") No. 115, "Accounting for Certain Investments in Debt and Equity Securities." These securities are comprised of certificates of deposits, commercial paper, U.S. government and agency obligations, and corporate bonds, all with purchased maturities greater than ninety days. Available-for-sale securities are carried at fair value, based upon quoted market prices, with unrealized gains and losses reported in stockholders' equity as a component of accumulated other comprehensive income (loss).

The following is a summary of our available-for-sale securities at September 30, 2008 and December 31, 2007:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
September 30, 2008				
Certificates of deposit	$ 5,700,000	$ 10,566	$ —	$ 5,710,566
Commercial paper	6,175,275	—	(12,618)	6,162,657
Government and agency bonds	11,240,538	—	(33,820)	11,206,718
Corporate bonds	30,963,223	224	(479,745)	30,483,702
Total available-for-sale securities	$54,079,036	$ 10,790	$(526,183)	$53,563,643
December 31, 2007				
Certificates of deposit	$ 2,721,321	$ 3,759	$ (6,925)	$ 2,718,155
Commercial paper	4,383,327	1,158	(92)	4,384,393
Government and agency bonds	5,541,885	15,681	—	5,557,566
Corporate bonds	50,704,757	24,104	(52,567)	50,676,294
Total available-for-sale securities	$63,351,290	$ 44,702	$ (59,584)	$63,336,408
At September 30, 2008, maturities of our available-for-sale securities were as follows:				
Less than one year	$48,572,482	$ 10,790	$(504,566)	$48,078,706
One to two years	5,506,554	—	(21,617)	5,484,937
Total available-for-sale securities	$54,079,036	$ 10,790	$(526,183)	$53,563,643

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, 2008	December 31, 2007
Raw materials	$ 5,763,384	$4,924,139
Work in process	457,794	386,535
Finished goods	4,016,472	4,099,069
	$10,237,650	$9,409,743

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. Historically, returns arising from warranty issues have been infrequent and immaterial. Accordingly, we expense warranty returns as incurred.

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. We may also receive consideration from the settlement of patent infringement litigation where there was no prior patent license agreement. We record the consideration related to the settlement of such patent infringement litigation as other income.

Up-front licensing fees are deferred and recognized ratably over the related license period. Product development revenues are recognized over the period in which the related product development efforts are performed. Amounts received prior to the

performance of product development efforts are recorded as deferred revenues. Grant revenue is recognized as the related work is performed and costs are incurred. We record shipping and handling charges billed to our customers as product revenue and the related expense as cost of products sold. Taxes assessed by governmental authorities, such as sales or value-added taxes, are excluded from product revenues.

Significant Customer Concentration. The Company had the following significant concentrations in revenue and accounts receivable:

	Percentage of Total Revenues			
	Three Months Ended September 30,		Nine Months Ended September 30,	
Customer	2008	2007	2008	2007
Quest Diagnostics, Incorporated	11%	12%	10%	11%
Abbott Laboratories	10	10	10	10
Prestige Brands Holdings, Inc.	—	11	—	9

	Percentage of Accounts Receivable	
	September 30, 2008	December 31, 2007
Quest Diagnostics, Incorporated	10%	11%
Abbott Laboratories	11	9
SSL International plc	2	13
National Aids Control Program	10	4

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 costs associated with contract research organizations, or CROs. The invoicing from CROs can precede the services provided or can lag the service period by several months. Invoices paid prior to service being provided are recorded as a prepaid expense and then expensed appropriately as services are provided. We accrue the cost of services rendered but unbilled by CROs based on purchase order estimates provided by the CRO. Differences between the actual and estimated clinical trial expenses recorded are generally not material and are adjusted for in the period in which they become known.

Earnings Per Share. We have presented basic and diluted earnings (loss) per share pursuant to SFAS No. 128, “Earnings per Share.” In accordance with SFAS No. 128, basic earnings (loss) per share is computed by dividing net income (loss) by the weighted average number of shares of common stock outstanding during the period. Diluted earnings (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 price 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,	
	2008	2007	2008	2007
Net income (loss)	$ (1,761,652)	$ 4,059	$ (2,003,209)	$ 2,445,137
Weighted average shares of common stock outstanding:				
Basic	46,691,600	46,340,646	46,773,750	46,392,692
Dilutive effect of stock options, warrants and restricted stock	—	647,525	—	500,232
Diluted	46,691,600	46,988,171	46,773,750	46,892,924
Earnings (loss) per share:				
Basic	$ (0.04)	$ —	$ (0.04)	$ 0.05
Diluted	$ (0.04)	$ —	$ (0.04)	$ 0.05

For the three-month periods ended September 30, 2008 and 2007, outstanding common stock options and unvested restricted stock, representing 4,956,171 and 981,293 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, 2008 and 2007, outstanding common stock options, warrants, and unvested restricted stock representing 4,244,881 and 2,055,454 shares, respectively, were excluded from the computation of diluted earnings per share, as their inclusion would have been anti-dilutive.

Other Comprehensive Income (Loss). We follow SFAS No. 130, "Reporting Comprehensive Income." This statement requires the classification of items of other comprehensive income (loss) by their nature and disclosure of the accumulated balance of other comprehensive income (loss), separately from accumulated deficit and additional paid-in capital, in the stockholders' equity section of our balance sheet. Other comprehensive income (loss) at September 30, 2008 and December 31, 2007 consisted of currency translation adjustments and net unrealized gains or losses on marketable securities. Comprehensive income (loss) was $(2,015,409) and $(1,486) for the three months ended September 30, 2008 and 2007, respectively, and $(2,318,578) and $2,306,179 for the nine months ended September 30, 2008 and 2007, respectively.

Recent Accounting Pronouncements. In September 2006, the Financial Accounting Standards Board ("FASB") issued SFAS No. 157, "Fair Value Measurements." This Statement defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. On February 8, 2008, the FASB issued Staff Position 157-2, "Effective Date of FASB 157", which deferred the provisions of SFAS No. 157 to annual periods beginning after November 15, 2008 for non-financial assets and liabilities. Non-financial assets include fair value measurements associated with business acquisitions and impairment testing of tangible and intangible assets. See additional disclosures in Note 8, Fair Value of Financial Instruments, regarding the impact of the adoption of SFAS No. 157.

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities – Including an amendment of FASB Statement No. 115." SFAS No. 159 permits entities to elect to measure many financial instruments and certain other items at fair value. Unrealized gains and losses on items for which the fair value option has been elected will be recognized in earnings at each subsequent reporting date. SFAS No. 159 is effective in the first quarter of fiscal year 2008. We have elected not to apply the fair value option to any of our financial instruments.

3. Stock-Based Compensation

We grant stock-based awards under the OraSure Technologies, Inc. 2000 Stock Award Plan, as amended and restated (the "2000 Plan"). The 2000 Plan enables us to grant 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, 2008 and 2007 was $1.87 and $4.69 per share, respectively. The weighted average grant date fair value of stock options granted during the nine months ended September 30, 2008 and 2007 was $3.03 and $3.71 per share, respectively.

Total compensation cost related to stock options for the three months ended September 30, 2008 and 2007 was $559,905 ($392,465, net of tax) and $776,836 ($564,343, net of tax), respectively, of which $13,615 and $74,732 was capitalized into inventory during the quarters ended September 30, 2008 and 2007, respectively. The amounts recognized in cost of products sold for amounts previously capitalized were $40,023 and $15,781 for the three months ended September 30, 2008 and 2007, respectively. Total compensation cost related to stock options for the nine months ended September 30, 2008 and 2007 was $1,657,736 ($1,124,342, net of tax) and $2,258,446 ($1,657,957, net of tax), respectively, of which $92,201 and $235,864 was capitalized into inventory during the nine-month periods ended September 30, 2008 and 2007, respectively. The amounts recognized in cost of products sold for amounts previously capitalized were $160,205 and $214,799 for the nine-month periods ended September 30, 2008 and 2007, respectively.

The following table summarizes the stock option activity for the nine months ended September 30, 2008:

	Options
Outstanding on January 1, 2008	4,726,541
Granted	520,629
Exercised	(14,786)
Forfeited	(144,251)
Outstanding on September 30, 2008	5,088,133

As of September 30, 2008, there was $2,804,243 of unrecognized compensation expense related to unvested option awards that is expected to be recognized over a weighted average period of 1.7 years.

Net cash proceeds from the exercise of stock options were $92,517 and $1,742,999 for the nine months ended September 30, 2008 and 2007, 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. Generally, these shares are nontransferable and are subject to three-year vesting requirements or forfeiture, as determined by the Compensation Committee of our Board of Directors. The market value of these shares at the date of grant is recognized on a straight-line basis over the period during which the restrictions lapse. During the nine months ended September 30, 2008, we granted 418,565 restricted shares of our common stock, with a weighted average grant date fair value of $7.97 per share, to certain key officers and members of management. Compensation cost of $917,584 and $728,582 related to restricted shares was recognized during the three months ended September 30, 2008 and 2007, respectively. Compensation cost of $2,657,945 and $2,133,362 related to restricted shares was recognized during the nine months ended September 30, 2008 and 2007, respectively.

The following table summarizes restricted stock award activity for the nine months ended September 30, 2008:

	Shares
Issued and unvested, January 1, 2008	882,961
Granted	418,565
Vested	(386,070)
Forfeited	(45,646)
Issued and unvested, September 30, 2008	869,810

As of September 30, 2008, there was $5,314,983 of unrecognized compensation expense related to unvested restricted stock awards that is expected to be recognized over a weighted average period of 2.7 years. In connection with the vesting of restricted shares during the nine months ended September 30, 2008 and 2007, 132,302 and 87,619 shares, respectively, with aggregate values of $983,834 and $760,856, respectively, were withheld and retired in satisfaction of minimum tax withholding obligations.

4. Share Repurchase Program

On August 5, 2008, our Board of Directors approved a share repurchase program pursuant to which we are permitted to acquire up to $25 million of our outstanding common shares. During the three months ended September 30, 2008, we purchased and retired 626,385 shares of our common stock at an average price of $4.87 per share. Accordingly, we recorded a $3,051,899 reduction to additional paid-in capital during this same period. Included in accrued expenses at September 30, 2008 is $527,788 related to this repurchase program.

5. Accrued Expenses

	September 30, 2008	December 31, 2007
Payroll and related benefits	$ 3,137,667	$ 3,771,489
Royalties	1,960,515	2,485,869
Deferred revenue	1,779,266	2,841,640
Contract research obligation	608,948	191,903
Professional fees	417,150	1,371,850
Other	1,324,885	1,332,959
	$ 9,228,431	$ 11,995,710

Deferred revenue at September 30, 2008 and December 31, 2007 included customer prepayments of $1,653,566 and $2,726,440, respectively.

6. Other Income

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

In January 2007, our shares in a privately-held nonaffiliated company were sold and we received $1,765,943 for our ownership interest. Accordingly, during the first quarter of 2007, we recorded a $1,428,691 pre-tax gain on the sale of this investment in other income.

7. Geographic Information

Based on guidance in SFAS No. 131, "Disclosures about Segments of an Enterprise and Related Information," we believe we operate within one reportable segment. Our products are sold principally in the United States and Europe. Segmentation of operating income and identifiable assets is not applicable since our revenues outside the United States are export sales, and we do not have significant operating assets outside the United States.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
United States	$14,226	$16,806	$44,059	$49,682
Europe	1,175	1,654	5,527	7,042
Other regions	1,459	2,955	4,309	6,153
	$16,860	$21,415	$53,895	$62,877

8. Fair Value of Financial Instruments

Effective January 1, 2008, we adopted SFAS No. 157 for financial assets and liabilities measured on a recurring basis. SFAS No. 157 applies to all financial assets and liabilities that are being measured and reported on a fair value basis. Upon adoption of SFAS No. 157, there was no impact to our consolidated financial statements. The statement requires that fair value measurements be classified and disclosed in one of the following three categories:

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

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

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

All our available for sale securities described in Note 2 were classified and measured as Level 1 instruments.

9. Subsequent Event

On October 28, 2008, we submitted to the U.S. Food and Drug Administration a pre-market approval ("PMA") application for a rapid test for antibodies to the Hepatitis C virus ("HCV") utilizing our OraQuick® technology platform. The filing of this PMA application represents a specific development milestone under the terms of our license agreement with third parties, pursuant to which we have been granted a limited, personal, non-transferable, non-exclusive license related to certain HCV patents held by those parties. Achievement of this milestone requires us to make a $1.0 million payment to such parties, which we will record as in-process research and development expense in the fourth quarter of 2008.

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, expenses, cash flow or other financial performance or development, expected regulatory filings and approvals, planned business transactions, views of future industry, competitive or market conditions, and other factors that could affect our future operations, results of operations or financial position. These statements often include the words "believes," "expects," "anticipates," "intends," "plans," "estimates," "may," "will," "should," "could," or similar expressions. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include, but are not limited to: ability to market and sell products; changes in relationships, including disputes or disagreements, with strategic partners and reliance on strategic partners for the performance of critical activities under collaborative arrangements; failure of distributors or other customers to meet purchase forecasts or minimum purchase requirements for the Company's products; impact of replacing distributors; inventory levels at distributors and other customers; impact of competitors, competing products and technology changes; ability to develop, commercialize and market new products; market acceptance of oral fluid testing or other products; changes in market acceptance of products based on product performance; 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; volatility of our stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including changes in international funding sources; loss or impairment of sources of capital; ability to meet financial covenants in agreements with financial institutions; ability to retain qualified personnel; exposure to patent infringement, product liability, and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; ability to identify, complete and realize the full benefits of potential acquisitions; and general political, business and economic conditions. These and other factors are discussed more fully in our Securities and Exchange Commission ("SEC") filings, including our registration statements, Annual Report on Form 10-K for the year ended December 31, 2007, Quarterly Reports on Form 10-Q, and other filings with the SEC. Although forward-looking statements help to provide complete 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 *in vitro* diagnostic tests that are used on other specimen types, and other medical devices used for the removal of warts and other benign skin lesions by cryosurgery, or freezing. Our diagnostic products include tests which are performed on a rapid basis at the point of care and tests which are processed in a laboratory. These products are sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, distributors, government agencies, physicians' offices, and commercial and industrial entities. One of our products has been sold in the over-the-counter ("OTC") or consumer retail market in the United States, Canada, Europe, Mexico and Australia.

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

During the first nine months of 2008, our total revenues were $53.9 million, which represents a 14% decrease from the same period in 2007. Our net loss for the nine months ended September 30, 2008 was $2.0 million, compared to net income of $2.4 million for the nine months ended September 30, 2007. Our net loss during the first nine months of 2008 includes a $4.9 million payment received from Schering-Plough Healthcare Products, Inc. ("Schering-Plough") as a result of our licensing and settlement agreement entered into to resolve our patent infringement litigation, which has been recorded in other income. Net income during the first nine months of 2007 includes a pre-tax gain of $1.4 million related to the sale of our investment in a privately-held nonaffiliated company. Cash flow used in operating activities for the nine months ended September 30, 2008 was $3.7 million, as compared to $7.8 million provided by operating activities for the nine months ended September 30, 2007, primarily as a result of increases in accounts receivable and inventories coupled with a decrease in accounts payable and accrued expenses, offset by non-cash charges for stock-based compensation, depreciation and amortization. As of September 30, 2008, we had $85.4 million in cash, cash equivalents and short-term investments, a $10.2 million decrease from December 31, 2007.

Sales into the infectious disease testing market increased by 11% in the first nine months of 2008 as a result of increased demand for our OraQuick *ADVANCE*® rapid HIV-1/2 antibody test. This increase resulted largely from increased sales directly to various public health organizations and reflects continued growth of our base business.

Abbott Laboratories ("Abbott") is our exclusive distributor in the U.S. hospital market and a non-exclusive distributor in the U.S. physicians' office marketplace. As our exclusive distributor to hospitals, Abbott sells OraQuick *ADVANCE*® to federal hospitals under the terms and conditions of our Federal Supply Schedule that is on file with the U.S. General Services Administration. We have retained exclusive rights to all other markets, including the public health and criminal justice markets, the military, the Centers for Disease Control and Prevention ("CDC"), the Substance Abuse and Mental Health Services Administration ("SAMHSA") and other government agencies.

On October 31, 2008, we mutually agreed with Abbott to terminate our distribution agreement. As a result, beginning in 2009, we will sell OraQuick *ADVANCE*® directly to hospitals and reference laboratories and continue to sell this product to physicians' offices through distributors. Pursuant to a transition agreement with Abbott, we will pay a one-time, lump sum termination fee, and Abbott will assist in transitioning its OraQuick *ADVANCE*® customers to us. Upon payment of the termination fee, which will occur during the first quarter of 2009, we will have no royalty or similar ongoing financial obligation to Abbott as a result of the termination of the distribution agreement. We are in the process of expanding our hospital sales force and related support resources in order to handle the expansion of our direct sales business.

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

Sales of our cryosurgical products decreased 58% during the first nine months of 2008 compared to 2007 as a result of the termination of the distribution agreement for our domestic OTC product (as described below), as well as a decrease in sales of our OTC product internationally. The cryosurgical systems market represents sales of Histofreezer® into both the domestic and international physicians'

office markets and sales of the OTC formulation of this product through international distributors. Prestige Brands Holdings, Inc. ("Prestige") previously distributed our cryosurgical wart removal product under its Compound W Freeze Off® tradenames in the OTC market in the United States and Canada. Our distribution agreement with Prestige terminated on December 31, 2007. As a result, we are currently preparing to re-enter the U.S. OTC cryosurgery marketplace in the first quarter of 2009 with our own branded product offering.

SSL International plc ("SSL") distributes our cryosurgical product under its Scholl's and Dr. Scholl trademarks in the OTC market in several European countries, Australia and New Zealand. Genomma Labs ("Genomma") also distributes a similar product to the OTC market in Mexico and has rights to Argentina, Brazil and various other Central and South American countries. Overall, our international OTC cryosurgical sales decreased 61% in the first nine months of 2008 compared to the same period in the prior year due to an unanticipated inventory buildup at Genomma and a decline in revenues experienced by SSL in key markets outside of the United Kingdom.

Sales to the substance abuse testing market decreased 15% during the first nine months of 2008, due primarily to declining employment and economic conditions in the United States and international funding issues. Our workplace testing business has been impacted by the decline in employment rates in some of the markets that use our Intercept® collection device and related assays. We do not expect renewed growth in the utilization of our Intercept® product line until employment conditions in the U.S. recover and international criminal justice funding is increased.

Sales to the insurance risk assessment market increased 14% during the nine months ended September 30, 2008 compared to 2007. The increase was largely due to the timing of purchases by our laboratory distributors and increased sales of our Western Blot HIV-1 confirmatory test.

Because of the regulatory approvals needed for most of our products, we often are required to rely on sole source providers for critical components and materials and on related products supplied by third parties. This is particularly true for our OraQuick *ADVANCE*® test, our OraSure® oral fluid collection device and our oral fluid Western blot HIV-1 confirmatory product. If we are unable to obtain necessary components or materials from our sole source providers or if third parties do not continue to sell their related products, the time required to develop replacements and obtain the required Food and Drug Administration ("FDA") approvals could disrupt our ability to sell the affected products.

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

We also rely heavily on distributors to purchase and resell many of our products. For example, SSL has exclusive rights to distribute our wart removal product in the OTC market in Europe, Australia and New Zealand. We also granted Genomma exclusive rights to distribute our wart removal product in the OTC market in Mexico, Argentina, Brazil and various other Central and South American countries.

We expect to enter into additional distribution agreements for new and future products in the U.S. and internationally. If our distributors are unable or unwilling to meet the minimum purchase commitments set forth in their agreements or otherwise substantially reduce the volume of their purchases, our revenues and results of operations could be adversely affected.

During the nine months ended September 30, 2008, we generated 82% of our revenues in the U.S. marketplace. We are continually evaluating strategies to increase our sales penetration in markets outside the U.S. As our business in foreign countries increases, we could be exposed to other economic, political, exchange rate, regulatory and cultural risks.

Results of Operations

Three months ended September 30, 2008 compared to September 30, 2007

Total revenues decreased 21% to $16.9 million in the third quarter of 2008 from $21.4 million in the comparable quarter in 2007. Increased sales of our OraQuick *ADVANCE*® rapid HIV-1/2 antibody test were more than offset by expected decreased sales of our cryosurgical and substance abuse testing products. Revenues derived from products sold to customers outside the U.S. were $2.6 million and $4.6 million, or 16% and 22% of total revenues, in the third quarters of 2008 and 2007, respectively.

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	2008	2007	Change	2008	2007
Infectious disease testing	$ 9,743	$ 8,233	18%	58%	38%
Substance abuse testing	3,581	4,070	(12)	21	19
Cryosurgical systems	1,671	6,738	(75)	10	31
Insurance risk assessment	1,163	1,620	(28)	7	8
Product revenues	16,158	20,661	(22)	96	96
Licensing and product development	702	754	(7)	4	4
Total revenues	$16,860	$21,415	(21)%	100%	100%

Infectious Disease Testing Market

Sales to the infectious disease testing market increased 18% to $9.7 million in the third quarter of 2008, primarily as a result of the continued strong performance of our OraQuick *ADVANCE*® rapid HIV-1/2 antibody test in an increasingly competitive environment. OraQuick® sales totaled $8.9 million and $7.5 million in the third quarters of 2008 and 2007, respectively. Sales of our OraSure® oral fluid collection device totaled $830,000 and $702,000 in the third quarters of 2008 and 2007, respectively.

The table below shows a breakdown of our total OraQuick® revenues (in thousands, except %) during the third quarters of 2008 and 2007.

	Three Months Ended September 30,		
Customers	2008	2007	% Change
Direct to U.S. Public Health	$ 6,147	$ 4,492	37%
Abbott	1,799	2,159	(17)
International	957	850	13
SAMHSA / CDC	10	30	(67)
Total OraQuick® revenues	$ 8,913	$ 7,531	18%

During the third quarter of 2008, OraQuick® revenue derived from direct sales to the U.S. public health market increased 37% compared to the same period of 2007. This increase is the result of continued growth in our base business and incremental sales driven by the efforts of the CDC to increase HIV testing. In September 2007, the CDC awarded incremental funding to expand HIV testing and prevention programs in populations disproportionately affected by HIV, primarily African Americans. These funds were allocated to targeted state and public health agencies for utilization during 2008.

For the three months ended September 30, 2008, sales to our hospital distributor, Abbott, decreased 17% to $1.8 million, compared to $2.2 million in 2007. This decrease was largely the result of Abbott's ordering patterns, the impact of negotiations to end our distribution agreement at the end of 2008 and increased competition in the U.S. hospital market.

We believe that our OraQuick *ADVANCE*® device, which is FDA-approved for detecting antibodies to both HIV-1 and HIV-2 in oral fluid, finger-stick and venous whole blood, and plasma samples, and has received a waiver under the Clinical Laboratory Improvements Amendment of 1988 ("CLIA") for use with all sample types except plasma, provides a significant competitive advantage, thereby enabling us to fully implement a strategy for selling OraQuick® internationally. We received CE mark approval for our OraQuick *ADVANCE*® test and we currently sell small quantities of this product in Europe. We have established distribution channels in several European countries and are pursuing other distributors elsewhere in the European Union.

International sales of our OraQuick® HIV test increased 13% to $957,000 in the three months ended September 30, 2008 compared to $850,000 in 2007 primarily due to increased sales in Latin America.

Substance Abuse Testing Market

Sales to the substance abuse testing market decreased 12% to $3.6 million in the third quarter of 2008 from $4.1 million in the third quarter of 2007, as sales of our Intercept® product for workplace testing were impacted by the continued decline in employment rates domestically and a decrease in criminal justice funding internationally.

The table below shows a breakdown of our total Intercept® revenues (in thousands, except %) generated in each market during the third quarters of 2008 and 2007.

	Three Months Ended September 30,		
Market	**2008**	**2007**	**% Change**
Workplace testing	$ 1,193	$ 1,845	(35)%
Criminal justice	637	641	(1)
International	481	525	(8)
Direct	303	273	11
Total Intercept® revenues	$ 2,614	$ 3,284	(20)%

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, are expected to come under increasing competitive pressure in the future from "home-brew" assays developed internally by our laboratory customers. Our oral fluid microplate assays also compete with urine-based homogeneous assays that are run on fully-automated, random access analyzers. We believe our competitors are developing oral fluid tests suitable for use on these fully automated homogeneous assay systems and these assays, if and when they are developed and commercialized, could represent a significant competitive threat to our oral fluid microplate business. In order to meet this competition, we are jointly developing and intend to commercialize fully-automated homogeneous oral fluid drugs of abuse assays with Roche Diagnostics for use with our Intercept® device.

Cryosurgical Systems Market

Sales of our products in the cryosurgical systems market (which includes both the physicians' office and OTC markets) decreased 75% to $1.7 million in the third quarter of 2008, compared to $6.7 million in the same period of the prior year. This decrease was primarily the result of the absence of U.S. OTC cryosurgical product sales as a result of the termination of our distribution relationship for this product at the end of 2007, coupled with a decrease in international OTC cryosurgical sales caused by an unanticipated inventory buildup at Genomma and lower outsales by SSL.

The table below shows a breakdown of our total cryosurgical systems revenues (in thousands, except %) generated in each market during the third quarters of 2008 and 2007.

	Three Months Ended September 30,		
Market	2008	2007	% Change
Professional domestic	$ 903	$ 1,028	(12)%
Professional international	401	574	(30)
OTC domestic	—	2,453	(100)
OTC international	367	2,683	(86)
Total cryosurgical systems revenues	$ 1,671	$ 6,738	(75)%

Our domestic OTC cryosurgical product, called Freeze Off®, was distributed in the United States and Canada by Prestige, owner of the Compound W® line of wart removal products. Our distribution agreement with Prestige terminated on December 31, 2007. Sales to Prestige were $2.5 million during the third quarter of 2007. We are currently preparing to reenter the U.S. OTC cryosurgery marketplace in the first quarter of 2009 with our own branded product offering.

We have an agreement with SSL under which we manufacture and supply, and SSL distributes on an exclusive basis, our cryosurgical wart removal product in the OTC market in Europe, Australia and New Zealand. The product is manufactured and sold under SSL's Scholl and Dr. Scholl trademarks. Sales to SSL under the distribution agreement were $367,000 and $597,000 in the third quarters of 2008 and 2007, respectively. The decline in the current quarter was due to lower outsales by SSL in key markets outside the United Kingdom.

We have entered into agreements with Genomma pursuant to which Genomma distributes on an exclusive basis our cryosurgical wart removal product in the OTC market in Mexico, Argentina, Brazil and various other Central and South American countries. Sales to Genomma relate primarily to Mexico and were $2.1 million in the third quarter of 2007 with no sales in the third quarter of 2008. In the Mexican OTC market, Genomma reduced their purchase forecast as a result of an unexpected return of product to them by a number of retail outlets in the latter part of the first quarter of 2008 due to overstocking of inventory during the winter months. We are working closely with Genomma to drive greater uptake of our product in the retail channel in Mexico and to generate new sales in other Central and South American countries. We believe these markets represent potential sales opportunities for our cryosurgery product, but the full realization of such sales will take time.

Sales of our Histofreezer® product to physicians' offices in the U.S and internationally during the third quarter of 2008 decreased 12% and 30%, respectively, compared to the same period in 2007. Histofreezer® sales in the U.S. continued to be impacted by the diversion of Histofreezer® product by several of our international distributors into the U.S. professional market. This situation occurs because product is sold at a lower price in some countries outside the U.S. since health care systems in those countries are more economically sensitive. We believe the alternate sourcing of lower cost Histofreezer® product from international distributors has adversely affected our sales in the U.S. and this negative impact on sales will continue over the balance of 2008 until those U.S. distributors work through inventory of previously-acquired lower cost product. We are addressing this situation by increasing

international pricing of our Histofreezer® product, changing product labeling and packaging, and exercising our contractual rights against certain international distributors. These actions negatively impacted international sales of Histofreezer® in the third quarter of 2008.

Insurance Risk Assessment Market

Sales to the insurance risk assessment market decreased 28% to $1.2 million in the third quarter of 2008 compared to $1.6 million in 2007. This decrease can be attributed to the ordering patterns of two of our largest laboratory distributors, as well as an overall decrease in life insurance policies as a result of current economic conditions.

License and Product Development

During the third quarter of 2008, licensing and product development revenues decreased $52,000 to $702,000 from $754,000 during 2007. Third quarter 2008 licensing revenue included royalties from Schering-Plough pursuant to our license and settlement agreement executed in January 2008.

In December 2006, we entered into a collaboration agreement with Schering-Plough Corporation ("SPC"), for the development and promotion of a rapid oral fluid test for the detection of antibodies to the Hepatitis C virus ("HCV"). During the three months ended September 30, 2007, we recognized $727,000 in revenues associated with funded research and development under this agreement. We do not expect to recognize any additional licensing and product development revenues pursuant to this agreement. However, in early 2008, we entered into a new collaboration agreement with SPC for the development and promotion of our rapid oral fluid HCV test on a worldwide basis. Under the terms of the new agreement, we will retain the rights to market and sell the HCV test throughout the world, and SPC will reimburse us for certain development and regulatory costs based on the achievement of certain milestones. SPC will also provide promotional support for the product in international markets. Revenues from this agreement are not expected to be material in 2008.

Gross Margin

Gross margin in the third quarter of 2008 was 58%, compared to 60% for the third quarter of 2007. Gross margin was impacted primarily by an unfavorable change in product mix versus the year ago period, partially offset by a decline in overhead costs, decreased scrap and spoilage expense and lower product support costs.

Operating Expenses

Research and development expenses increased 13% to $4.2 million in the third quarter of 2008 from $3.7 million in the same period in 2007, primarily as a result of costs associated with the clinical development of our OraQuick® HIV OTC test and OraQuick® HCV test. We expect research and development expenses to increase in the fourth quarter of 2008 primarily due to a $1.0 million milestone payment required to be made pursuant to our HCV patent license.

Sales and marketing expenses increased 7% to $5.3 million in the third quarter of 2008 from $5.0 million in the same period in 2007. This increase was largely due to increased staffing and related charges related to recent organizational changes, as well as increased marketing expenses. We expect sales and marketing expense to continue to increase in the fourth quarter of 2008 as a result of these organizational changes and as we prepare to transition to a direct sales model for OraQuick *ADVANCE*® in the hospital market.

General and administrative expenses decreased 30% to $3.6 million in the third quarter of 2008 from $5.1 million in the same period in 2007. This decrease was primarily attributable to a decrease in legal costs as a result of the conclusion of the Prestige and Schering-Plough legal proceedings. Fourth quarter 2008 general administrative expenses are expected to increase approximately $2.0 million as we incur additional legal costs related to patent infringement litigation with Inverness Medical and Church & Dwight and costs associated with terminating our distribution contract with Abbott.

Other Income/Expense

Interest expense decreased to $95,000 in the third quarter of 2008 from $168,000 in the third quarter of 2007, as a result of lower outstanding debt balances and a decreased interest rate. Interest income decreased to $667,000 in the third quarter of 2008 from $1.2 million in the third quarter of 2007, as a result of lower yields on our investment portfolio and lower investment balances.

We purchase some of our cryosurgical products from, or utilize the services of, vendors located in The Netherlands. As a result of the decline in the exchange rate between the United States dollar and the Euro, we recorded minimal gains on foreign currency transactions for the three months ended September 30, 2008 and 2007.

Income Taxes

During the three months ended September 30, 2008, we recorded a federal and state income tax benefit of $991,000, which reflects an effective tax rate of 36%. During the three months ended September 30, 2007, we recorded a provision for federal and state income taxes of $124,000. The estimated annual effective rate for the quarter ended September 30, 2008 reflects a projected loss for the fiscal year, offset by the impact of permanent differences generated by items which are not deductible on our income tax returns.

Nine months ended September 30, 2008 compared to September 30, 2007

Total revenues decreased 14% to $53.9 million for the first nine months of 2008 from $62.9 million in the comparable period in 2007. Increased sales of our OraQuick *ADVANCE*® rapid HIV-1/2 antibody test and insurance risk assessment testing products were more than offset by decreased sales of our cryosurgical and substance abuse testing products and lower licensing and product development revenue. Revenues derived from products sold to customers outside the U.S. were $9.8 million and $13.2 million, or 18% and 21% of total revenues, during the first nine months of 2008 and 2007, respectively.

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.

	Nine Months Ended September 30,				
	Dollars		%	Percentage of Total Revenues	
	2008	2007	Change	2008	2007
Infectious disease testing	$29,260	$26,350	11%	54%	42%
Substance abuse testing	10,554	12,396	(15)	20	20
Cryosurgical systems	7,726	18,190	(58)	14	29
Insurance risk assessment	4,395	3,859	14	8	6
Product revenues	51,935	60,795	(15)	96	97
Licensing and product development	1,960	2,082	(6)	4	3
Total revenues	$53,895	$62,877	(14)%	100%	100%

Infectious Disease Testing Market

Sales into the infectious disease testing market increased in the first nine months of 2008 as a result of the continued strong performance of our OraQuick *ADVANCE*® HIV-1/2 test in an increasingly competitive market. This increase resulted largely from increased sales directly to various public health organizations, and reflects continued growth of our base business and incremental sales resulting from the testing initiatives funded by the CDC and directed to populations disproportionately affected by HIV/AIDS. OraQuick® sales totaled $27.0 million and $24.0 million in the first nine months of 2008 and 2007, respectively. Sales of our OraSure® oral fluid collection device totaled $2.2 million and $2.4 million in the first nine months of 2008 and 2007, respectively.

The table below shows a breakdown of our total OraQuick® revenues (in thousands, except %) during the first nine months of 2008 and 2007.

	Nine Months Ended September 30,		
Customers	2008	2007	% Change
Direct to U.S. Public Health	$ 19,263	$ 14,339	34%
Abbott	5,489	6,087	(10)
International	2,303	2,110	9
SAMHSA / CDC	10	1,464	(99)
Total OraQuick® revenues	$ 27,065	$ 24,000	13%

OraQuick® revenue derived from direct sales to the U.S. public health market increased by 34% during the first nine months of 2008 compared to the same period of 2007. This increase is the result of continued growth in usage of the OraQuick *ADVANCE*® rapid HIV-1/2 antibody test in public health settings, including city-wide testing programs. In September 2007, the CDC awarded incremental funding to expand HIV testing and prevention programs in populations disproportionately affected by HIV. The funds were allocated to targeted state and public health agencies for utilization during 2008. Sales related to city-wide testing initiatives increased 33% to $1.6 million during the first nine months of 2008, compared to $1.2 million in 2007.

For the nine months ended September 30, 2008, sales to our hospital distributor, Abbott, decreased 10% to $5.5 million, as compared to $6.1 million in 2007. This decrease was largely the result of Abbott's ordering patterns, the impact of negotiations to end our distribution agreement at the end of 2008 and increased competition in the U.S. hospital market.

In previous periods, the CDC and SAMHSA placed bulk purchase orders for OraQuick *ADVANCE*® devices and related testing materials directly with us. It is not likely that comparable-sized bulk purchase orders from these governmental entities or others will be received in the future.

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

International sales of our OraQuick® HIV test increased 9% to $2.3 million during the first nine months of 2008 as compared to $2.1 million during the first nine months of 2007. This increase is due to higher sales in Africa and Latin America.

During the first nine months of 2008, sales of our OraSure® oral fluid collection device declined $155,000. Some customers who have purchased our OraSure® device for laboratory HIV-1 testing in the past are now electing instead to purchase our OraQuick *ADVANCE*® test. We believe this is the result of customers recognizing the benefits of rapid HIV testing, especially with oral fluid, and the CDC's efforts to increase rapid HIV testing in healthcare settings. We expect this decline in OraSure® sales to continue.

Substance Abuse Testing Market

Sales to the substance abuse testing market decreased 15% to $10.6 million in the first nine months of 2008 from $12.4 million in the first nine months of 2007, as sales of our Intercept® products for workplace testing were impacted by the continued decline in employment rates domestically and a decrease in criminal justice funding internationally.

The table below shows a breakdown of our total Intercept® revenues (in thousands, except %) generated in each market during the first nine months of 2008 and 2007.

	Nine Months Ended September 30,		
Market	2008	2007	% Change
Workplace testing	$ 3,480	$ 5,368	(35)%
Criminal justice	1,965	1,948	1
International	1,570	1,757	(11)
Direct	904	739	22
Total Intercept® revenues	$ 7,919	$ 9,812	(19)%

We do not expect renewed growth in the utilization of our Intercept® product line 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, are expected to come under increasing competitive pressure in the future from “home-brew” assays developed internally by our laboratory customers. Our oral fluid microplate assays also compete with urine-based homogeneous assays that are run on fully-automated, random access analyzers. We believe our competitors are developing oral fluid tests suitable for use on these fully automated homogeneous assay systems and these assays, if and when they are developed and commercialized, could represent a significant competitive threat to our oral fluid microplate business. In order to meet this competition, we are jointly developing and intend to commercialize fully-automated homogeneous oral fluid drugs of abuse assays with Roche Diagnostics for use with our Intercept® device.

Cryosurgical Systems Market

Sales of our products in the cryosurgical systems market (which includes both the physicians’ office and OTC markets) decreased 58% to $7.7 million for the first nine months of 2008, compared to $18.2 million in the same period of the prior year. This decrease was primarily the result of the absence of U.S. OTC cryosurgical product sales as a result of the termination of our distribution relationship for this product at the end of 2007, coupled with a decrease in international OTC cryosurgical sales caused by an unanticipated inventory buildup at Genomma and lower outsales by SSL.

The table below shows a breakdown of our total cryosurgical systems revenues (in thousands, except %) generated in each market during the first nine months of 2008 and 2007.

Market	Nine Months Ended September 30, 2008	2007	% Change
Professional domestic	$ 2,942	$ 3,441	(15)%
Professional international	1,802	1,551	16
OTC domestic	—	5,587	(100)
OTC international	2,982	7,611	(61)
Total cryosurgical systems revenues	$ 7,726	$ 18,190	(58)%

Our domestic OTC cryosurgical product, called Freeze Off®, was distributed in the United States and Canada by Prestige, owner of the Compound W® line of wart removal products. Our distribution agreement with Prestige terminated on December 31, 2007. Sales to Prestige were $5.6 million during the first nine months of 2007. We are currently preparing to reenter the U.S. OTC cryosurgery marketplace in the first quarter of 2009 with our own branded product offering.

We have an agreement with SSL under which we manufacture and supply, and SSL distributes on an exclusive basis, our cryosurgical wart removal product in the OTC market in Europe, Australia and New Zealand. The product is manufactured and sold under SSL's Scholl and Dr. Scholl trademarks. Sales to SSL under the distribution agreement were $2.6 million and $3.8 million in the nine months ended September 30, 2008 and 2007, respectively. The decrease of approximately $1.2 million is primarily due to a decline in outsales by SSL in certain key markets outside of the United Kingdom.

We have entered into an agreement with Genomma pursuant to which Genomma distributes on an exclusive basis our cryosurgical wart removal product in the OTC market in Mexico, Argentina, Brazil and various other Central and South American countries. Sales to Genomma relate primarily to Mexico and were $401,000 and $3.8 million during the nine months ended September 30, 2008 and 2007, respectively. In the Mexican OTC market, Genomma reduced their 2008 purchase forecast as a result of an unexpected return of product to them by a number of retail outlets in the first quarter of 2008, due to overstocking of inventory during the winter months. We are working closely with Genomma to drive greater uptake of our product in the retail channel in Mexico and to generate new sales in other Central and South American countries. We believe these markets represent potential sales opportunities for our cryosurgery product, but the full realization of such sales will take time.

Sales of our Histofreezer® product to physicians' offices in the U.S. decreased 15% while sales of Histofreezer® to international physicians' offices increased 16% during the first nine months of 2008. Histofreezer® sales in the U.S. continued to be impacted by the diversion of Histofreezer® product by several international distributors into the U.S. professional market. This situation occurs because product is sold at a lower price in some countries outside the U.S. since health care systems in those countries are more economically sensitive. We believe the alternate sourcing of lower cost Histofreezer® product from international distributors has adversely affected our sales in the U.S. and this negative impact on sales will continue over the balance of 2008 until those U.S. distributors work through inventory of previously-acquired lower cost product. We are addressing this situation by increasing international pricing of our Histofreezer® product, changing product labeling and packaging, and exercising our contractual rights against certain international distributors. The increase in international physician office sales of Histofreezer® is primarily the result of the engagement of new distributors in additional countries.

Insurance Risk Assessment Market

Sales to the insurance risk assessment market increased 14% to $4.4 million during the nine months ended September 30, 2008, compared to $3.9 million in 2007. This increase was primarily due to lower sales in the early months of 2007.

License and Product Development

During the first nine months of 2008, licensing and product development revenues decreased to $2.0 million, compared to $2.1 million during 2007. Licensing revenue for the first nine months of 2008 is primarily comprised of payments from Schering-Plough pursuant to our license and settlement agreement executed in January 2008.

In December 2006, we entered into a collaboration agreement with SPC for the development and promotion of a rapid oral fluid test for the detection of antibodies to HCV. During the first nine months of 2007, we recognized $2.0 million in revenues associated with funded research and development under this agreement. We do not expect to recognize any additional licensing and product development revenues pursuant to this agreement. However, in early 2008, we entered into a new collaboration agreement with SPC for the development and promotion of our rapid oral fluid HCV test on a worldwide basis. Under the terms of the new agreement, we will retain the rights to market and sell the HCV test throughout the world, and SPC will reimburse us for certain development and regulatory costs based on the achievement of certain milestones. SPC will also provide promotional support for the product in international markets. Revenues from this agreement are not expected to be material in 2008.

Gross Margin

Gross margin in the first nine months of 2008 was 58% compared to 62% for the first nine months of 2007. Gross margin was impacted primarily by an unfavorable change in product mix and increased scrap and spoilage expense, partially offset by improved absorption of overhead costs and lower product support costs.

Operating Expenses

Research and development expense increased 50% to $14.9 million in the first nine months of 2008 from $9.9 million in the same period in 2007, primarily as a result of costs associated with the clinical development of our OraQuick® HCV test and our OraQuick® HIV OTC test. We expect research and development expenses to increase in the fourth quarter of 2008 primarily due to a $1.0 million milestone payment required to be made pursuant to our HCV patent license.

Sales and marketing expenses increased 3% to $15.5 million in the nine month period ended September 30, 2008 from $15.0 million in the same period in 2007. This increase was primarily the result of increased staffing and related charges driven in part by recent organizational changes, partially offset by lower costs associated with reimbursable distributor advertising and promotional costs. We expect sales and marketing expense to continue to increase in the fourth quarter of 2008 as a result of these organizational changes and as we prepare to transition to a direct sales model for OraQuick *ADVANCE*® in the hospital market.

General and administrative expenses decreased 17% to $11.3 million in the first nine months of 2008 from $13.6 million in the same period in 2007. This decrease was primarily attributable to a decrease in legal costs as a result of the conclusion of the Prestige and Schering-Plough legal proceedings, lower consulting fees and a decrease in certain other corporate taxes. Fourth quarter 2008 general and administrative expenses are expected to increase approximately $2.0 million as we incur additional legal costs related to patent infringement litigation with Inverness Medical and Church & Dwight and costs associated with terminating our distribution contract with Abbott.

Other Income/Expense

Interest expense decreased to $251,000 for the nine month period ended September 30, 2008 from $499,000 in the same period of 2007, as a result of lower outstanding debt balances, a decreased interest rate, and an increase in capitalized interest related to construction-in-progress. Interest income decreased to $2.5 million in 2008 from $3.5 million in 2007, as a result of lower yields on our investment portfolio and lower investment balances.

We purchase some of our cryosurgical products from, or utilize the services of, vendors located in The Netherlands. As a result of the decline in the exchange rate between the United States dollar and the Euro, we recorded immaterial losses on foreign currency transactions for both the nine months ended September 30, 2008 and 2007.

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

In January 2007, we sold our ownership interest in a privately-held nonaffiliated company and recorded a $1.4 million pre-tax gain on the sale of this investment which was included in other income during the first quarter of 2007.

Income Taxes

During the nine months ended September 30, 2008 we recorded a benefit for federal and state income taxes of $1.1 million which reflects an effective tax rate of 35%. During the nine months ended September 30, 2007, we recorded a provision for federal and state income taxes of $2.2 million, which reflects a 48% effective tax rate. The estimated annual effective rate for the nine months ended September 30, 2008 reflects a projected loss for the fiscal year, offset by the impact of permanent differences generated by items which are not deductible on our income tax returns.

Liquidity and Capital Resources

	September 30, 2008	December 31, 2007
	(In thousands)	
Cash and cash equivalents	$ 31,818	$ 32,230
Short-term investments	53,564	63,336
Working capital	99,549	105,620

Our cash, cash equivalents and short-term investments decreased $10.2 million during the first nine months of 2008 to $85.4 million at September 30, 2008, primarily as a result of $3.7 million in cash flow used to fund operations, the purchase of $1.9 million of property and equipment, payment of licensing fees of $200,000, long-term debt repayments of $376,000, the purchase and retirement of $2.5 million of common stock under the terms of our recently announced stock repurchase plan, and the retirement of $984,000 of common stock used to satisfy minimum tax withholdings associated with the vesting of restricted shares during the period. Offsetting these uses of funds was $93,000 in cash received from the exercise of stock options during the nine months ended September 30, 2008.

Net cash used to fund operating activities was $3.7 million in the first nine months of 2008. Increases to operating cash during the nine months ended September 30, 2008 included the following non-cash items: stock-based compensation expense of $4.3 million, depreciation and amortization expense of $2.1 million; a provision for excess and obsolete inventories of $1.1 million; and a $1.3 million decrease in prepaid expenses and other assets. Offsetting these sources of cash was a net loss of $2.0 million; a deferred tax benefit of $1.3 million; a $1.9 million increase in inventories primarily related to increased raw material levels for our cryosurgical product line; a $1.1 million increase in accounts receivable, primarily due to the intra-quarter distribution of revenues; and decreases in accounts payable of $3.0 million and accrued expenses of $3.3 million, largely due to payments of our year-end royalty, legal, and other accruals.

Net cash provided by investing activities during the first nine months of 2008 was $7.1 million. During this period, we purchased $1.9 million of property and equipment and paid licensing fees of $200,000. We also had net proceeds from the maturity and redemption of short-term investments of $9.3 million during the nine months ended September 30, 2008. We expect additional capital expenditures of $500,000 during the remaining three months of 2008, as we purchase additional information systems equipment, upgrade certain older equipment and make improvements to our facilities.

Net cash used in financing activities during the first nine months of 2008 was $3.8 million, reflecting $376,000 of loan principal repayments, the purchase of 626,385 shares of common stock at an aggregate cost of $3.1 million, of which $2.5 million was disbursed by September 30, 2008, and $984,000 expended for the withholding and retirement of common stock related to restricted stock vesting. Offsetting these uses of cash was $93,000 in proceeds received from the exercise of stock options.

We have in place a $14 million credit facility (the “Credit Facility”) with Comerica Bank (“Comerica”) which is comprised of a $10 million facilities advance and a $4 million revolving working capital line of credit. At our option, interest on the facilities advance is payable monthly at either a fixed rate equal to the five-year U.S. Treasury Note rate plus 1.03% to 1.73%, or a variable rate equal to the 30, 180, or 360-day LIBOR plus 0.55% to 1.25%. Principal is repayable in periodic installments, based upon the rate option that we elect, with the remaining balance of unpaid principal due on June 27, 2011. 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 pus 2.55%, in each case determined at the time of funding.

In January 2008, we elected to fix the interest rate on the facilities advance at 4.15% until its maturity in June 2011, with principal and interest payable on a monthly basis.

As of September 30, 2008, we had $8.9 million in outstanding borrowings under the facilities advance and no outstanding borrowings under the $4 million revolving working capital line of credit.

All borrowings under the Credit Facility are collateralized by a first priority security interest in all of our assets, including present and future accounts receivable, chattel paper, contracts and contract rights, equipment and accessories, general intangibles, investments, instruments, inventories and a mortgage on our three facilities in Bethlehem, Pennsylvania. Borrowings under the revolving working capital line of credit are limited to commercially standard percentages of accounts receivable. The Credit Facility contains certain covenants that set forth minimum requirements for our quick ratio, liquidity and tangible net worth. We were in full compliance with all covenants at September 30, 2008. The Credit Facility also restricts our ability to pay dividends, to purchase stock, 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.

In the December 31, 2007 financial statements, we had NOL carryforwards of $45.5 million for federal income tax purposes. During the fourth quarter of 2005, the Company retained independent tax specialists to perform an ownership change study and analysis to determine the annual limitation amount applicable to utilization of the net operating loss (“NOL”) carryforwards due to past ownership changes, as defined in Section 382 of the Internal Revenue Code. We continue to review ownership changes on a quarterly basis. We do not believe that the ownership change limitations would impair our ability to use our NOL carryforwards against our forecasted taxable income.

The combination of our current cash and short-term investments, anticipated cash flow from operations and available borrowings under our Credit Facility is expected to be sufficient to fund our operating and capital needs for the foreseeable future, including our ability to fund the repurchase of common stock as described below. However, our cash requirements 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 magnitude of capital expenditures, changes in existing and potential relationships with business partners, the time and cost of obtaining regulatory approvals, the costs involved in obtaining and enforcing patents, proprietary rights and any necessary licenses, the cost and timing of expansion of sales and marketing activities, the timing of market launch of new products, market acceptance of new products, competing technological and market developments and other factors. In addition, we expect to use cash from working capital or our short-term investments to fund the repurchases of our common stock pursuant to the stock repurchase program announced on August 5, 2008, under which we may purchase up to $25 million of our outstanding common stock. We have obtained the consent of Comerica to implement this repurchase program, which may be discontinued at any time.

Summary of Contractual Obligations

The following sets forth our approximate aggregate obligations at September 30, 2008 for future payments under contracts and other contingent commitments, for 2008 and beyond:

Contractual Obligations	Total	Payments due by December 31, 2008	2009	2010	2011	2012	Thereafter
Long-term debt[1]	$ 8,998,631	$ 139,294	$ 557,897	$ 509,761	$ 7,791,679	$ —	$ —
Operating leases[2]	37,028	25,615	11,413	—	—	—	—
Employment contracts[3]	3,212,125	487,125	1,864,375	860,625	—	—	—
Purchase obligations[4]	5,110,433	4,412,884	697,549	—	—	—	—
Minimum commitments under contracts[5]	5,791,667	1,000,000	500,000	500,000	500,000	500,000	2,791,667
Total contractual obligations	$ 23,149,884	$ 6,064,918	$ 3,631,234	$ 1,870,386	$ 8,291,679	$ 500,000	$ 2,791,667

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 2007 Annual Report on Form 10-K filed with the SEC. We consider the following accounting estimates, which have been discussed with our Audit Committee, to be most critical in understanding the more complex judgments that are involved in preparing our financial statements and the uncertainties that could impact our results of operations, financial condition and cash flows.

Revenue Recognition. We follow SAB No. 104, "Revenue Recognition." This bulletin draws on existing accounting rules and provides specific guidance on revenue recognition for up-front non-refundable licensing and development fees. We license certain products or technology to outside third parties, in return for which we receive up-front licensing fees. Some of these fees can be significant. In accordance with SAB No. 104, we recognize this revenue ratably over the related license period.

We also enter into research and development contracts with corporate, government and/or private entities. These contracts generally provide for payments to us upon achievement of certain research or development milestones. Product development revenues from these contracts are recognized only if the specified milestone is achieved and accepted by the customer and payment from the customer is probable. Any amounts received prior to the performance of product development efforts are recorded as deferred revenues. Recognition of revenue under these contracts can be sporadic, as it is the result of achieving specific research and development milestones. Furthermore, revenue from future milestone payments will not be recognized if the underlying research and development milestone is not achieved.

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 net of allowances for any discounts or rebates. We do not grant product return rights to our customers, except for warranty returns. Where a product fails to comply with its limited warranty, we can either replace the product or provide the customer with a refund of the purchase price or credit against future purchases. Historically, returns arising from warranty issues have been infrequent and immaterial. Accordingly, we expense warranty returns as incurred. While such returns have been immaterial in the past, we cannot guarantee that we will continue to experience the same rate of warranty claims as we have in the past. Any significant increase in product warranty claims could have a material adverse impact on our operating results for the period in which the claims occur.

Allowance for Uncollectible Accounts Receivable. Accounts receivable are reduced by an estimated allowance for amounts that may become uncollectible in the future. On an ongoing basis, we perform credit evaluations of our customers and adjust credit limits based upon the customer's payment history and creditworthiness, as determined by a review of their current credit information. We also continuously monitor collections and payments from our customers.

Based upon historical experience and any specific customer collection issues that are identified, we use our judgment to establish and evaluate the adequacy of our allowance for estimated credit losses, which was $104,373 at September 30, 2008. While credit losses have been within our expectations and the allowance provided, these losses can vary from period to period ($40,914, $16,022 and $(4,771) in 2007, 2006 and 2005, respectively). Furthermore, there is no assurance that we will experience credit losses at the same rates as we have in the past. Also, at September 30, 2008, $3.8 million, or 31% of our accounts receivable, was due from three major customers. Any significant changes in the liquidity or financial position of these customers, or others, could have a material adverse impact on the collectibility of our accounts receivable and future operating results.

Inventories. Our inventories are valued at the lower of cost or market, determined on a first-in, first-out basis, and include the cost of raw materials, labor and overhead. The majority of our inventories are subject to expiration dating. We continually evaluate the carrying value of our inventories and when, in the opinion of management, factors indicate that impairment has occurred, either a reserve is established against the inventories' carrying value or the inventories are completely written off. We base these decisions on the level of inventories on hand in relation to our estimated forecast of product demand, production requirements over the next twelve months and the expiration dates of raw materials and finished goods. During 2007, 2006 and 2005, we wrote off inventory which had a cost of $922,000, $751,000 and $2.1 million, respectively, as a result of scrap and product expiration issues and a $1.3 million provision for loss on our UP*link*® product recorded in 2005. Although we make every effort to ensure the accuracy of our forecasts of future product demand, any significant unanticipated changes in demand could have a significant impact on the carrying value of our inventories and reported operating results.

Stock-based Compensation. Commencing January 1, 2006, we adopted SFAS No. 123 (revised 2004), "Share-Based Payment," which requires us to recognize the fair value of equity-based awards as compensation expense in our statement of operations. The fair value of our stock option awards was estimated using a Black-Scholes option valuation model. This valuation model incorporates highly subjective assumptions, such as the expected stock price volatility and the estimated life of each award, in the model's computations. The fair value of awards, after considering the effect of expected forfeitures, is then amortized, generally on a straight-line basis, over the related vesting period of the award.

Long-lived and Intangible Assets. Our long-lived assets are comprised of property and equipment and our intangible assets primarily consist of patents and product rights. Together, these assets have a net book value of $26.0 million, or 16.3% of our total assets, at September 30, 2008. Property and equipment, and patents and product rights are depreciated or amortized on a straight-line basis over their useful lives, which we determine based upon our estimate of the period of time over which each asset will generate revenues. In August 2005, we recorded a $1.5 million intangible asset related to a payment under a license agreement to certain patents related to the Hepatitis C Virus. We recorded an additional $3.0 million related to this license in 2006. Management's intent in executing this license is to provide for various alternatives for use, including uses in the international market, that would not require additional research and development efforts or regulatory approvals. This $4.5 million asset was capitalized based on management's estimate of the cash flows to be received from future product sales in these international markets. A similar analysis of estimated future cash flows will be prepared upon payment of additional license fees under this agreement, or upon changes in circumstances, to determine the appropriate accounting treatment for payments under this license agreement. An impairment of long-lived or intangible assets could occur whenever events or changes in circumstances indicate that the net book value of these assets may not be recoverable. Events which could trigger an asset impairment include significant underperformance relative to expected historical or projected future operating results, significant changes in the manner of our use of an asset or in our overall business strategy, significant negative industry or economic trends, and shortening of product life-cycles or changes in technology. If we believe impairment of an asset has occurred, we measure the amount of such impairment by comparing the net book value of the affected assets to the fair value of these assets, which is generally determined based upon the present value of the expected cash flows associated with the use of these assets. If the net book value exceeds the fair value of the impaired assets, we would incur an impairment expense equal to this difference. In June 2005, we recorded a $196,000 provision for loss on our UP*link*® fixed assets as a result of our inability to reach an agreement to transfer these assets to our distribution partner or determine an alternative outlet for these assets. We currently believe the future cash flows to be received from all other long-lived and intangible assets will exceed their book value and, as such, we have not recognized any additional impairment losses through September 30, 2008. Any unanticipated significant impairment in the future, however, could have a material adverse impact on our balance sheet and future operating results.

Deferred Tax Assets. In the December 31, 2007 financial statements, we had NOL carryforwards of $45.5 million. The net deferred tax asset associated with these NOL carryforwards and other temporary differences was $23.8 million and $22.3 million at September 30, 2008 and December 31, 2007, respectively. In assessing the realizability of deferred tax assets, we consider whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the period in which those temporary differences become deductible or the NOL carryforwards and credit carryforwards can be utilized. We consider the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in making this assessment. For the nine month period ended September 30, 2008, the Company had a pre-tax loss of $3.1 million, and it is projected to have a pre-tax loss for the year ending December 31, 2008. Should the Company continue to incur pre-tax losses, it is possible that we may not be able to realize the federal and state income tax benefits associated with those losses and we may need to consider recording a valuation allowance on all or part of our net deferred tax asset.

Our ability to use our NOL carryforwards to offset future federal income tax obligations also could be limited by changes in the ownership of our stock. IRC Section 382 contains provisions that limit the amount of federal NOL carryforwards that can be used in any given year in the event of specified occurrences, including significant ownership changes. We completed an analysis through December 31, 2007 to determine if any IRC Section 382 ownership changes have occurred that would limit the amount of NOLs that could be utilized to offset future taxable income. As a result of this analysis, we concluded that prior ownership changes may impose a limitation on the amount of NOL carryforwards that can be utilized in a given year. We do not believe, however, that this limitation will impair our future ability to utilize NOL carryforwards to offset our forecasted taxable income or to realize the related deferred tax asset.

We have begun providing for income taxes at a rate equal to our combined federal and state effective rates. Subsequent revisions to the estimated net realizable value of the deferred tax asset could cause our provision for income taxes to vary significantly from period to period.

Clinical Trial Accruals. Some of our research and development is conducted by third parties, including contract research and development service providers. All such costs are charged to research and development expense systematically as incurred, which may be measured by patient enrollment or the passage of time. At the end of each quarter, we compare the payments made to each service provider to the estimated progress toward completion of the research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the estimated service provided, we record net prepaid or accrued expense relating to these costs.

Contingencies. In the ordinary course of business, we have entered into various contractual relationships with strategic corporate partners, customers, distributors, research laboratories and universities, licensors, licensees, suppliers, vendors and other parties. As such, we could be subject to litigation, claims or assessments arising from any or all of these relationships. We account for contingencies such as these in accordance with SFAS No. 5, "Accounting for Contingencies." SFAS No. 5 requires us to record an estimated loss contingency when information available prior to issuance of our financial statements indicates that it is probable that an asset has been impaired or a liability has been incurred at the date of the financial statements and the amount of the loss can be reasonably estimated. Accounting for contingencies arising from contractual or legal proceedings requires that we use our best judgment when estimating an accrual related to such contingencies. As additional information becomes known, our accrual for a loss contingency could fluctuate, thereby creating variability in our results of operations from period to period. Likewise, an actual loss arising from a loss contingency which significantly exceeds the amount accrued for in our financial statements could have a material adverse impact on our operating results for the period in which such actual loss becomes known.

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, commercial paper, U.S. government and agency obligations, and U.S. corporate bonds. All such instruments are classified as available-for-sale securities. The primary objective of our investment activities 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. 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.

At September 30, 2008, we had approximately $9.0 million of outstanding debt. In January 2008, we elected to fix the interest rate at 4.15% until the debt's maturity in June 2011. As a result, we have no exposure to interest rate changes.

As of September 30, 2008, we did not have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. We have operations in The Netherlands, which are subject to foreign currency fluctuations. As currency rates change, translation of revenues and expenses for these operations from Euros to U.S. dollars affects year-to-year comparability of operating results. Sales denominated in a foreign currency represented approximately $50,000 of our total revenues for the nine months ended September 30, 2008. 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, has 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, 2008. 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, 2008 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 is 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 is 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, 2008 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. We expect to file our response on November 7, 2008 and the plaintiffs will have an opportunity to reply further on or before November 14, 2008.

We believe that none of our products, including the OraQuick *ADVANCE*® HIV test, infringe 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 financial statements.

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, 2007.

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

The following is a summary of share repurchase activity during the three months ended September 30, 2008.

Pursuant to our 2000 Stock Award Plan and in connection with the vesting of restricted shares, we retired 27,750 shares to satisfy minimum tax withholding obligations.

In addition, on August 5, 2008, our Board of Directors approved a share repurchase program pursuant to which we are permitted to acquire up to $25.0 million of outstanding shares.

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as part of a publicly Announced Plan or Program [1]	Maximum Dollar Value of Shares that may yet be Purchased Under the Plan or Program [2]
July 1, 2008 - July 31, 2008	—	—	—	—
August 1, 2008 - August 31, 2008	225,661	$ 4.72	218,171	$23,971,404
September 1, 2008 - September 30, 2008	428,474	$ 4.95	408,214	21,948,101
Total	654,135	$ 4.87	626,385	

1 These shares were purchased under our $25.0 million stock repurchase program.

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

Item 6. EXHIBITS

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

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 6, 2008

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

/s/ Mark L. Kuna

Date: November 6, 2008

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

Table of Contents

EXHIBIT INDEX

Exhibit	
3	OraSure Technologies, Inc. Bylaws, as amended and restated as of August 19, 2008, are incorporated by reference to Exhibit 3 to the Company's Current Report on Form 8-K filed August 22, 2008.
31.1	Certification of Douglas A. Michels required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Ronald H. Spair required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
32.1	Certification of Douglas A. Michels required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Ronald H. Spair required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Exhibit 31.1

Certification

I, Douglas A. Michels, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 6, 2008

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

Exhibit 31.2

Certification

I, Ronald H. Spair, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 6, 2008

/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, 2008 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 6, 2008

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, 2008 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 6, 2008