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, 2006.

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, or a non-accelerated filer. See definition of "accelerated filer" and "large accelerated filer" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐

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 3, 2006: 45,953,908

Item 1. FINANCIAL STATEMENTS

ORASURE TECHNOLOGIES, INC.
BALANCE SHEETS
(Unaudited)

	September 30, 2006	December 31, 2005
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 17,029,930	$ 32,826,740
Short-term investments	72,503,668	44,793,046
Accounts receivable, net of allowance for doubtful accounts of $286,377 and $278,066	10,235,595	11,602,127
Inventories	4,812,088	4,128,029
Deferred income taxes	3,511,136	6,503,946
Prepaid expenses and other	1,646,401	1,553,545
Total current assets	109,738,818	101,407,433
PROPERTY AND EQUIPMENT, net	16,477,881	5,815,233
PATENTS AND PRODUCT RIGHTS, net	2,477,170	2,879,958
DEFERRED INCOME TAXES	20,579,658	20,204,352
OTHER ASSETS	461,024	440,227
	$ 149,734,551	$ 130,747,203
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	$ 636,286	$ 456,541
Accounts payable	2,518,907	2,546,621
Accrued expenses and other	8,526,281	7,733,941
Total current liabilities	11,681,474	10,737,103
LONG-TERM DEBT	10,302,838	884,021
OTHER LIABILITIES	374,347	207,037
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Preferred stock, par value $.000001, 25,000,000 shares authorized, none issued	—	—
Common stock, par value $.000001, 120,000,000 shares authorized, 45,949,839 and 45,775,625 shares issued and outstanding	46	46
Additional paid-in capital	226,913,086	226,218,469
Deferred compensation	—	(3,334,792)
Accumulated other comprehensive loss	(97,795)	(282,825)
Accumulated deficit	(99,439,445)	(103,681,856)
Total stockholders' equity	127,375,892	118,919,042
	$ 149,734,551	$ 130,747,203

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,	
	2006	2005	2006	2005
REVENUES:				
Product	$17,508,622	$18,049,479	$50,124,008	$51,097,873
Licensing and product development	130,693	27,313	297,046	237,391
	17,639,315	18,076,792	50,421,054	51,335,264
COSTS OF PRODUCTS SOLD	6,365,346	6,432,218	18,516,174	20,772,981
Gross profit	11,273,969	11,644,574	31,904,880	30,562,283
COSTS AND EXPENSES:				
Research and development	1,752,519	1,297,900	5,149,782	3,750,534
Acquired in-process technology	—	—	600,000	—
Sales and marketing	3,632,373	3,965,284	11,976,687	12,289,073
General and administrative	3,409,811	3,167,760	9,509,870	9,131,967
	8,794,703	8,430,944	27,236,339	25,171,574
Operating income	2,479,266	3,213,630	4,668,541	5,390,709
INTEREST EXPENSE	(182,265)	(23,210)	(224,452)	(75,809)
INTEREST INCOME	1,112,195	618,940	2,896,761	1,458,204
FOREIGN CURRENCY GAIN (LOSS)	(9,899)	(1,259)	(65,506)	39,011
Income before income taxes	3,399,297	3,808,101	7,275,344	6,812,115
INCOME TAX PROVISION	1,264,751	—	3,032,933	—
NET INCOME	$ 2,134,546	$ 3,808,101	$ 4,242,411	$ 6,812,115
EARNINGS PER SHARE:				
BASIC	$ 0.05	$ 0.08	$ 0.09	$ 0.15
DILUTED	$ 0.05	$ 0.08	$ 0.09	$ 0.15
SHARES USED IN COMPUTING EARNINGS PER SHARE:				
BASIC	45,922,110	45,372,065	45,888,349	44,936,111
DILUTED	47,247,439	46,676,379	47,712,101	45,850,378

The accompanying notes are an integral part of these statements.

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

	Nine Months Ended September 30,	
	2006	2005
OPERATING ACTIVITIES:		
Net income	$ 4,242,411	$ 6,812,115
Adjustments to reconcile net income to net cash provided by operating activities:		
Stock-based compensation cost	4,280,054	1,270,980
Deferred income taxes	2,617,504	—
Depreciation and amortization	1,440,409	1,808,772
Acquired in-process technology	600,000	—
Provision for excess and obsolete inventories	472,081	1,792,775
Provision for loss on property and equipment	—	196,011
Changes in assets and liabilities:		
Accounts receivable	1,369,379	(3,158,487)
Inventories	(1,155,693)	(1,507,221)
Prepaid expenses and other assets	(49,717)	6,834
Accounts payable, accrued expenses, and other liabilities	235,093	1,242,257
Net cash provided by operating activities	14,051,521	8,464,036
INVESTING ACTIVITIES:		
Purchases of marketable securities	(65,900,901)	(44,685,183)
Proceeds from maturities and redemptions of short-term investments	38,375,046	42,279,373
Purchases of property and equipment	(11,552,057)	(1,394,749)
Payments for licenses or acquired in–process technology	(200,000)	(1,800,000)
Increase in other assets	—	(90,000)
Net cash used in investing activities	(39,277,912)	(5,690,559)
FINANCING ACTIVITIES:		
Proceeds from long-term debt	10,000,000	—
Repayments of long-term debt	(401,438)	(838,138)
Proceeds from issuance of common stock	344,304	4,649,442
Withholding and retirement of common stock	(519,117)	(450,853)
Net cash provided by financing activities	9,423,749	3,360,451
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	5,832	(35,023)
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(15,796,810)	6,098,905
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	32,826,740	10,121,208
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 17,029,930	$ 16,220,113

The accompanying notes are an integral part of these statements.

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 the United States, Canada, and Europe.

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, 2005. Results of operations for the three-month and nine-month periods ended September 30, 2006 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, 2006 and December 31, 2005, cash equivalents consisted of commercial paper, U.S. government agency obligations, state and local government agency obligations, and corporate bonds.

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, state and local government 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 loss.

The following is a summary of our available-for-sale securities at September 30, 2006 and December 31, 2005:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
September 30, 2006				
Certificates of deposit	$ 800,000	$ —	$ —	$ 800,000
Commercial paper	33,673,776	277,867	—	33,951,643
Government and agency bonds	5,838,701	—	(11,385)	5,827,316
Corporate bonds	31,968,152	—	(43,443)	31,924,709
Total available-for-sale securities	$72,280,629	$277,867	$(54,828)	$72,503,668
December 31, 2005				
Certificates of deposit	$10,385,000	$ —	$ (464)	$10,384,536
Commercial paper	1,984,999	—	(1,059)	1,983,940
Government and agency bonds	18,544,871	—	(43,851)	18,501,020
State and local government agency obligations	75,000	—	—	75,000
Corporate bonds	13,874,242	1,261	(26,953)	13,848,550
Total available-for-sale securities	$44,864,112	$ 1,261	$(72,327)	$44,793,046
At September 30, 2006, maturities of investments were as follows:				
Less than one year	$69,075,864	$277,867	$(52,267)	$69,301,464
1 – 2 years	3,204,765	—	(2,561)	3,202,204
Total available-for-sale securities	$72,280,629	$277,867	$(54,828)	$72,503,668

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, 2006	December 31, 2005
Raw materials	$ 2,733,953	$2,625,889
Work-in-process	847,917	718,804
Finished goods	1,230,218	783,336
	$ 4,812,088	$4,128,029

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 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.

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.

Significant Customer Concentration. For the three-month period ended September 30, 2005, Prestige Brands Holdings, Inc. (“Prestige”) accounted for 17 percent of total revenues. There were no sales to Prestige for the three months ended September 30, 2006. For the nine-month period ended September 30, 2006, Prestige accounted for 8

percent of total revenues as compared to 19 percent for the same period of 2005. Prestige accounted for 15 percent of accounts receivable as of December 31, 2005. We are pursuing resolution of a dispute with Prestige regarding its recent acquisition of the Wartner® cryosurgical wart removal product, which competes against the Freeze Off® product in the U.S. and Canadian over-the-counter markets.

For the three-month periods ended September 30, 2006 and 2005, Quest Diagnostics (including its wholly-owned subsidiary, Lab*One*, Inc.) ("Quest") accounted for 15 percent and 13 percent of total revenues, respectively. For both the nine-month periods ended September 30, 2006 and 2005, Quest accounted for 14 percent of total revenues, Quest accounted for 16 percent and 8 percent of accounts receivable as of September 30, 2006 and December 31, 2005, respectively.

For the three-month periods ended September 30, 2006 and 2005, Abbott Laboratories ("Abbott") accounted for 9 percent and 10 percent of total revenues, respectively. For the nine-month periods ended September 30, 2006 and 2005, Abbott accounted for 9 percent and 7 percent of total revenues, respectively. Abbott accounted for 6 percent of accounts receivable as of September 30, 2006 and December 31, 2005.

Additionally, SSL International plc accounted for 17 percent and 20 percent of accounts receivable as of September 30, 2006 and December 31, 2005, respectively.

Research and Development. Research and development costs are charged to expense as incurred.

Foreign Currency Translation. Pursuant to SFAS No. 52, "Foreign Currency Translation," the assets and liabilities of our foreign operations are translated from euros into U.S. dollars at current exchange rates as of the balance sheet date, and revenues and expenses are translated at average exchange rates for the period. Resulting translation adjustments are reflected as a component of accumulated other comprehensive loss within stockholders' equity.

Earnings Per Share. We have presented basic and diluted earnings per share pursuant to SFAS No. 128, "Earnings per Share." In accordance with SFAS No. 128, basic earnings per share is computed by dividing net income by the weighted average number of shares outstanding during the period. Diluted earnings per share is computed in a manner similar to basic earnings per share except that the weighted average number of shares is increased to include incremental shares from the assumed vesting or exercise of all 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 stock was 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 per share are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Net income	$ 2,134,546	$ 3,808,101	$ 4,242,411	$ 6,812,115
Weighted average shares of common stock outstanding:				
Basic	45,922,110	45,372,065	45,888,349	44,936,111
Dilutive effect of stock options, warrants and restricted stock	1,325,329	1,304,314	1,823,752	914,267
Diluted	47,247,439	46,676,379	47,712,101	45,850,378
Earnings per share:				
Basic	$ 0.05	$ 0.08	$ 0.09	$ 0.15
Diluted	$ 0.05	$ 0.08	$ 0.09	$ 0.15

For the three-month and nine-month periods ended September 30, 2006 and 2005, outstanding common stock options, warrants, and unvested restricted stock, representing 2,159,179, 349,980, 1,092,909, and 1,410,714 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 loss at September 30, 2006 and December 31, 2005 consisted of currency translation adjustments and net unrealized gains or losses on marketable securities. Comprehensive income was $2,274,496 and $3,843,321 for the three months ended September 30, 2006 and 2005, respectively, and $4,427,441 and $6,845,852 for the nine months ended September 30, 2006 and 2005, respectively.

Recent Accounting Pronouncements. In July 2006, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation ("FIN") No. 48, "Accounting for Uncertainty in Income Taxes – an Interpretation of FASB Statement No. 109," which clarifies what criteria must be met prior to recognition of the financial statement benefit of a position taken in a tax return. FIN No. 48 will require companies to include additional qualitative and quantitative disclosures within their financial statements. The disclosures will include potential tax benefits from positions recognized for tax return purposes but not recognized for financial reporting purposes, as well as a tabular presentation of significant changes in such benefits during each period. The disclosures will also include a discussion of the nature of uncertainties, factors that could cause a change, and an estimated range of reasonably possible changes in tax uncertainties. FIN No. 48 will require a company to recognize a financial statement benefit for a position taken for tax return purposes when it will be more-likely-than-not that the position will be sustained. FIN No. 48 will be effective for fiscal years beginning after December 15, 2006. We are currently assessing the impact FIN No. 48 will have on our financial statements.

In September 2006, the United States Securities and Exchange Commission issued Staff Accounting Bulletin No. 108 ("SAB No. 108") "Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements." SAB No. 108 requires companies to evaluate the materiality of identified unadjusted errors using both the income statement approach and the balance sheet approach. In the initial year of adoption, if a company determines that an adjustment to prior year financial statements is required under either approach, SAB No. 108 allows for a one-time cumulative-effect adjustment to beginning retained earnings. SAB No. 108 is effective for interim periods of the first fiscal year ending after November 15, 2006. We are currently assessing the impact, if any, that SAB No. 108 will have on our financial statements.

In September 2006, the 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. We are currently assessing the impact, if any, that SFAS No. 157 will have on our financial statements.

3. Stock-Based Compensation

We grant stock-based awards under the OraSure Technologies, Inc. 2000 Stock Award Plan, as amended and restated (the "2000 Plan"). The 2000 Plan permits stock-based awards to employees, outside directors, and consultants or other third-party advisors. Awards that 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.

Under the terms of the 2000 Plan, qualified incentive stock options and nonqualified options for shares of our common stock may be granted to eligible employees, including our officers, and members of our Board of Directors. To date, options generally have been granted with an exercise price not less than the fair market value of our

common stock on the date of grant. Options generally vest over four years, with one quarter of the options vesting one year after grant and the remainder vesting on a monthly basis over the next three years. The options have a term of up to ten years during which they may be exercised and a specified vesting period, in each case as determined by our Board of Directors or its Compensation Committee, which administers the 2000 Plan.

Prior to 2006, we accounted for stock-based compensation to employees and directors using the intrinsic value method in accordance with Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations. Under APB Opinion No. 25, no stock-based compensation expense was recognized on stock options granted to employees or directors, as the exercise price was equal to the market price of our common stock on the date of grant. We account for stock-based compensation to nonemployees using the fair value method in accordance with SFAS No. 123 (revised), ("SFAS No. 123R"), "Share-Based Payment," and Emerging Issues Task Force Issue No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services."

Effective January 1, 2006, we adopted SFAS No. 123R, which eliminated the ability to account for stock-based compensation under APB Opinion No. 25 and requires us to recognize compensation expense based on the fair value of our stock-based awards. We elected the modified prospective transition method as permitted by SFAS No. 123R. Accordingly, results from prior periods have not been restated. Under this transition method, stock-based compensation expense for the three-month and nine-month periods ended September 30, 2006 include:

(a) compensation expense for all stock-based awards granted prior to January 1, 2006, but not yet vested, based on the grant date fair value previously estimated in accordance with the original provisions of SFAS No. 123, "Accounting for Stock-Based Compensation," and

(b) compensation expense for all stock-based awards granted, modified or settled subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123R.

Upon the adoption of SFAS No. 123R, our deferred compensation balance of $3,334,792 was reclassified against additional paid-in capital. Consistent with our past practice under the disclosure requirements of SFAS No. 123, we have elected to 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.

Pursuant to the disclosure requirements of SFAS No. 123, the table below illustrates the effect on net income and earnings per share had compensation expense for our stock-based awards been determined based upon the fair value of the awards at the date of grant for the three-month and nine-month periods ended September 30, 2005:

	Three months ended September 30, 2005	Nine months ended September 30, 2005
Net income:		
As reported	$ 3,808,101	$ 6,812,115
Add: stock-based employee compensation expense included in net income	294,474	1,178,354
Deduct: total stock-based employee compensation expense determined under the fair value-based method for all awards	(1,153,229)	(4,210,973)
Pro forma	$ 2,949,346	$ 3,779,496
Basic and diluted earnings per share:		
As reported	$ 0.08	$ 0.15
Pro forma	$ 0.06	$ 0.08

The fair value of each stock option was 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-month periods ended September 30, 2006 and 2005 was $4.69 and $4.48, respectively. The weighted-average grant date fair value of stock options granted during the nine-month periods ended September 30, 2006 and 2005 was $4.95 and $3.15, respectively.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Black-Scholes Option Valuation Assumptions				
Risk-free interest rate[1]	4.88%	4.08%	4.53%	3.71%
Expected dividend yield	—	—	—	—
Expected stock price volatility[2]	55%	58%	56%	58%
Expected life of stock options (in years)[3]	5	4	5	4

(1) Based on the Treasury Securities constant maturity interest rate whose term is consistent with the expected life of our stock options.
(2) Expected stock price volatility is based on historical experience.
(3) Expected life of stock options is based upon historical experience.

Total compensation cost related to stock options for the three-month and nine-month periods ended September 30, 2006, was $934,079 ($711,006 net of tax) and $2,838,880 ($2,174,710 net of tax), respectively, of which $62,182 and $270,191 was capitalized into inventory during these periods, respectively. There was no compensation cost related to stock options for the three-month and nine-month periods ended September 30, 2005.

The aggregate intrinsic value of options (the amount by which the market price of the stock on the date of exercise exceeded the exercise price) exercised during the three-month periods ended September 30, 2006 and 2005 was $39,270 and $2,018,067, respectively, and during the nine-month periods ended September 30, 2006 and 2005 was $262,478 and $2,821,705, respectively.

The following table summarizes the stock option activity for the nine months ended September 30, 2006:

	Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding on January 1, 2006	4,216,785	$ 7.08		
Granted	721,900	9.36		
Exercised	(70,177)	5.80		
Cancelled	(53,140)	7.75		
Outstanding on September 30, 2006	4,815,368	$ 7.43	7.77	$3,606,277
Vested or expected to vest as of September 30, 2006	4,784,550	$ 7.43	7.77	$3,583,197
Exercisable on September 30, 2006	3,378,710	$ 7.06	7.45	$3,777,769

As of September 30, 2006, there was $5,148,649 of unrecognized compensation expense related to unvested option awards that is expected to be recognized over a weighted-average period of 1.8 years.

Net cash proceeds from the exercise of stock options were $344,304 and $4,649,442 for the nine months ended September 30, 2006 and 2005, respectively. As a result of the Company’s net operating loss carryforward position, no actual income tax benefit was realized from stock option exercises for these periods.

During the nine months ended September 30, 2006, we granted 465,313 restricted shares of our common stock, with a grant date fair value of $9.16, to certain key officers and members of management. These shares are nontransferable and are generally subject to three-year vesting requirements. The market value of these shares was calculated at the date of grant and is being recognized on a straight-line basis over the period during which the restrictions lapse. Compensation cost of $1,434,400 and $1,178,354 related to these and previous grants was recognized during the nine months ended September 30, 2006 and 2005, respectively. Compensation cost of $426,771 and $294,474 related to these and previous grants was recognized during the three months ended September 30, 2006 and 2005, respectively.

The following table summarizes restricted stock award activity for the nine months ended September 30, 2006:

	Shares	Weighted-Average Grant Date Fair Value
Issued and unvested, January 1, 2006	606,445	$ 6.90
Granted	465,313	9.16
Vested	(155,653)	6.55
Cancelled	(65,071)	7.56
Issued and unvested, September 30, 2006	851,034	$ 8.15
Issued and expected to vest, September 30, 2006	851,034	$ 8.15

As of September 30, 2006, there was $5,670,805 of unrecognized compensation expense related to unvested restricted stock awards that is expected to be recognized over a weighted average period of 3.8 years.

In connection with the vesting of restricted shares during the nine-month periods ended September 30, 2006 and 2005, 51,616 and 49,177 shares with aggregate values of $519,117 and $450,853, respectively, were withheld and retired in satisfaction of minimum tax withholding obligations.

4. Property Acquisition

On June 30, 2006, we exercised purchase options contained in the commercial leases for two of our facilities located in Bethlehem, Pennsylvania and acquired both facilities for an aggregate purchase price of approximately $9,100,000, including settlement costs. As a result of these purchases, the leases for these facilities, which required minimum annual rental payments of $1,051,000, were terminated.

5. Long-term Debt

On June 27, 2006, we executed an amendment to our $11,900,000 credit facility (“Credit Facility”), with Comerica Bank, pursuant to which we are permitted to borrow up to an additional $15,000,000 in advances in order to fund the purchase and future expansion of our facilities in Bethlehem, Pennsylvania. On June 29, 2006, we borrowed $10,000,000 under the terms of the Credit Facility, in order to purchase two of our previously-leased Bethlehem facilities. We can borrow the remaining $5,000,000 at any time before June 30, 2007. At our option, interest on outstanding borrowings 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 rate plus 0.55% to 1.25%. The rate is determined at the date of the advance and is based upon the amount of cash and cash equivalents that we invest and retain at Comerica Securities, Inc. We can also choose the fixed rate option, without penalty, at the expiration of a previously elected LIBOR period. 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. This amendment also extended the maturity date of our $4,000,000 revolving working capital line of credit to June 29, 2007. All other terms of the Credit Facility, as previously amended, remain in effect, except for our financial covenant related to liquidity, which was modified to require a minimum liquidity of not less than $25,000,000, of which at least $15,000,000 must be held by Comerica or its affiliates.

At September 30, 2006, interest on the $10,000,000 borrowing is currently payable monthly, at the 180-day LIBOR rate plus 0.9%, or 6.5175%. Principal is repayable in installments, due at the end of each LIBOR rate period, based upon a twenty-year amortization schedule and the number of months in the expiring LIBOR rate period, with any remaining unpaid principal amount due on June 27, 2011. Accordingly, on December 25, 2006, we will be required to make a six-month $250,000 principal repayment, and the interest rate on this loan will be reset.

6. Accrued Expenses

	September 30, 2006	December 31, 2005
Royalties	$ 2,348,744	$ 1,925,679
Payroll and related benefits	1,843,001	2,510,240
Deferred revenue	1,897,233	1,302,791
Advertising	482,934	757,906
Accrued license fees	200,000	—
Professional fees	600,486	487,712
Laboratory testing fees	257,857	210,604
Other	896,026	539,009
	$ 8,526,281	$ 7,733,941

Accrued royalties at September 30, 2006 and December 31, 2005 are primarily related to our OraQuick® rapid HIV testing product. At September 30, 2006, accrued payroll and related benefits decreased primarily as a result of the payment of annual bonuses during the first quarter. Deferred revenue at September 30, 2006 and December 31, 2005 consisted primarily of customer prepayments, totaling $1,644,433 and $1,012,891, respectively. Advertising accruals at September 30, 2006 and December 31, 2005 are related to the Freeze Off® product. Accrued license fees of $200,000 at September 30, 2006 are related to the HIV-2 sublicense agreement as described in Note 7.

7. Acquired In-Process Technology

In June 2004, we entered into a sublicense agreement with a third party, pursuant to which we have been granted a limited, worldwide, non-exclusive sublicense to certain HIV-2 patents held by such party. This agreement also contained an option to expand the application of this sublicense to other immunoassay platforms, in addition to our OraQuick® platform. On June 8, 2006, we exercised this option, which requires us to pay the third party a non-refundable license fee of $600,000, of which $200,000 was paid in July 2006. Two remaining contractually obligated payments of $200,000 each are due on or before July 8, 2007 and July 8, 2008. As of September 30, 2006, $200,000 of this obligation is included in accrued expenses, with the remaining $200,000 included in other liabilities. We have recognized the $600,000 license fee as acquired in-process technology because other immunoassay platforms for the detection of HIV-2 will require additional research and development efforts and subsequent regulatory approvals.

8. Geographic Information

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

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,	
	2006	2005	2006	2005
United States	$14,136	$15,912	$42,120	$46,233
Europe	3,053	1,610	7,089	3,896
Other regions	450	555	1,212	1,206
	$17,639	$18,077	$50,421	$51,335

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, 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 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 our products; impact of competitors, competing products and technology changes; ability to develop, commercialize and market new products; market acceptance of oral fluid testing products and other new products or technology; 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 projects 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; ability to obtain, and the 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; loss or impairment of sources of capital; ability to meet financial covenants in agreements with financial institutions; ability to retain qualified personnel; exposure to product liability, patent infringement, 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, war and civil unrest; ability to complete consolidation or restructuring activities; ability to identify, complete and realize the full benefits of potential acquisitions; and general political, business and economic conditions. These and other factors that could cause the forward-looking statements to be materially different are described in greater detail in our filings with the Securities and Exchange Commission, including our registration statements, our Annual Report on Form 10-K for the year ended December 31, 2005 and our Quarterly Reports on Form 10-Q. Although forward-looking statements help to provide complete information about future prospects, they 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 worldwide $22 billion *in vitro* diagnostics business. We develop, manufacture and market oral fluid specimen collection devices using proprietary oral fluid technologies, diagnostic products including immunoassays, and other *in vitro* diagnostic tests. We also manufacture and sell a medical device for the removal of warts and other benign skin lesions by cryosurgery, or freezing.

Our diagnostic product offerings primarily target the infectious disease and substance abuse testing segments of the *in vitro* diagnostic market, and are used in both laboratories as well as the emerging, and rapidly growing, point-of-care marketplace. Our OraSure® and Intercept® oral fluid collection devices, and their related assays, are processed in a laboratory, while the OraQuick *ADVANCE*® rapid HIV-1/2 antibody test is designed for use at the point-of-care. Our cryosurgical products are also used at the point of care.

In vitro diagnostics have traditionally used blood or urine as the body fluids upon which tests are conducted. However, we have targeted the use of oral fluid in our products as a differentiating competitive 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 and, when combined with their ease of use, non-invasive and dignified nature, and cost effectiveness, represent a competitive alternative to the more traditional testing methods in the diagnostic space.

During the first nine months of 2006, our total revenues were $50.4 million, a decrease of 2% from the same period in 2005, and our net income was $4.2 million, representing a decrease of $2.6 million from the first nine months of 2005. Net income during the first nine months of 2006 includes a pre-tax charge of $2.8 million related to the expensing of stock options as well as a provision for income taxes of $3.0 million. Neither the expense related to stock options nor a provision for income taxes was recorded in the same period in 2005. Our liquidity improved, as we reported $14.1 million in cash flow from operations during the first nine months of 2006 compared to $8.5 million for the first nine months of 2005, and we had $89.5 million in cash, cash equivalents, and short-term investments as of September 30, 2006.

Sales into the infectious disease testing market during the first nine months of 2006 increased due to the continued market acceptance of our OraQuick *ADVANCE*® device. This resulted largely from sales directly to various public health organizations and sales through Abbott Laboratories ("Abbott") into the hospital market.

In February 2005, we entered into an agreement for the distribution of OraQuick *ADVANCE*® with Abbott. Under this agreement, Abbott was appointed as our exclusive distributor in the U.S. hospital market and as 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 filed 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. We utilize a small internal sales force to support Abbott and work together with them to maximize the penetration of OraQuick *ADVANCE*® in the hospital market.

The markets for rapid HIV testing are very competitive and the level of competition is expected to increase, which could affect sales of our OraQuick *ADVANCE*® test. For example, the Ortho Diagnostics division of Johnson & Johnson, Bio-Rad Laboratories, Abbott, and bioMerieux Inc., each sells competing laboratory-based HIV-1 enzyme immunoassays, and Bayer Diagnostics recently received United States Food and Drug Administration ("FDA") approval for its laboratory-based random access immunoassay for HIV-1/2 and Sub-Type O peptide. Maxim Biomedical sells a rapid HIV-1 screening test for urine, in the United States. In addition, MedMira and Trinity Biotech each sells competing rapid HIV-1 blood tests and Bio-Rad Laboratories and ChemBio each received FDA approval for rapid HIV-1/2 blood tests. Under their current FDA approvals, these tests compete with our OraQuick *ADVANCE*® test in the hospital or other laboratory settings. Trinity Biotech has also received CLIA (Clinical Laboratory Improvement Amendments of 1988) waiver for its rapid fingerstick HIV-1 blood test, and this test competes with our OraQuick *ADVANCE*® test in markets outside of the traditional hospital and laboratory settings. ChemBio is seeking CLIA waiver for its rapid HIV blood tests and recently granted distribution rights to its rapid HIV tests to Inverness Medical Systems. These companies, or others, may continue to expand the types of body fluids with which a rapid HIV test may be performed or develop and commercialize new rapid tests, either of which would provide further competition for our OraQuick *ADVANCE*® test.

Sales to the substance abuse testing market also increased during the first nine months of 2006, reflecting the growing acceptance of our Intercept® collection device and related oral fluid drug assays, as both corporate and international customers continued to shift to oral fluid and away from traditional urine-based drug testing. We expect continuing growth in the utilization of our Intercept® product line, primarily in the United States.

In April 2004, SAMHSA published proposed guidelines that would, if adopted, include oral fluid testing as an accepted drug testing method for federal employees. However, these proposed guidelines have been withdrawn with no action taken, and it is unclear when further action, if any, will be taken to permit the use of oral fluid as an accepted drug testing method in this market.

Sales to the cryosurgical systems market declined during the first nine months of 2006. The cryosurgical systems market represents sales of Histofreezer® into both the domestic and international physicians' office markets and sales of the over-the-counter ("OTC") formulation of this product to our domestic distributor, Prestige Brands Holdings, Inc. ("Prestige"), and our international distributor, SSL International plc ("SSL"). Prestige distributes our cryosurgical wart removal product under its Compound W Freeze Off® trademarks in the OTC market in the United States and Canada. SSL distributes a similar product under its Scholl's and Dr. Scholl trademarks, in the OTC footcare market in several European countries. Sales in the U.S. OTC cryosurgery marketplace have declined as a result of the disappointing performance by Prestige. Sales to Prestige for 2006 are projected to be less than 50% of the $11.6 million recorded in 2005. Sales to SSL for 2006 will be lower than expected as a result of delayed or slower launch of the OTC product in various European countries.

Prestige recently announced the purchase of the Wartner® cryosurgical wart removal product line, which is sold in the OTC market in the United States in direct competition against the Freeze Off® product. We believe that the acquisition by Prestige of the Wartner® product line constitutes a material breach of the distribution agreement between the parties, which includes a covenant not to compete prohibiting Prestige and its affiliates from selling or acquiring an ownership interest in a cryosurgical product that competes directly with the Freeze Off® product. We have notified Prestige of this breach as well as certain others under the distribution agreement. If Prestige does not cure these breaches in accordance with the agreement, we intend to enforce our contractual and legal remedies. The agreement contains a mandatory mediation and arbitration provision for the resolution of disputes between the parties, and we have initiated mediation under this provision. We are evaluating alternative arrangements for distributing this product in the event a resolution with Prestige cannot be reached. As a result of this ongoing dispute, it is not possible to predict at this time the potential impact this matter may have on sales of Freeze Off® in 2007 or beyond.

We also recently received a notice in which Prestige stated that it did not intend to renew our Freeze Off® distribution agreement beyond the December 31, 2007 expiration of its initial term, and that Prestige intends to purchase all of its requirements of the Freeze Off® product under the agreement through such date. We have advised Prestige that (i) we disagree that Prestige has a right to elect not to renew the agreement because such a right is not afforded to either party in the agreement; (ii) the agreement will automatically renew for successive one-year periods if Prestige meets its annual minimum purchase requirements under the agreement, which it has done through 2006 and has indicated it will do in 2007; and (iii) in light of Prestige's material breach of the covenant not to compete in the agreement as a result of its recent acquisition of the competing Wartner® product, we are not willing to continue discussions regarding a renegotiated distribution agreement for the Freeze Off® product without an acceptable resolution first being reached with respect to Prestige's breach.

In July 2004, we filed a lawsuit against Schering-Plough Healthcare Products, Inc. ("Schering-Plough") for infringement of several of our patents relating to the technology for the cryosurgical removal (i.e., freezing) of warts and other benign skin lesions. The suit was commenced in the United States District Court for the Eastern District of Pennsylvania, and alleges that Schering-Plough's manufacture and sale of its Dr. Scholl's® Freeze Away™ cryosurgical wart removal product in the OTC market infringes three of our patents. We are seeking injunctive relief and the payment of damages, and Schering-Plough has raised several defenses, including that their Freeze Away™ device does not infringe our patents and that our patents are either invalid or unenforceable. On November 2, 2005, a pretrial conference was held in this matter, at which the Court heard oral argument on motions for summary judgment filed by the parties. We expect a new trial schedule to be set after the Court rules on these motions.

Sales to the insurance risk assessment market declined in the first nine months of 2006, primarily as a result of a reduction in the number of applications for life insurance and an increase in the average policy amount. Insurance companies are more likely to use a blood test to test for multiple risk factors rather than oral fluid for higher face value policies. Revenues from this market are expected to decline from the levels attained in 2005.

Because of the regulatory approvals needed for most of our products, we often are required to rely on sole source providers for critical components and materials and on related products supplied by third parties. This is particularly

true for our OraQuick *ADVANCE*® test, our OraSure® oral fluid collection device and our oral fluid Western blot HIV-1 confirmatory product. If we are unable to obtain necessary components or materials from these sole sources, the time required to develop replacements and obtain the required FDA approvals could disrupt our ability to sell the affected products. Any delay or interruption in our ability to manufacture the oral fluid Western blot HIV-1 confirmatory test would adversely affect sales of our OraSure® oral fluid collection device, as our customers are not expected to purchase OraSure® devices if an oral fluid Western blot HIV-1 confirmatory test is not readily available. In addition, if the HIV-1 enzyme immunoassay approved by the FDA for use with our OraSure® collection device, which is manufactured by a third party, is either unavailable or experiences quality or performance problems, sales of our OraSure® device could be adversely affected.

We also rely heavily on distributors to purchase and resell many of our products. For example, Prestige has exclusive distribution rights to the Freeze Off® product in the OTC markets in United States and Canada, and SSL has exclusive rights to a similar product in the OTC footcare market in Europe, Australia and New Zealand. Similarly, Abbott has exclusive rights to distribute our OraQuick *ADVANCE*® test to hospitals in the U.S. We expect to enter into additional distribution agreements for new and future products, for distribution in the U.S. and internationally. If our distributors are unable or unwilling to meet the minimum purchase commitments set forth in their agreements or otherwise substantially reduce the volume of their purchases, our revenues and results of operations could be adversely affected.

Results of Operations

Three months ended September 30, 2006 compared to September 30, 2005

Total revenues decreased to $17.6 million in the third quarter of 2006 from $18.1 million in the same period of 2005, primarily as a result of a decline in sales of our cryosurgical systems products, partially offset by increased sales in the infectious disease testing, substance abuse testing and insurance risk assessment markets. Revenues derived from products sold to customers outside the U.S. were $3.5 million and $2.2 million, or 20% and 12% of total revenues, in the third quarters of 2006 and 2005, 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		% Change	Percentage of Total Revenues	
	2006	2005		2006	2005
Market					
Infectious disease testing	$ 7,536	$ 7,037	7%	42%	39%
Substance abuse testing	4,213	3,595	17	24	20
Cryosurgical systems	4,025	6,143	(34)	23	34
Insurance risk assessment	1,734	1,275	36	10	7
Product revenues	17,508	18,050	(3)	99	100
Licensing and product development	131	27	385	1	—
Total revenues	$17,639	$18,077	(2)%	100%	100%

Sales to the infectious disease testing market increased 7% to $7.5 million in the third quarter of 2006, from $7.0 million in the same period in 2005, primarily as a result of the continuing strength of our OraQuick *ADVANCE*® rapid HIV-1/2 antibody test. OraQuick® sales totaled $6.6 million and $5.9 million in the third quarters of 2006 and 2005, respectively. Sales of OraQuick® to the public health market increased substantially during the third quarter of 2006 compared to the same period in 2005. These increases were partially offset by a reduction in sales to the hospital market through our distributor, Abbott. OraSure® sales totaled $906,000 and $1.1 million in the third quarters of 2006 and 2005, respectively.

The table below shows a breakdown of our total OraQuick® revenues (in thousands, except %) during the third quarters of 2006 and 2005.

	Three Months Ended September 30,		
	2006	2005	% Change
Customers			
Direct to U.S. Public Health	$ 3,837	$ 2,120	81%
Abbott	1,651	1,958	(16)
SAMHSA	—	867	(100)
CDC	748	606	23
International	394	376	5
Direct to Hospitals	—	2	(100)
Total OraQuick® revenues	$ 6,630	$ 5,929	12%

We believe that our OraQuick *ADVANCE*® device, which is FDA-approved for detecting antibodies to both HIV-1 and 2 in oral fluid, fingerstick and venous whole blood, and plasma samples, and is CLIA-waived for use with all sample types except plasma, provides a significant competitive advantage and is allowing us to more fully implement a strategy to sell OraQuick® internationally. We are currently pursuing CE marking for our OraQuick *ADVANCE*® product which would allow us to sell our product in Europe. Our goal is to obtain a CE mark for OraQuick *ADVANCE*® as soon as possible and thereafter obtain several country-specific registrations, which would allow us to launch the product in Europe.

In previous periods, the CDC and SAMHSA have placed bulk purchase orders for OraQuick *ADVANCE*® devices and related testing materials. In the first quarter of 2006, we received an additional bulk purchase order from SAMHSA and, in the second quarter of 2006, we received bulk purchase orders for OraQuick *ADVANCE*® devices from the CDC, the City of New York and Washington, D.C. We expect that federal and other governmental agencies will make future bulk purchases of OraQuick *ADVANCE*® for further distribution to the public health and other markets throughout the United States. However, the failure to receive, any delays in receiving or deploying, or any reduction in the size of, any current or future bulk orders for OraQuick *ADVANCE*® from these governmental agencies could adversely affect our financial performance.

We are beginning to see evidence that sales of OraQuick *ADVANCE*® are negatively impacting sales of our OraSure® oral fluid collection device in the infectious disease testing market. Some customers who have purchased our OraSure® device for laboratory-based HIV-1 testing in the past are electing instead to purchase our OraQuick *ADVANCE*® test. However, it is not possible at this time to estimate the extent of this change in purchasing patterns or the financial impact of replacing OraSure® sales with sales of our OraQuick *ADVANCE*® test.

Sales to the substance abuse testing market increased 17% to $4.2 million in the third quarter of 2006 from $3.6 million in the same period in 2005, primarily as a result of increased sales of our Intercept® oral fluid drug testing service and Q.E.D.®, our rapid oral fluid alcohol test. Intercept® sales increased as a result of continued growth across all markets for this product. Increased sales of our Q.E.D.® test are attributed to a change in regulation that is increasing demand for this product.

The table below shows a breakdown of our total Intercept® revenues (in thousands, except %) generated in each market in the third quarters of 2006 and 2005.

	Three Months Ended September 30,		
	2006	2005	% Change
Market			
Workplace testing	$ 1,679	$ 1,547	9%
Criminal justice	640	464	38
International	599	537	12
Direct	175	134	31
Total Intercept® revenues	$ 3,093	$ 2,682	15%

Sales of our products in the cryosurgical systems market (which includes both the physicians' office and OTC markets) decreased 34% to $4.0 million in the third quarter of 2006 from $6.1 million in the same period in 2005. This decrease was primarily the result of lower sales of our domestic OTC cryosurgical products and of our professional cryosurgical product in the United States, partially offset by increased sales of our international OTC cryosurgical product in Europe.

Our domestic OTC cryosurgical product, called Freeze Off®, is distributed in the United States and Canada by Prestige, the owner of the Compound W® line of wart removal products. There were no sales of Freeze Off® to Prestige during the third quarter of 2006. According to Prestige, the absence of Freeze Off® sales was purportedly the result of competition from other OTC cryosurgical products, the ongoing efforts of Prestige to reduce inventory levels and lower advertising expenditures by Prestige. However, we believe the complete absence of third quarter sales was due in large part to Prestige's recent acquisition of the competing Wartner® OTC cryosurgical wart removal product, in violation of a covenant not to compete contained in our distribution agreement with Prestige. Sales of Freeze Off® to Prestige were $3.0 million in the third quarter of 2005.

In June 2005, we entered into 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 footcare market in Europe, Australia and New Zealand. The product is manufactured and sold under SSL's Scholl and Dr. Scholl trademarks, and was made initially available for retail purchase in pharmacies and other retail outlets in several European countries during the fourth quarter of 2005. Sales to SSL under the distribution agreement were $1.7 million and $476,000 in the third quarters of 2006 and 2005, respectively. SSL continues to build distribution networks in pharmacies and mass merchandisers throughout Europe, an activity which we believe will continue during 2007.

Sales of our Histofreezer® product to physicians' offices in the U.S. market decreased 17% to $1.8 million in the third quarter of 2006, from $2.1 million in the third quarter of 2005. Sales of Histofreezer® in the international market increased by 4% to $576,000, from $554,000 in the third quarter of 2005. We believe that these changes were due to fluctuations in distributor ordering patterns.

We are beginning to see some evidence that sales of our OTC cryosurgical products may reduce the number of individuals that will seek to obtain treatment of their warts by a physician, which in turn could negatively affect sales of our Histofreezer® product in the professional market. However, it is not possible at this time to estimate the magnitude of the financial impact of this change.

We expect aggregate sales of our cryosurgical systems products (both OTC and physicians' office) to approximate $4.5 million in the fourth quarter of 2006. Of this total, approximately $2.3 million is expected from sales of our OTC cryosurgical products.

Sales in the OTC cryosurgery marketplace for the full year 2006 are expected to be less than the level reported for 2005 as a result of the disappointing performance by Prestige. Sales to Prestige for 2006 are now projected to be less than 50% of the $11.6 million recorded in 2005. Partially offsetting this decline will be increased OTC revenues expected from SSL. We anticipate that U.S. and international sales of Histofreezer® in the physicians' office market during the remainder of 2006 will approximate 2005 levels.

Sales to the insurance risk assessment market increased 36% to $1.7 million in the third quarter of 2006 from $1.3 million in the same period in 2005. We believe this increase is due to fluctuations in laboratory ordering patterns. Despite this increase during the third quarter, we currently expect that our full-year 2006 revenues in this market will decline approximately $1.0 million below the levels attained in 2005.

Licensing and product development revenues increased 385% to $131,000 during the third quarter of 2006, from $27,000 in the same period in 2005. Licensing and product development revenues are primarily related to our collaborative oral fluid research project with The University of Pennsylvania and New York University, under a grant awarded by the National Institutes of Health. The current annual phase of this grant expired in September 2006.

Quest Diagnostics (including its wholly-owned subsidiary, Lab*One*, Inc.) accounted for 15% and 13% of total revenues for the third quarter of 2006 and 2005, respectively. Abbott accounted for 9% and 10% of total revenues for the third quarter of 2006 and 2005, respectively. Prestige accounted for 17% of total revenues for the third quarter of 2005. There were no sales to Prestige for the three months ended September 30, 2006.

Gross margin was 64% in both the third quarter of 2006 and 2005.

Research and development expenses increased 35% to $1.8 million in the third quarter of 2006 from $1.3 million in the same period in 2005, primarily as a result of costs associated with clinical testing and studies, increased staffing and outside services as well as increased stock-based compensation charges. Research and development costs are expected to increase in 2006, as compared to 2005, primarily as a result of costs associated with the development of new product offerings and product enhancements for the infectious disease and substance abuse testing markets, including OraQuick® OTC clinical trials expense, and the expensing of stock options.

Sales and marketing expenses decreased 8% to $3.6 million in the third quarter of 2006 from $4.0 million in the same period in 2005. This decrease was primarily the result of decreased advertising and market research expenses, partially offset by higher payroll and stock-based compensation charges. Included in advertising expenses for the third quarter of 2005 was $497,000, payable to Prestige as reimbursement for marketing expenses incurred for the Freeze Off® product. There were no such expenses during the third quarter of 2006. Pursuant to our agreement with Prestige, we will continue to co-invest in Prestige's marketing activities for the Freeze Off® product during 2006 by reimbursing Prestige for a portion of Prestige's out-of-pocket costs of advertising and promoting this product in the OTC market.

General and administrative expenses increased 8% to $3.4 million in the third quarter of 2006 from $3.2 million in the same period in 2005. This increase was primarily attributable to charges for stock-based compensation and higher consulting costs, partially offset by lower legal fees and rent expense. General and administrative expenses are expected to increase in 2006 versus 2005 primarily as a result of increased stock-based compensation expense and expenses related to the implementation of a new enterprise resource planning system.

Interest expense was $182,000 in the third quarter of 2006 compared to $23,000 in the same period in 2005. Interest expense increased as a result of an additional $10.0 million of borrowings incurred to purchase two previously leased facilities on June 30, 2006. Interest income increased to $1.1 million in the third quarter of 2006 from $619,000 in the same period in 2005, as a result of higher yields on our investment portfolio and greater balances available for investment.

Based on our 2005 results and our projections for future taxable income, we have begun providing for income taxes at a rate equal to our estimated combined federal and state effective rates. As such, for the three months ended September 30, 2006, a provision for income taxes of $1.3 million was recorded, which represents a 37.2% effective tax rate. No provision for income taxes was recorded in the third quarter of 2005.

Nine months ended September 30, 2006 compared to September 30, 2005

Total revenues decreased 2% to $50.4 million in the first nine months of 2006 from $51.3 million in the same period in 2005, primarily as a result of decreased sales of our cryosurgical systems and insurance risk assessment products, partially offset by increased revenues from the infectious disease and substance abuse testing markets. Revenues derived from products sold to customers outside the U.S. were $8.3 million and $5.1 million, or 16% and 10% of total revenues, during the first nine months of 2006 and 2005, 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	
	2006	2005	Change	2006	2005
Market					
Infectious disease testing	$21,239	$19,672	8%	42%	38%
Substance abuse testing	11,694	10,060	16	23	20
Cryosurgical systems	13,063	16,002	(18)	26	31
Insurance risk assessment	4,128	5,364	(23)	8	11
Product revenues	50,124	51,098	(2)	99	100
Licensing and product development	297	237	25	1	—
Total revenues	$50,421	$51,335	(2)%	100%	100%

Sales to the infectious disease testing market increased 8% to $21.2 million in the first nine months of 2006 from $19.7 million in the same period in 2005, primarily as a result of the continuing strength of our OraQuick *ADVANCE*® rapid HIV-1/2 antibody test. OraQuick® sales totaled $18.5 million and $16.2 million in the first nine months of 2006 and 2005, respectively. Although sales of OraQuick® to the public health market and to the hospital market through our distributor, Abbott, increased substantially during the first nine months of 2006 compared to 2005, these increases were partially offset by a significant reduction in shipments of product during this period under bulk purchase orders from the CDC and SAMHSA. OraSure® sales totaled $2.8 million and $3.4 million in the first nine months of 2006 and 2005, respectively.

The table below shows a breakdown of our total OraQuick® revenues (in thousands, except %) during the first nine months of 2006 and 2005.

	Nine Months Ended September 30,		
	2006	2005	% Change
Customers			
Direct to U.S. Public Health	$10,794	$ 5,928	82%
Abbott	5,224	3,579	46
SAMHSA	256	2,586	(90)
CDC	1,009	2,321	(57)
International	1,185	1,093	8
Direct to Hospitals	—	736	(100)
Total OraQuick® revenues	$18,468	$16,243	14%

We believe that our OraQuick *ADVANCE*® device, which is FDA-approved for detecting antibodies to both HIV-1 and 2 in oral fluid, fingerstick and venous whole blood, and plasma samples, and is CLIA-waived for use with all sample types except plasma, provides a significant competitive advantage and is allowing us to more fully implement a strategy to sell OraQuick® internationally. We are currently pursuing CE marking for our OraQuick *ADVANCE*® product which would allow us to sell our product in Europe. Our goal is to obtain a CE mark for OraQuick *ADVANCE*® as soon as possible and thereafter obtain several country-specific registrations, which would allow us to launch the product in Europe.

In previous periods, the CDC and SAMHSA have placed bulk purchase orders for OraQuick *ADVANCE*® devices and related testing materials. In the first quarter of 2006, we received an additional bulk purchase order from SAMHSA and, in the second quarter of 2006, we received bulk purchase orders for OraQuick *ADVANCE*® devices from the CDC, the City of New York and Washington, D.C. We expect that federal and other governmental agencies will make future bulk purchases of OraQuick *ADVANCE*® for further distribution to the public health and other markets throughout the United States. However, the failure to receive, any delays in receiving or deploying, or any reduction in the size of, any current or future bulk orders for OraQuick *ADVANCE*® from these governmental agencies could adversely affect our financial performance.

We are beginning to see evidence that sales of OraQuick *ADVANCE*® are negatively impacting sales of our OraSure® oral fluid collection device in the infectious disease testing market. Some customers who have purchased our OraSure® device for HIV-1 testing in the past are electing instead to purchase our OraQuick *ADVANCE*® test. However, it is not possible at this time to estimate the extent of this change in purchasing patterns or the financial impact of replacing OraSure® sales with sales of our OraQuick *ADVANCE*® test.

Sales to the substance abuse testing market increased 16% to $11.7 million in the first nine months of 2006 from $10.1 million in the same period in 2005, primarily as a result of increased sales of our Intercept® oral fluid drug testing service and Q.E.D.®, our rapid oral fluid alcohol test. Intercept® sales increased as a result of continued growth across all markets for this product. Increased sales of our Q.E.D.® test are attributed to a change in regulation that is increasing demand for this product.

The table below shows a breakdown of our total Intercept® revenues (in thousands, except %) generated in each market in the first nine months of 2006 and 2005.

	Nine Months Ended September 30,		
	2006	2005	% Change
Market			
Workplace testing	$ 4,675	$ 4,301	9%
Criminal justice	1,428	1,259	13
International	1,615	1,402	15
Direct	528	374	41
Total Intercept® revenues	$ 8,246	$ 7,336	12%

Sales of our products in the cryosurgical systems market (which includes both the physicians' office and OTC markets) decreased 18% to $13.1 million in the first nine months of 2006 from $16.0 million in the same period in 2005. This decrease was primarily the result of lower sales of our domestic OTC cryosurgical product, partially offset by increased sales of our international OTC cryosurgical product.

Our domestic OTC cryosurgical product, called Freeze Off®, is distributed in the United States and Canada by Prestige, the owner of the Compound W® line of wart removal products. Sales of Freeze Off® to Prestige were $4.0 million in the first nine months of 2006 compared to $9.8 million during the first nine months of 2005. According to Prestige, this decrease is the result of competition from other OTC cryosurgical products, the ongoing efforts of Prestige to reduce inventory levels, and lower advertising expenditures by Prestige. However, we believe the decrease was due in large part to Prestige's recent acquisition of the competing Wartner® OTC cryosurgical wart removal product, in violation of a covenant not to compete contained in our distribution agreement with Prestige.

In June 2005, we entered into 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 footcare market in Europe, Australia and New Zealand. The product is manufactured and sold under SSL's Scholl and Dr. Scholl trademarks, and was made available for retail purchase in pharmacies and other retail outlets in several European countries during the fourth quarter of 2005. Sales to SSL under the distribution agreement were $3.5 million and $476,000 in the first nine months of 2006 and 2005, respectively. SSL continues to build distribution networks in pharmacies and mass merchandisers throughout Europe, an activity which we believe will continue during 2007.

Sales of our Histofreezer® product to physicians' offices in the U.S. market decreased 2% to $4.2 million in the first nine months of 2006, from $4.3 million in the first nine months of 2005. Sales of Histofreezer® in the international market increased 7% to $1.5 million in the first nine months of 2006, from $1.4 million in the first nine months of 2005. We believe these changes were due to fluctuations in distributor ordering patterns.

We are beginning to see some evidence that sales of our OTC cryosurgical products may reduce the number of individuals that will seek to obtain treatment of their warts by a physician, which in turn could negatively affect sales of our Histofreezer® product in the professional market. However, it is not possible at this time to estimate the magnitude of the financial impact of this change.

We expect aggregate sales of our cryosurgical systems products (both OTC and physicians' office) to approximate $4.5 million in the fourth quarter of 2006. Of this total, approximately $2.3 million is expected from sales of our OTC cryosurgical products.

Sales in the OTC cryosurgery marketplace for the full year 2006 are expected to be less than the level reported for 2005 as a result of the continued disappointing performance expected from Prestige. Sales to Prestige for 2006 are now projected to be less than 50% of the $11.6 million recorded in 2005. Partially offsetting this decline are increased OTC revenues expected from SSL. We anticipate that U.S. and international sales of Histofreezer® in the physicians' office market during the remainder of 2006 will approximate 2005 levels.

Sales to the insurance risk assessment market decreased 23% to $4.1 million in the first nine months of 2006 from $5.4 million in the same period in 2005. We believe this decrease is due to a continued reduction in the number of life insurance applications and an increase in the average policy amount. We currently expect that our full-year 2006 revenues in this market will decline approximately $1.0 million below the levels attained in 2005.

Licensing and product development revenues increased by 25% to $297,000 during the first nine months of 2006, from $237,000 in the same period in 2005. Licensing and product development revenues are primarily related to our collaborative oral fluid research project with The University of Pennsylvania and New York University, under a grant awarded by the National Institutes of Health. The current annual phase of this grant expired in September 2006.

Quest Diagnostics (including its wholly-owned subsidiary, Lab*One*, Inc.) accounted for 14% of total revenues for the first nine months of both 2006 and 2005. Abbott accounted for 9% and 7% of total revenues for the first nine months of 2006 and 2005, respectively. Prestige accounted for 8% and 19% of total revenues for the first nine months of 2006 and 2005, respectively.

Gross margin in the first nine months of 2006 was 63%, compared to 60% for the first nine months of 2005. In the first nine months of 2005, gross margin was negatively affected by a $1.5 million charge associated with the UP*link*® assets.

Research and development expenses increased 37% to $5.1 million in the first nine months of 2006 from $3.8 million in the same period in 2005, primarily as a result of costs associated with the development of a rapid hepatitis C testing product, preparation for OraQuick® OTC clinical trials and process improvements, as well as increased staffing and stock-based compensation charges. Research and development costs are expected to increase in 2006, as compared to 2005, primarily as a result of costs associated with the development of new product offerings and product enhancements for the infectious disease and substance abuse testing markets, including OraQuick® OTC clinical trials expense, and the expensing of stock options.

A charge of $600,000 for in-process technology was recorded in the first nine months of 2006 related to the exercise of an option to expand the scope of our HIV-2 patent license to cover products other than our OraQuick *ADVANCE*® test.

Sales and marketing expenses decreased by 3% to $12.0 million in the first nine months of 2006 from $12.3 million in the same period in 2005. This decrease was primarily the result of lower advertising credits to Prestige together with lower market research expenses, commissions and consulting fees, partially offset by increases in staffing, stock-based compensation and travel expenses.

General and administrative expenses increased 4% to $9.5 million in the first nine months of 2006 from $9.1 million in the same period in 2005. This increase was primarily attributable to charges for stock-based compensation and higher consulting fees, partially offset by lower legal fees associated with the Schering-Plough litigation and lower rent expense. General and administrative expenses are expected to increase in 2006 versus 2005 primarily as a result of increased stock-based compensation expense and expenses related to the implementation of a new enterprise resource planning system.

Interest expense increased to $224,000 in the first nine months of 2006 from $76,000 in the same period in 2005, as a result of an additional $10.0 million of borrowings incurred to purchase two previously leased facilities on June 30, 2006. Interest income increased to $2.9 million in the first nine months of 2006 from $1.5 million in the same period in 2005, as a result of higher yields on our investment portfolio and greater balances available for investment.

Based on our 2005 results and our projections for future taxable income, we have begun providing for income taxes at a rate equal to our estimated combined federal and state effective rates. As such, for the nine months ended September 30, 2006, a provision for income taxes of $3.0 million was recorded, which represents a 41.7% effective tax rate. No provision for income taxes was recorded in the first nine months of 2005.

Liquidity and Capital Resources

	September 30, 2006	December 31, 2005
	(In thousands)	
Cash and cash equivalents	$ 17,030	$ 32,827
Short-term investments	72,504	44,793
Working capital	98,057	90,670

Our cash, cash equivalents, and short-term investments increased $11.9 million during the first nine months of 2006 to $89.5 million at September 30, 2006, as a result of the Company’s $14.1 million positive cash flow from operations, $10.0 million in new bank borrowings, and $344,000 in proceeds from the exercise of stock options, partially offset by the purchase of $11.6 million of property and equipment, $401,000 of debt repayments, and $519,000 associated with the retirement of common stock to pay minimum tax withholding obligations on the vesting of restricted shares. At September 30, 2006, the Company’s working capital was $98.1 million.

Net cash provided by operating activities was $14.1 million in the first nine months of 2006. The $14.1 million of cash provided by operating activities resulted from net income of $4.2 million, stock-based compensation of $4.3 million, deferred income taxes of $2.6 million, depreciation and amortization of $1.4 million, acquired in-process technology of $600,000, provisions for excess and obsolete inventories of $472,000, a decrease of $1.4 million in accounts receivable, and increases of $1.2 million in inventories, $50,000 in prepaid expenses and other assets, and $235,000 in accounts payable and accruals.

Net cash used in investing activities during the first nine months of 2006 was $39.3 million. We purchased $11.6 million of property and equipment, of which $9.1 million related to the purchase of the Company’s two previously leased facilities in Bethlehem, Pennsylvania. During the first nine months of 2006, we also purchased a net amount of $27.5 million of short-term investments and made a payment of $200,000 related to acquired in-process technology.

Net cash provided by financing activities was $9.4 million, reflecting $10.0 million in new borrowings from Comerica Bank to finance the purchase of the two previously leased facilities and $344,000 received from the issuance of common stock, partially offset by $401,000 of loan principal repayments and $519,000 used for the purchase and retirement of common stock.

We have in place an $11.9 million credit facility (the “Credit Facility”) with Comerica Bank, which is comprised of an $887,000 mortgage loan, a $3.0 million term loan, a $4.0 million non-revolving line of credit for the purchase of both capital equipment and software, and a $4.0 million revolving working capital line of credit. As of September 30, 2006, we had no outstanding borrowings under the $3.0 million term loan, the $4.0 million non-revolving line of credit, or the $4.0 million revolving working capital line of credit. On June 27, 2006, we executed an amendment to our Credit Facility, pursuant to which we are permitted to borrow up to an additional $15.0 million in advances in order to fund the purchase and future expansion of two leased facilities in Bethlehem, Pennsylvania. On June 29, 2006, we borrowed $10.0 million under the terms of this Credit Facility, as amended, and purchased our two Bethlehem facilities. We can borrow the remaining $5.0 million at any time before June 30, 2007. At our option, interest on outstanding borrowings 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 rate plus 0.55% to 1.25%. In each case, the interest rate is determined at the date of the advance and is based upon the amount of cash and cash equivalents we invest and retain at Comerica Securities, Inc. We also can choose the fixed rate option, without penalty, at the expiration of a previously elected LIBOR period. 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. This amendment also extended the maturity date of our $4.0 million revolving working capital line of credit to June 29, 2007. All other terms of the Credit Facility, as previously amended, remain in effect, except for our financial covenant related to liquidity, which was modified to require a minimum liquidity, as defined by Comerica, of not less than $25.0 million, of which at least $15.0 million must be held by Comerica or its affiliates.

At September 30, 2006, interest on the new $10.0 million borrowing is currently payable monthly, at the 180-day LIBOR rate plus 0.9%, or 6.5175%. Principal is repayable in installments, due at the end of each LIBOR rate period, based upon a twenty-year amortization schedule and the number of months in the expiring LIBOR rate period. Accordingly, on December 25, 2006, we will be required to make a $250,000 principal repayment, and the interest rate on this loan will be reset.

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 one of our manufacturing 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, 2006 and expect to remain in compliance with all covenants during the remainder of 2006. The Credit Facility also restricts our ability to pay dividends, to make certain investments, to incur additional indebtedness, to sell or otherwise dispose of a substantial portion of assets, and to merge or consolidate operations with an unaffiliated entity, without the consent of Comerica.

The combination of our current cash position, 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. 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.

Recent Accounting Pronouncements. In July 2006, the Financial Accounting Standards Board (“FASB”) issued FASB Interpretation (“FIN”) No. 48, “Accounting for Uncertainty in Income Taxes – an Interpretation of FASB Statement No. 109,” which clarifies what criteria must be met prior to recognition of the financial statement benefit of a position taken in a tax return. FIN No. 48 will require companies to include additional qualitative and quantitative disclosures within their financial statements. The disclosures will include potential tax benefits from

positions recognized for tax return purposes but not recognized for financial reporting purposes, as well as a tabular presentation of significant changes in such benefits during each period. The disclosures will also include a discussion of the nature of uncertainties, factors that could cause a change, and an estimated range of reasonably possible changes in tax uncertainties. FIN No. 48 will require a company to recognize a financial statement benefit for a position taken for tax return purposes when it will be more-likely-than-not that the position will be sustained. FIN No. 48 will be effective for fiscal years beginning after December 15, 2006. We are currently assessing the impact FIN No. 48 will have on our financial statements.

In September 2006, the United States Securities and Exchange Commission issued Staff Accounting Bulletin ("SAB") No. 108 "Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements." SAB No. 108 requires companies to evaluate the materiality of identified unadjusted errors using both the income statement approach and the balance sheet approach. In the initial year of adoption, if a company determines that an adjustment to prior year financial statements is required under either approach, SAB No. 108 allows for a one-time cumulative-effect adjustment to beginning retained earnings. SAB No. 108 is effective for interim periods of the first fiscal year ending after November 15, 2006. We are currently assessing the impact, if any, that SAB No. 108 will have on our financial statements.

In September 2006, the 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. We are currently assessing the impact, if any, that SFAS No. 157 will have on our financial statements.

Summary of Contractual Obligations

The following sets forth our approximate aggregate obligations at September 30, 2006 for future payments under contracts and other contingent commitments, for the years 2006 and beyond:

		Payments due by December 31,					
Contractual Obligations	**Total**	**2006**	**2007**	**2008**	**2009**	**2010**	**Thereafter**
Long-term debt[1]	$ 10,939,124	$ 300,481	$ 608,807	$ 593,147	$ 597,411	$ 552,741	$ 8,286,537
Operating leases[2]	59,905	36,972	22,933	—	—	—	—
Employment contracts[3]	2,945,475	507,725	1,739,100	698,650	—	—	—
Purchase obligations[4]	6,963,129	6,963,129	—	—	—	—	—
Minimum commitments under contracts[5]	10,591,667	3,000,000	725,000	725,000	650,000	650,000	4,841,667
Total contractual obligations	$ 31,499,300	$ 10,808,307	$ 3,095,840	$ 2,016,797	$ 1,247,411	$ 1,202,741	$ 13,128,204

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-cancelable purchase orders related to inventory, capital expenditures and other goods or services.

[5] Represents payments required pursuant to certain research, licensing and royalty agreements executed by the Company. These agreements are cancelable within a specified number of days of communication by the Company to terminate the agreement. Additional payments up to $5.5 million may be required for the achievement of specific development and/or commercial milestones, pursuant to one of the licensing agreements.

Critical Accounting Policies and Estimates

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, accruals, income taxes, revenue recognition, stock-based compensation, 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.

Our significant accounting policies are described in Note 2 to the financial statements included in our 2005 Annual Report on Form 10-K filed with the Securities and Exchange Commission. 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 of 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 ratably recognize this revenue 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 price protection or 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 $286,377 at September 30, 2006. While credit losses have been within our expectations and the allowance provided, these losses can vary from period to period. 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, 2006, $4.0 million, or 39% of our accounts receivable, were 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 the inventories' carrying value is reduced 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 2005, 2004, and 2003, we wrote-off inventory which had a cost of $2.1 million, $839,000, and $540,000, respectively, as a result of scrap levels, product expiration issues and a $1.5 million provision for loss on our UP*link*® product 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.

Long-lived and Intangible Assets. Our long-lived assets are comprised of property and equipment and an investment in a nonaffiliated entity, and our intangible assets primarily consist of patents and product rights. Together, these assets had a net book value of $19.3 million or 13% of our total assets at September 30, 2006. Our investment in the privately-held nonaffiliated company is recorded under the cost method of accounting, because we do not have a controlling interest in this company, nor do we have the ability to exert significant influence over the operating and financial policies of this company. Property and equipment, patents, and product rights are 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. 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 strategy for our overall business, significant negative industry or economic trends, shortening of product life-cycles or changes in technology, and negative financial performance of our nonaffiliated investee company. 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 and eventual disposition 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. We currently believe the future cash flows to be received from our long-lived and intangible assets will exceed their book value and, as such, we have not recognized any impairment losses through September 30, 2006. 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. At December 31, 2005, we had federal net operating loss carryforwards ("NOLs") of $66.6 million. The deferred tax asset associated with these NOLs and other temporary differences was $26.7 million at December 31, 2005. 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 asset will not be realized. The ultimate realization of the deferred tax asset is dependent upon the generation of future taxable income during the period in which those temporary differences become deductible or the NOLs 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.

Our ability to use our NOLs to offset future federal income tax obligations could be limited by changes in the ownership of our stock. Internal Revenue Code ("IRC") Section 382 contains provisions that limit the amount of federal NOLs that can be used in any given year in the event of specified occurrences, including significant ownership changes. In the fourth quarter of 2005, the Company completed an analysis, with the assistance of independent tax specialists, 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, the Company concluded that prior period ownership changes may impose a limitation on the amount of NOLs that can be utilized in a given year. The Company does not believe, however, that this limitation will impair our future ability to utilize NOLs to offset our forecasted taxable income or to realize the related deferred tax asset.

Prior to December 31, 2005, a valuation allowance had been established for the full amount of the net deferred tax asset created by these carryforwards and other items. Based on our 2005 results and our projections for future taxable income over the periods in which the deferred tax assets are deductible or the NOLs and credit carryforwards can be utilized, we believed a significant portion of the deferred tax asset was realizable at December 31, 2005. As such, we recorded the estimated net realizable value of the deferred tax asset at December 31, 2005 and have begun providing for income taxes at a rate equal to our estimated combined federal and state effective rates. As we provide for income taxes, our deferred tax asset will be reduced as we utilize our NOLs. 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. Additionally, our effective tax rate is impacted by several factors, which can also cause our provision for income taxes to vary significantly from period to period. These factors include, among other things, our actual annual pre-tax income, changes in our stock price and its effect on executive compensation, and the significance of permanent differences related to stock compensation.

Stock-Based Compensation. We grant stock options to our employees and non-employee directors as part of their compensation. The amount of stock option compensation expense incurred and to be incurred in future periods is dependent upon a number of factors, such as the number of options granted, the timing of stock option exercises and actual forfeiture rates. We estimate the fair value of all stock option awards as of the date of grant by applying the Black-Scholes option-pricing model. The application of this valuation model involves assumptions, some of which are judgmental and highly sensitive, in the determination of stock option compensation expense. These assumptions include our expected stock price volatility, the expected life of our stock options, and an estimated forfeiture rate, which are all based primarily on our historical experience.

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 market risk to report under this Item for such instruments.

Our holdings of financial instruments are comprised of certificates of deposit, commercial paper, U.S. government agency obligations, and corporate bonds. All such instruments are classified as available-for-sale securities. Our debt security portfolio represents funds held temporarily pending use in our business and operations. We seek reasonable assuredness of the safety of principal and market liquidity by investing in rated fixed income securities while at the same time seeking to achieve a favorable rate of return. Market risk exposure consists principally of exposure to changes in interest rates. If changes in interest rates would affect the investments adversely, we could decide to hold the security to maturity or sell the security. Our holdings are also exposed to the risks of changes in the credit quality of issuers. We typically invest in the shorter end of the maturity spectrum.

We do not currently 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 the statement of operations for this operation from euros to U.S. dollars affects year-to-year comparability of operating results. Sales denominated in a foreign currency represented $549,000 and $1.5 million, or 3%, of our total revenues for both the three months and nine months ended September 30, 2006, respectively. We do not expect the risk of foreign currency fluctuations to be material.

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, 2006. Based on that evaluation, the Company's management, including such officers, concluded that the Company's disclosure controls and procedures are adequate and effective 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 Securities and Exchange Commission.

(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, 2006, 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.

Prestige Brands Holdings, Inc. (“Prestige”), through an affiliate, is the exclusive distributor of our cryosurgical wart removal product in the over-the-counter (“OTC”) market in the United States and Canada. Prestige distributes this product under its Compound W Freeze Off® trade name. In September 2006, Prestige announced that it had acquired the Wartner® cryosurgical wart removal product line, which directly competes with the Freeze Off® product in the OTC market.

Our distribution agreement with Prestige contains a covenant not to compete which precludes Prestige from acquiring, manufacturing, distributing or selling a cryosurgical product that directly competes with the Freeze Off® product. We have notified Prestige that its acquisition of the Wartner® product constitutes a material breach of the distribution agreement and that certain of its other actions constitute additional breaches under the agreement. On September 27, 2006, we filed a special petition and application with the Supreme Court of the State of New York, New York County, for a preliminary injunction against Prestige pursuant to New York Civil Practice Law and Rules §7502(c) in support of the arbitration to be commenced between the parties. On November 8, 2006, the Court issued a decision dated October 30, 2006 finding that Prestige had breached the covenant not to compete, but denied our application. We intend to file a motion for reargument with the Court, seeking reconsideration and reversal of the decision.

We have also notified Prestige that we have initiated the mandatory alternative dispute resolution procedures under the agreement, which include mediation and binding arbitration. The alternative dispute resolution process is currently scheduled to begin in November 2006.

Unless we are able to resolve this matter with Prestige, we intend to vigorously enforce our rights and remedies under the agreement, including seeking specific performance of the covenant not to compete.

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, 2005.

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 9, 2006

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

/s/ Mark L. Kuna

Date: November 9, 2006

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

EXHIBIT INDEX

Exhibit	
10.1	Employment Agreement, dated as of October 2, 2006, between Mark L. Kuna and OraSure Technologies, Inc., is incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K filed October 5, 2006.
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.

* Management contract or compensatory plan or arrangement.

Exhibit 31.1

Certification

I, Douglas A. Michels, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 9, 2006

/s/ Douglas A. Michels

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

Exhibit 31.2

Certification

I, Ronald H. Spair, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 9, 2006

/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, 2006 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 9, 2006

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, 2006 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 9, 2006