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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, 2004.

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 an accelerated filer (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 October 29, 2004: 44,549,167

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Item 1. FINANCIAL STATEMENTS

ORASURE TECHNOLOGIES, INC.
BALANCE SHEETS
(Unaudited)

	September 30, 2004	December 31, 2003
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 13,314,755	$ 30,695,177
Short-term investments	52,141,341	33,328,610
Accounts receivable, net of allowance for doubtful accounts of $292,614 and $359,158	7,098,339	8,233,869
Inventories	4,663,500	4,003,519
Prepaid expenses and other	725,974	922,820
Total current assets	77,943,909	77,183,995
PROPERTY AND EQUIPMENT, net of accumulated depreciation of $16,120,215 and $14,862,075	5,940,706	6,471,209
PATENTS AND PRODUCT RIGHTS, net of accumulated amortization of $2,681,524 and $2,162,486	2,267,424	1,886,171
OTHER ASSETS	577,900	609,932
	$ 86,729,939	$ 86,151,307
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	$ 1,125,515	$ 1,126,423
Accounts payable	1,625,154	3,511,148
Accrued expenses	6,976,143	5,375,851
Total current liabilities	9,726,812	10,013,422
LONG-TERM DEBT	1,612,085	2,456,454
OTHER LIABILITIES	219,638	172,142
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, 44,549,167 and 44,260,931 shares issued and outstanding	45	44
Additional paid-in capital	209,608,434	204,867,765
Deferred compensation	(3,254,608)	(614,515)
Accumulated other comprehensive loss	(298,004)	(173,704)
Accumulated deficit	(130,884,463)	(130,570,301)
Total stockholders' equity	75,171,404	73,509,289
	$ 86,729,939	$ 86,151,307

The accompanying notes are an integral part of these statements.

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ORASURE TECHNOLOGIES, INC.
STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
REVENUES:				
Product	$14,086,266	$10,221,656	$39,497,173	$28,002,175
Licensing and product development	89,746	109,615	302,160	568,590
	14,176,012	10,331,271	39,799,333	28,570,765
COSTS OF PRODUCTS SOLD	5,721,750	4,002,032	16,437,016	11,403,023
Gross profit	8,454,262	6,329,239	23,362,317	17,167,742
COSTS AND EXPENSES:				
Research and development	1,464,918	2,201,946	4,745,692	6,221,932
Sales and marketing	3,956,266	2,512,999	11,387,748	7,485,533
General and administrative	3,513,828	1,601,819	8,085,973	5,124,809
	8,935,012	6,316,764	24,219,413	18,832,274
Operating income (loss)	(480,750)	12,475	(857,096)	(1,664,532)
INTEREST EXPENSE	(32,157)	(44,520)	(103,551)	(140,333)
INTEREST INCOME	228,877	78,360	664,659	247,306
FOREIGN CURRENCY GAIN (LOSS)	(5,057)	8,977	(3,726)	5,181
Income (loss) before income taxes	(289,087)	55,292	(299,714)	(1,552,378)
INCOME TAXES	4,987	2,674	14,448	18,117
NET INCOME (LOSS)	$ (294,074)	$ 52,618	$ (314,162)	$ (1,570,495)
EARNINGS (LOSS) PER SHARE:				
BASIC	$ (0.01)	$ 0.00	$ (0.01)	$ (0.04)
DILUTED	$ (0.01)	$ 0.00	$ (0.01)	$ (0.04)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING:				
BASIC	44,538,745	38,665,545	44,425,625	38,444,062
DILUTED	44,538,745	39,777,279	44,425,625	38,444,062

The accompanying notes are an integral part of these statements.

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

	Nine Months Ended September 30,	
	2004	2003
OPERATING ACTIVITIES:		
Net loss	$ (314,162)	$ (1,570,495)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Stock-based compensation expense	536,057	33,900
Depreciation and amortization	1,824,782	1,914,022
Loss on disposition of property and equipment, net	4,339	—
Write-off of inventory	737,396	438,069
Changes in assets and liabilities:		
Accounts receivable	1,135,530	(1,827,011)
Inventories	(1,397,377)	(362,028)
Prepaid expenses and other assets	196,846	378,015
Accounts payable and accrued expenses	(503,534)	1,929,835
Net cash provided by operating activities	2,219,877	934,307
INVESTING ACTIVITIES:		
Purchases of short-term investments	(48,535,983)	(13,995,647)
Proceeds from maturities and redemptions of short-term investments	29,613,090	10,358,896
Purchases of property and equipment	(785,618)	(862,186)
Proceeds from the sale of property and equipment	2,260	—
Purchase of patents and product rights	(600,000)	(250,000)
(Increase) decrease in other assets	847	(1,360)
Net cash used in investing activities	(20,305,404)	(4,750,297)
FINANCING ACTIVITIES:		
Borrowings of long-term debt	—	211,590
Repayments of long-term debt	(845,277)	(822,482)
Proceeds from issuance of common stock	1,564,520	3,558,093
Net cash provided by financing activities	719,243	2,947,201
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	(14,138)	27,603
NET DECREASE IN CASH AND CASH EQUIVALENTS	(17,380,422)	(841,186)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	30,695,177	4,364,308
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 13,314,755	$ 3,523,122

The accompanying notes are an integral part of these statements.

OraSure Technologies, Inc.
Notes to Financial Statements (Unaudited)

1. The Company

We develop, manufacture and market oral specimen collection devices using our proprietary oral fluid technologies, diagnostic products including *in vitro* diagnostic tests, and other medical devices. These products are sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, distributors, government agencies, physicians' offices, and commercial and industrial entities.

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 the results 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, 2003. Results of operations for the three-month and nine-month periods ended September 30, 2004 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, 2004 and December 31, 2003, cash equivalents consisted of certificates of deposit, commercial paper and U.S. government and agency obligations.

Short-term Investments. We consider all short-term investments to be available-for-sale securities, in accordance with Statement of Financial Accounting Standards ("SFAS") No. 115, "Accounting for Certain Investments in Debt and Equity Securities." These securities are comprised of certificates of deposits, commercial paper, U.S. government and agency obligations, state and local government agency obligations, corporate bonds, and asset-backed obligations, 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, 2004 and December 31, 2003:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
September 30, 2004				
Certificates of deposit	$19,445,691	$ 163	$(19,687)	$19,426,167
Commercial paper	1,293,630	—	(598)	1,293,032
Government and agency bonds	21,208,947	—	(45,220)	21,163,727
State and local government agency obligations	632,440	254	(405)	632,289
Corporate bonds	8,642,626	84	(30,674)	8,612,036
Asset-backed obligations	1,016,018	—	(1,928)	1,014,090
Total available-for-sale securities	$52,239,352	$ 501	$(98,512)	$52,141,341
December 31, 2003				
Certificates of deposit	$14,047,127	$ 1,167	$ (5,586)	$14,042,708
Commercial paper	1,296,941	121	—	1,297,062
Government and agency bonds	14,483,893	7,667	—	14,491,560
State and local government agency obligations	629,999	1,118	(3)	631,114
Corporate bonds	2,867,261	1,641	(2,736)	2,866,166
Total available-for-sale securities	$33,325,221	$ 11,714	$ (8,325)	$33,328,610
At September 30, 2004, maturities of investments were as follows:				
Less than one year	$49,042,063	$ 417	$(75,654)	$48,966,826
1 – 2 years	3,197,289	84	(22,858)	3,174,515
Total available-for-sale securities	$52,239,352	$ 501	$(98,512)	$52,141,341

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, 2004	December 31, 2003
Raw materials	$ 3,186,981	$2,862,169
Work-in-process	882,894	486,284
Finished goods	593,625	655,066
	$ 4,663,500	$4,003,519

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 and nine-month periods ended September 30, 2004, one customer accounted for 28 percent and 26 percent, respectively, of total revenues as compared to 16 percent and 10 percent, respectively, for the same periods of 2003. The same customer accounted for approximately 31 percent and 23 percent of accounts receivable as of September 30, 2004 and December 31, 2003, respectively.

For the three-month and nine-month periods ended September 30, 2004, another customer accounted for 10 percent and 12 percent, respectively, of total revenues as compared to 20 percent for the same periods of 2003. This customer accounted for approximately 5 percent and 8 percent of accounts receivable as of September 30, 2004 and December 31, 2003, 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 in accumulated other comprehensive loss, which is a separate component of stockholders' equity.

Earnings (Loss) Per Common Share. We have presented basic and diluted earnings (loss) per common share pursuant to SFAS No. 128, "Earnings per Share." In accordance with SFAS No. 128, basic earnings (loss) per share is computed by dividing net income (loss) by the weighted average number of shares outstanding during the period. Diluted earnings (loss) per share is computed in a manner similar to basic earnings (loss) per share, except that the weighted average number of shares outstanding is increased to include incremental shares from the assumed conversion 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 shares were vested, and the proceeds from such exercises or conversions were used to acquire shares of common stock at the average market price during the reporting period.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Net income (loss)	$ (294,074)	$ 52,618	$ (314,162)	$ (1,570,495)
Weighted average shares of common stock outstanding:				
Basic	44,538,745	38,665,545	44,425,625	38,444,062
Dilutive effect of stock options, warrants and restricted shares	—	1,111,734	—	—
Diluted	44,538,745	39,777,279	44,425,625	38,444,062
Earnings (loss) per share:				
Basic	$ (0.01)	$ 0.00	$ (0.01)	$ (0.04)
Diluted	$ (0.01)	$ 0.00	$ (0.01)	$ (0.04)

The computation of diluted earnings (loss) per share exclude the effect of outstanding common stock options, warrants and unvested restricted stock representing 5,630,221 and 374,460 common shares, for the three-month periods ended September 30, 2004 and 2003, respectively, and 5,630,221 and 4,097,326 common shares, for the nine-month periods ended September 30, 2004 and 2003, respectively, as their inclusion would have been anti-dilutive.

Stock-Based Compensation. We account for stock-based compensation to employees and directors using the intrinsic value method in accordance with Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations. We account for stock-based compensation to nonemployees using the fair value method in accordance with SFAS No. 123, "Accounting for Stock-Based Compensation," 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."

We have elected to adopt the disclosure provisions of SFAS No. 123, as amended by SFAS No. 148, "Accounting for Stock-Based Compensation – Transition and Disclosure." Under SFAS No. 123, compensation expense related to stock awards granted to employees and directors is computed based on the fair value of the award at the date of grant using an option valuation methodology, typically the Black-Scholes option pricing model. Pursuant to the disclosure requirements of SFAS No. 123, had compensation expense for our common stock awards been determined based upon the fair value of the awards at the date of grant, our net income (loss) for the three-month and nine-month periods ended September 30, 2004 and 2003 would have been as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2004	2003	2004	2003
Net income (loss):				
As reported	$ (294,074)	$ 52,618	$ (314,162)	$(1,570,495)
Add: stock-based employee compensation expense included in net income (loss)	—	—	—	33,900
Deduct: total stock-based employee compensation expense determined under the fair value-based method for all awards	(1,247,191)	(1,010,111)	(3,689,928)	(3,267,470)
Pro forma	$(1,541,265)	$ (957,493)	$(4,004,090)	$(4,804,065)
Basic and diluted income (loss) per share:				
As reported	$ (0.01)	$ 0.00	$ (0.01)	$ (0.04)
Pro forma	$ (0.03)	$ (0.02)	$ (0.09)	$ (0.12)

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.

3. Patents and Product Rights

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. The agreement requires us to pay the third party a one-time non-refundable license fee of $900,000, $600,000 of which was paid in August 2004. The remaining $300,000 obligation is payable by June 30, 2005 and is included in Accrued Expenses in the accompanying balance sheet at September 30, 2004. The $900,000 was recorded as additional Patent and Product Rights and is being amortized through June 30, 2014.

Under the terms of this sublicense agreement, we are also obligated to pay royalties based upon a percentage of our net sales of certain products, which incorporate the technology covered by the licensed patents. Commencing in June 2005, our minimum annual royalty obligation is $100,000, increasing to $300,000 in the second contract year and $500,000 for the third contract year through 2018, when the last of the applicable patents expire. Royalties from our commercial sale of products covered by the sublicense can be credited against these minimum royalty obligations.

4. Long-Term Debt

In September 2003, we executed an amendment to our $10.9 million credit facility with Comerica Bank, pursuant to which the maturity date of our $4.0 million revolving working capital line of credit (the "Revolving Line") was extended until September 10, 2004. On September 27, 2004, we executed a letter agreement with Comerica Bank extending the maturity date of the Revolving Line until April 30, 2005. All other terms of the Revolving Line agreement, as amended, remain in effect.

5. Accrued Expenses:

	September 30, 2004	December 31, 2003
Payroll and related benefits	$ 1,822,327	$1,449,151
Professional fees	1,106,027	222,710
Advertising	906,243	474,817
Royalties	810,963	1,428,816
Deferred revenue	756,919	705,817
Laboratory testing fees	380,580	305,647
License fees	300,000	—
Other	893,084	788,893
	$ 6,976,143	$5,375,851

At September 30, 2004 and December 31, 2003, accrued royalties and advertising expenses are related to launching two new products during 2003. For the nine months ended September 30, 2004, accrued royalties decreased as a result of $2.2 million in royalty payments and a $575,000 favorable resolution of an estimated prior period royalty obligation, offset by $2.1 million in accruals for recurring royalty obligations. License fees at September 30, 2004 are related to the new sublicense agreement, which we entered into in June 2004, as discussed in Note 3. Professional fees at September 30, 2004 are primarily comprised of legal, accounting, and consulting fees related to current litigation, Sarbanes-Oxley Act compliance and strategic planning.

6. Stockholders' Equity

During the nine-month period ended September 30, 2004, we granted 410,000 restricted shares of our common stock to certain key officers. These shares are nontransferable and are subject to vesting requirements, in varying increments, over varying periods of time, spanning one to ten years. Upon granting of these restricted shares, deferred compensation expense equivalent to the market value at the date of grant was charged to stockholders' equity and is being amortized over the related vesting period during which the restrictions lapse. In connection with these restricted share grants, we recorded $3,176,150 of deferred compensation during the nine-month period ended September 30, 2004. Amortization of deferred compensation related to these and previous grants was $338,105 and $536,057 during the three-month and nine-month periods ended September 30, 2004, respectively. No such expense was recorded in the same periods of 2003.

7. Commitments and Contingencies

On June 22, 2004, Michael J. Gausling resigned from his position as President, Chief Executive Officer and a Director of the Company and his successor was named. Pursuant to a transition agreement we entered into with Mr. Gausling in March 2004, he will continue to be employed by the Company for the purpose of transferring his responsibilities to his successor as needed until December 31, 2004, unless his employment is terminated earlier for cause, as defined in the transition agreement. During the remainder of 2004, Mr. Gausling will receive his annual base salary of $333,864, will be entitled to full executive benefits under our group health and other benefit arrangements, and will be entitled to a cash bonus under our 2004 Self-Funding Annual Bonus Plan, payable, if at all, at the same time as other executives participating in the plan receive bonuses. Mr. Gausling was also granted a

non-qualified option to purchase 100,000 shares of common stock, pursuant to our 2000 Stock Award Plan. During 2005, Mr. Gausling will receive salary continuation payments in an aggregate amount of $333,864, payable in four equal installments at the end of each fiscal quarter during 2005. Also, beginning January 1, 2005, if Mr. Gausling elects to obtain continuing coverage under our health benefit plan pursuant to COBRA, we will reimburse Mr. Gausling for the cost of his COBRA premiums for the 12-month period ending December 31, 2005.

In June and July 2004, we entered into several new employment agreements with certain officers of our Company. Under the terms of these agreements, we are required to pay each individual a base salary for continuing employment with our Company, through either 2006 or 2007. Collectively, these employment agreements and the transition agreement discussed above require salary payments of $448,752 during the remaining three months of 2004 and $1,795,008, $930,572 and $200,000 in the years ending December 31, 2005, 2006 and 2007, respectively.

8. Geographic Area Information

Under the disclosure requirements of SFAS No. 131, “Segment Disclosures and Related Information,” we operate within one segment. Our products are sold principally in the United States and Europe. Segmentation of operating income and identifiable assets is not applicable since our revenues outside the United States are export sales and we do not have significant operating assets outside the United States.

The following table represents total revenues by geographic area (amounts in thousands):

	For the three months ended September 30,		For the nine months ended September 30,	
	2004	2003	2004	2003
United States	$12,416	$ 9,273	$35,138	$25,178
Europe	1,132	721	3,116	2,256
Other regions	628	337	1,545	1,137
	$14,176	$10,331	$39,799	$28,571

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 include statements about expected revenues, earnings, expenses, cash flow or other financial performance, products, markets, and regulatory filings and approvals. Forward-looking statements are not guarantees of future performance or results. Factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include: ability to market 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 up-converting phosphor technology products; 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 timing of obtaining necessary regulatory approvals; 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; 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 and other types of litigation; changes in international, federal or state laws and regulations; changes in relationships with strategic partners and reliance on strategic partners for the performance of critical activities under collaborative arrangements; changes in accounting practices or interpretation of accounting requirements; customer inventory practices and consolidations; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks, war and civil unrest; ability to identify, complete and realize the full benefits of potential acquisitions; and general business, political 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, 2003 and our Quarterly Reports on Form 10-Q. Although forward-looking statements help to provide 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

Our Company operates 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® rapid HIV antibody test and UP*link*® oral fluid rapid drug detection system are designed for use at the point-of-care. Our cryosurgical products, which are sold under the names Histofreezer® and Freeze Off™, are also used at the point-of care.

In vitro diagnostics have traditionally used blood or urine as the bodily 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. In addition, because of their ease of use, non-invasive and dignified nature, and cost effectiveness, we believe these tests represent a competitive alternative to the more traditional testing methods in the diagnostic space.

During the third quarter and first nine months of 2004, we continued to increase our sales and gain market acceptance for most of our products.

Sales into the infectious disease testing market during the third quarter and first nine months of 2004 increased significantly due to the continued market acceptance of our OraQuick® device. This resulted largely from sales directly to various public health organizations, sales to the Centers for Disease Control and Prevention ("CDC") for further distribution in the public health market, and sales to Abbott Laboratories ("Abbott") for distribution primarily to hospitals. There were also international sales of this product during these periods.

In 2003, the CDC placed purchase orders totaling approximately $4.0 million for 500,000 OraQuick® devices, with equal amounts to be shipped in 2003 and 2004. We completed our shipment of devices in satisfaction of these orders by September 30, 2004, and we will continue to pursue an additional bulk purchase order from the CDC during the final months of 2004.

In the first quarter of 2004, our agreement with Abbott to distribute OraQuick® in the United States was converted from co-exclusive to non-exclusive. Abbott has continued to purchase and sell OraQuick® devices in the United States throughout the first nine months of 2004. Early in the second quarter, we established an internal sales force for selling OraQuick® directly into the hospital market. We also intend to address the market potential of physicians' offices by engaging one or more distribution partners, as we believe it would be impractical to build and sustain an internal sales force large enough to adequately service that market.

During 2003, two competitors received U.S. Food and Drug Administration ("FDA") approval for rapid HIV tests. Based on their current FDA approvals, these tests are being sold, and compete with our OraQuick® test, primarily in the hospital market in the United States. One competitor has recently received FDA approval for a finger stick whole blood test for use in detecting antibodies to HIV-1 and has applied for CLIA (Clinical Laboratory Improvements Amendments of 1988) waiver. Under CLIA, laboratories are precluded from performing *in vitro* diagnostic tests unless there is in effect for such laboratories a certificate issued by the U.S. Department of Health and Human Services applicable to the category of examination or procedure performed. A CLIA waiver allows non-laboratory customers to use waived products that may not have been available for use by these customers without complying with the quality control and other requirements mandated for certified laboratories under CLIA. If this competitor is successful in obtaining CLIA waiver for its finger stick whole blood test, it could compete with our OraQuick® test in the public health market.

During March 2004, we received FDA approval to use the OraQuick® test to detect HIV-2 antibodies in finger stick whole blood and venipuncture whole blood samples, HIV-1 antibodies in oral fluid samples and both HIV-1 and HIV-2 antibodies in plasma samples. In June 2004, we received FDA approval to use the OraQuick® test to detect antibodies to HIV-2 in oral fluid and we also obtained a CLIA waiver for the OraQuick® HIV-1/2 test for all specimen types except plasma.

Additionally, in June 2004 we received a nonexclusive, worldwide sublicense to certain HIV-2 patents held by Bio-Rad Laboratories ("Bio-Rad"). We believe that the recent FDA approvals, together with the sublicense from Bio-Rad, will provide a significant competitive advantage by allowing us to sell a versatile rapid HIV test that is capable of detecting antibodies to both the HIV-1 and HIV-2 strains of the virus in oral fluids, finger stick whole blood, venous whole blood and plasma.

In mid July 2004, we received data from an investigational clinical trial that indicated a higher rate of unconfirmed positive results from the use of our OraQuick® test in oral fluid samples than was shown in the clinical data that we compiled in support of our FDA approval of an oral fluid claim, including data from Company-sponsored trials and independent CDC studies. Similar results were not indicated for blood samples tested with the device. We conducted a multi-faceted assessment including an evaluation of this particular study site, a review of manufacturing records, testing of device retains, and a thorough analysis of oral fluid testing data generated to date with the product which included several multiple-site studies. Additionally, as part of the assessment, we performed both clinical and non-clinical studies to determine whether such unusual results are likely to reoccur. Data from over 7,000 oral fluid samples from multiple study sites were analyzed in detail and over 12,000 additional test readings were reviewed.

The results from these studies indicated that the test device is working as per specifications and with an accuracy of greater than 99%. After carefully reviewing this data and after consultation with both the FDA and CDC, we announced the launch of the OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test in late October, with initial shipments of this product expected to begin in early November 2004. OraQuick® ADVANCE is the only FDA approved, CLIA waived rapid test that can test for antibodies to both HIV-1 and HIV-2 in oral fluid, fingerstick whole blood, venipuncture blood and plasma.

In July 2004, we responded to a Request for Proposal ("RFP") issued by the Substance Abuse and Mental Health Services Administration ("SAMHSA") for the sole source supply of oral fluid rapid HIV tests along with lab-based oral fluid test kits for confirmatory testing purposes. In early August 2004, we were awarded a $4.0 million contract under which SAMHSA committed to purchase the Company's OraQuick® rapid HIV antibody tests and HIV confirmatory test services. The OraQuick® tests and related confirmatory services purchased by SAMHSA are expected to be deployed to over 22,000 substance abuse treatment and prevention sites throughout the United States. We expect to begin supplying product in the fourth quarter of 2004.

Sales to the substance abuse testing market also increased during the third quarter and first nine months of 2004, reflecting the growing acceptance of our Intercept® collection device and related oral fluid drug assays, as corporate and criminal justice 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 and United Kingdom. This increase was partially offset by lower sales of our drug assays to the forensic toxicology market.

In March 2004, the FDA responded to our application for 510(k) clearance of the UP*link*® rapid oral fluid drugs of abuse detection system, by indicating that additional performance data would be needed in order to obtain clearance. We are evaluating the FDA's requirements and whether any modifications to our UP*link*® system will be required in order to provide that data. At this time, we cannot predict if or when we will be able to resubmit an application for 510(k) clearance of the UP*link*® system. However, the absence of 510(k) clearance will not affect our ability to sell the UP*link*® system internationally. In April 2004, we launched our UP*link*® system in Germany and other European countries, primarily in the roadside testing market, with our partner, Dräger Safety.

In April 2004, SAMHSA published proposed guidelines that would, if adopted, include oral fluid testing as an accepted drug testing method for federal employees. We have responded to SAMHSA's proposed guidelines with a comment letter and await the final guidelines that will apply to both our Intercept® and UP*link*® drugs of abuse test. We are unable to predict at this time whether additional modifications may be required to bring our UP*link*® or Intercept® drug testing systems into compliance with the guidelines when finally adopted or what affect, if any, non-compliance with the final guidelines will have on our product offerings outside of the federal workplace.

Sales to the cryosurgical systems market during the third quarter and first nine months of 2004 have grown substantially. 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, called Freeze Off™, to our partner, Medtech Holdings, Inc. ("Medtech"), a wholly-owned subsidiary of Prestige Brands, Inc. Medtech distributes Freeze Off™ to consumers under its Compound W® trademark in the OTC market.

While we are pleased with the level of Freeze Off™ sales and hope that they continue at the same or higher levels, these sales were received in anticipation of and during the wart season in the U.S., which runs from Spring to Fall. Because of the seasonality of this product as well as increasing competition in the OTC cryosurgical market, Freeze Off™ sales are not expected to continue at the same level during the fourth quarter of 2004 and the first quarter of 2005.

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 over-the-counter market infringes three of our patents. In late September 2004, we announced that a final trial on the merits in this matter is expected to occur in February 2005.

Sales to the insurance risk assessment market continued to decline in the third quarter of 2004, primarily as a result of lower device and assay sales to our largest customer, Lab*One*, Inc. The assays have experienced substantial competitive pressure from "home-brew" assays internally developed by this customer. Sales of these products are not expected to recover. We anticipate little growth and we may continue to experience declines in the insurance risk assessment market until we are successful in developing new oral fluid based diagnostic tests for additional predictive health markers desired by the insurance industry.

In March 2004, we received all necessary FDA approvals to transfer the manufacture of our Intercept® and OraSure® collection devices and our oral fluid Western blot HIV-1 confirmatory test from Oregon to our facilities in Bethlehem, Pennsylvania. This transfer has been completed and is expected to reduce our annual operating expenses and improve our ability to control the quality of the transferred products.

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. This is particularly true for our OraQuick® test and oral fluid Western blot HIV-1 confirmatory product. If we are unable to obtain necessary components or materials from these sole sources, the time required to develop replacements and obtain the required FDA approvals could disrupt our ability to sell the affected products. In addition, 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.

Results of Operations

Three months ended September 30, 2004 compared to September 30, 2003

Total revenues increased 37% to approximately $14.2 million in the third quarter of 2004 from approximately $10.3 million in the comparable quarter in 2003, primarily as a result of increased sales of our Freeze Off™ cryosurgical product, OraQuick® rapid HIV-1 antibody test and Intercept® oral fluid drug test, partially offset by lower sales in the insurance risk assessment market. Product revenues for the third quarter of 2004 increased 38% to approximately $14.1 million compared to approximately $10.2 million for the third quarter of 2003. International sales accounted for 12% of total revenues in the third quarter of 2004.

The table below shows the amount of total revenues (in thousands, except %) generated in each of our principal markets and by licensing and product development activities.

	Three Months ended September 30,				
	Dollars			Percentage of Total Revenues	
	2004	2003	% Change	2004	2003
Market Revenues					
Insurance risk assessment	$ 1,808	$ 2,827	(36)%	13%	27%
Infectious disease testing	3,702	2,295	61	26	22
Substance abuse testing	2,745	1,801	52	19	18
Cryosurgical systems	5,831	3,298	77	41	32
Product revenues	14,086	10,221	38	99	99
Licensing and product development	90	110	(18)	1	1
Total revenues	$14,176	$10,331	37	100%	100%

Sales to the insurance risk assessment market decreased 36% to approximately $1.8 million in the third quarter of 2004 as a result of lower sales of assays and OraSure® oral fluid collection devices. We expect that sales of our assays, including oral fluid assays, will continue to come under competitive pressure. Our laboratory customers have

reduced and are expected to continue to reduce their purchases of these products and instead use lower cost, internally-developed (i.e., “home-brew’) assays or testing products purchased from our competitors. We do not expect to recover this business, and our revenues are expected to be negatively impacted by as much as $1.5 million in 2004, when compared to 2003 revenues in the insurance risk assessment market.

Sales to the infectious disease testing market increased 61% to approximately $3.7 million in the third quarter of 2004, primarily as a result of the continued strength of our OraQuick® rapid HIV-1 antibody test in the public health marketplace. We sell the OraQuick® test directly to public health entities and to the CDC, which in turn distributes the product in the public health marketplace. OraQuick® sales totaled approximately $2.6 million and $1.1 million in the third quarters of 2004 and 2003, respectively. OraSure® sales totaled approximately $1.1 million and $1.2 million in the third quarters of 2004 and 2003, respectively.

In the third quarter of 2004, we recorded approximately $909,000 in direct sales of OraQuick® to the U.S. public health market and approximately $610,000 to the CDC. We also had OraQuick® sales of approximately $350,000 to Abbott, approximately $230,000 directly to hospital customers, and approximately $495,000 to the international marketplace.

During the remaining months of 2004, we will pursue an additional bulk purchase order for OraQuick® from the CDC as we have fulfilled all CDC requirements under previously received purchase orders. In August 2004, we were awarded a $4.0 million contract from SAMHSA for the purchase of our OraQuick® rapid HIV antibody tests and HIV confirmatory test services. We expect to begin supplying product to SAMHSA in the fourth quarter of 2004.

Although sales of our OraQuick® test are expected to increase, such sales are expected to negatively impact sales of our OraSure® oral fluid collection device in the infectious disease testing market. Customers who now or in the future may purchase our OraSure® device for HIV-1 testing may elect instead to purchase our OraQuick® test. It is not possible at this time, however, to estimate the timing or extent of such change in purchasing patterns or the financial impact of replacing OraSure® sales with sales of our OraQuick® test.

In March 2004, we received approval from the FDA for use of the OraQuick® device to detect HIV-2 antibodies in finger stick and venipuncture whole blood samples, HIV-1 antibodies in oral fluid samples and both HIV-1 and HIV-2 antibodies in plasma samples. In June 2004, we received approval from the FDA for use of the OraQuick® device to detect antibodies to HIV-2 in oral fluid and we received a CLIA waiver for the OraQuick® HIV-1/2 device for use with oral fluids, finger stick whole blood and venipuncture whole blood.

In June 2004, we received a worldwide, non-exclusive sublicense to certain HIV-2 patents held by Bio-Rad that provides us rights to sell a test to detect antibodies to the HIV-2 virus on the OraQuick® platform. The sublicense expires upon the expiration of the last-to-expire licensed patent, is royalty bearing and requires upfront and milestone based fees and minimum annual royalties.

We believe that an OraQuick® device which is approved for detecting antibodies to both HIV-1 and 2 in oral fluid, finger stick and venous whole blood, and plasma samples, and is CLIA-waived for use with all sample types except plasma, will enhance the versatility of our OraQuick® test, provide a significant competitive advantage, and allow us to more fully implement a strategy to sell OraQuick® internationally. The OraQuick® ADVANCE rapid HIV-1/2 antibody test, which has all of the above claims, was commercially launched in late October and initial shipments of this product are expected to begin in early November 2004.

Sales to the substance abuse testing market increased 52% to approximately $2.7 million in the third quarter of 2004, primarily as a result of increased sales of our Intercept® oral fluid drug testing service in the U.S. workplace and criminal justice market and sales of our UP*link*® rapid point-of-care oral fluid drug detection system to Dräger Safety. Sales of Intercept® into the U.S. workplace and criminal justice markets increased 88% and 42% to approximately $1,068,000 and $358,000, respectively, in the third quarter of 2004, compared to 2003. Sales of drug assays into the forensic toxicology market totaled approximately $410,000 and $450,000 in the third quarters of 2004 and 2003, respectively.

In April 2004, we launched our UP*link*® rapid oral fluid drug detection system, including assays for the detection of drugs of abuse commonly identified by the National Institute for Drug Abuse ("NIDA") as the NIDA-5 (i.e. cocaine, opiates, amphetamines/methamphetamines, PCP and marijuana) with our partner, Dräger Safety. This product is being initially sold to the roadside testing market in Europe. Revenues from this product were approximately $269,000 in the third quarter of 2004.

Sales of our products in the cryosurgical systems market (which includes both the physicians' office and OTC markets) increased 77% to approximately $5.8 million in the third quarter of 2004, compared to 2003. This increase was primarily the result of $3.9 million in sales of our OTC cryosurgical system, called Freeze Off™, to Medtech, the owner of the Compound W® line of wart removal products. In 2003, we entered into a distribution agreement with Medtech following receipt of FDA 510(k) clearance for the sale of our cryosurgical system in the OTC market in the U.S. The Freeze Off™ product was launched by Medtech in the third quarter of 2003, and there were $1.6 million of sales to Medtech during the three months ended September 30, 2003.

The Freeze Off™ product is being sold under Medtech's Compound W® trademark. Our five-year distribution agreement with Medtech requires minimum purchases of at least $2.0 million each year over the life of the contract in order for Medtech to maintain its exclusive distribution rights to the OTC market in the U.S. Based on purchase orders received to date, we expect sales of Freeze Off™ to Medtech to total at least $12.5 million for the full year 2004.

Sales of our Histofreezer® product to physicians' offices in the U.S. increased 5% to approximately $1.5 million in the third quarter of 2004, when compared to the same period in 2003, primarily as a result of higher distributor sales. We are investing in promotional programs to raise the brand awareness of Histofreezer® in the U.S. professional marketplace and expect our 2004 full-year revenues for this product to increase by approximately $1.0 million over 2003. Sales of Histofreezer® in the international market increased by 80% to approximately $411,000 in the third quarter of 2004, but on an annual basis are expected to remain at approximately 2003 levels until we are able to secure additional distributors in countries where this product is currently not sold.

It is possible that sales of the Freeze Off™ product in the U.S. OTC market 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. To date, we have not seen evidence of this and it is not possible at this time to estimate the timing or financial impact of such a change, if it occurs at all.

Licensing and product development revenues decreased by 18% to $90,000 during the third quarter of 2004, compared to the same period in 2003, primarily as a result of lower payments for our collaborative UP*link*® and oral fluid research project with The University of Pennsylvania, under a grant awarded by the National Institutes of Health. The current annual phase of this grant expires in June 2005 and our share of funding is expected to be approximately $308,000 for that period.

Gross margin in the third quarter of 2004 was approximately 60%, a decrease from the gross margin of approximately 61% recorded in the third quarter of 2003. Gross margin was positively affected by both a favorable resolution of an outstanding royalty obligation and a more efficient utilization of our manufacturing capacity, offset by a less favorable product sales mix, higher production costs associated with our recently-launched UP*link*® oral fluid drug detection system and higher scrap and spoilage charges.

Research and development expenses decreased 33% to approximately $1.5 million in the third quarter of 2004 from approximately $2.2 million in the same period in 2003, primarily as a result of lower staffing related expenses, a decrease in expenses related to the transfer of manufacturing operations to our Bethlehem, Pennsylvania facilities, and lower clinical trial costs. We expect research and development expenses during the remainder of 2004 to be slightly higher than the level incurred during the third quarter.

Sales and marketing expenses increased 57% to approximately $4.0 million in the third quarter of 2004 from approximately $2.5 million in the same period in 2003. This increase was primarily the result of higher product advertising expenditures, costs associated with our hospital sales force, increased staffing related expenses and higher consulting fees.

Included in advertising expenses for the third quarters of 2004 and 2003 were amounts payable to Medtech as reimbursement for marketing expenses incurred for the Freeze Off™ product, totaling approximately $918,000 and $376,000, respectively. Pursuant to our agreement with Medtech, we will continue to co-invest in Medtech's marketing activities for the Freeze Off™ product, and we will reimburse Medtech, on a declining basis over the first four years of the agreement, for a portion of Medtech's out-of-pocket costs of advertising and promoting this product in the OTC market.

We expect sales and marketing expenses to remain at the current quarterly level for the remainder of 2004.

General and administrative expenses increased 119% to approximately $3.5 million in the third quarter of 2004 from approximately $1.6 million in the same period in 2003. This increase was primarily attributable to legal fees associated with the Schering-Plough litigation, transition costs for the retirement of our former Chief Executive Officer and the additional costs of hiring our new Chief Executive Officer, consulting fees for strategic planning, increased staffing related expenses and increased professional fees related to compliance with the requirements of the Sarbanes-Oxley Act of 2002. General and administrative expenses are expected to increase further in 2004 as a result of significantly higher legal fees associated with the Schering-Plough patent litigation, additional strategic planning consulting fees, and costs associated with complying with the requirements of the Sarbanes-Oxley Act of 2002.

In July 2004, we filed a lawsuit against Schering-Plough Healthcare Products, Inc. ("Schering-Plough") for infringement of several of our patents that cover our Histofreezer® and Freeze Off™ products. This suit relates to the Dr. Scholls® Freeze Away™ wart removal product sold by Schering-Plough in the United States OTC market, which competes with our Freeze Off™ product. This litigation is expected to result in a significant increase in legal fees during the term of the litigation. We expect to incur a minimum of $300,000 in incremental legal fees for this matter in the fourth quarter of 2004 and an additional $200,000 to $400,000 during the first quarter of 2005, when compared to the level of legal fees incurred in the third quarter of 2004.

Interest expense decreased to $32,000 in the third quarter of 2004 from $45,000 in the same period in 2003, primarily as a result of lower outstanding debt balances. Interest income increased to $229,000 in the third quarter of 2004 from $78,000 in the same period in 2003, as a result of substantially larger balances available for investment.

During the third quarters of 2004 and 2003, we recorded provisions for foreign income taxes of approximately $5,000 and $3,000, respectively.

Results of Operations

Nine months ended September 30, 2004 compared to September 30, 2003

Total revenues increased 39% to approximately $39.8 million for the nine months ended September 30, 2004 from approximately $28.6 million in the comparable period in 2003, primarily as a result of increased sales of our Freeze Off™ and Histofreezer® cryosurgical products, OraQuick® rapid HIV-1 antibody test and Intercept® oral fluid drug test, partially offset by lower sales in the insurance risk assessment market. Product revenues for the first nine months of 2004 increased 41% to approximately $39.5 million compared to approximately $28.0 million for the same period in 2003. International sales accounted for 12% of total revenues during the first nine months of 2004.

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	
	2004	2003	% Change	2004	2003
Market Revenues					
Insurance risk assessment	$ 5,997	$ 8,285	(28)%	15%	29%
Infectious disease testing	11,009	7,766	42	28	27
Substance abuse testing	7,329	5,234	40	18	18
Cryosurgical systems	15,162	6,717	126	38	24
Product revenues	39,497	28,002	41	99	98
Licensing and product development	302	569	(47)	1	2
Total revenues	$39,799	$28,571	39	100%	100%

Sales to the insurance risk assessment market decreased 28% to approximately $6.0 million for the nine months ended September 30, 2004 as a result of lower sales of assays and OraSure® oral fluid collection devices. We expect that sales of our assays, including oral fluid assays, will continue to come under competitive pressure. Our laboratory customers have reduced and are expected to continue to reduce their purchases of these products and instead use lower cost, internally-developed (i.e., “home-brew’) assays or testing products purchased from our competitors. We do not expect to recover this business, and our revenues are expected to be negatively impacted by as much as $1.5 million in 2004, when compared to 2003 revenues in the insurance risk assessment market.

Sales to the infectious disease testing market increased 42% to approximately $11.0 million for the nine months ended September 30, 2004, primarily as a result of the continued strength of our OraQuick® rapid HIV-1 antibody test in the public health marketplace. We sell the OraQuick® test directly to public health entities and to the CDC, which in turn distributes the product in the public health marketplace. OraQuick® sales totaled approximately $7.1 million and $3.6 million in the first nine months of 2004 and 2003, respectively. OraSure® sales totaled approximately $3.9 million and $4.2 million in the first nine months of 2004 and 2003, respectively.

In the first nine months of 2004, we recorded OraQuick® sales of approximately $2.3 million to the CDC, approximately $2.2 million to the U.S. public health market and approximately $1.4 million to Abbott. We also sold approximately $944,000 of OraQuick® to the international marketplace and approximately $296,000 directly to hospital customers. OraQuick® revenues from the hospital market during the first nine months of 2004 were generated by our new direct sales force, which was not fully deployed until early in the second quarter of 2004.

During the remaining months of 2004, we will pursue an additional bulk purchase order for OraQuick® from the CDC as we have fulfilled all CDC requirements under previously received purchase orders. In August 2004, we were awarded a $4.0 million contract from SAMHSA for the purchase of our OraQuick® rapid HIV antibody tests and HIV confirmatory test services. We expect to begin supplying product to SAMHSA in the fourth quarter of 2004.

Although sales of our OraQuick® test are expected to increase, such sales are expected to negatively impact sales of our OraSure® oral fluid collection device in the infectious disease testing market. Customers who now or in the future may purchase our OraSure® device for HIV-1 testing may elect instead to purchase our OraQuick® test. It is not possible at this time, however, to estimate the timing or extent of such change in purchasing patterns or the financial impact of replacing OraSure® sales with sales of our OraQuick® test.

In March 2004, we received approval from the FDA for use of the OraQuick® device to detect HIV-2 antibodies in finger stick and venipuncture whole blood samples, HIV-1 antibodies in oral fluid samples and both HIV-1 and HIV-2 antibodies in plasma samples. In June 2004, we received approval from the FDA for use of the OraQuick® device to detect antibodies to HIV-2 in oral fluid and we received a CLIA waiver for the OraQuick® HIV-1/2 device for use with oral fluids, finger stick whole blood and venipuncture whole blood.

In June 2004, we received a worldwide, non-exclusive sublicense to certain HIV-2 patents held by Bio-Rad that provides us rights to sell a test to detect antibodies to the HIV-2 virus on the OraQuick® platform. The sublicense expires upon the expiration of the last-to-expire licensed patent, is royalty bearing and requires upfront and milestone based fees and minimum annual royalties.

We believe that an OraQuick® device which is approved for detecting antibodies to both HIV-1 and 2 in oral fluid, finger stick whole blood, venous whole blood, and plasma, and is CLIA-waived for use with all sample types except plasma, will enhance the versatility of our OraQuick® test, provide a significant competitive advantage, and allow us to more fully implement a strategy to sell OraQuick® internationally. The OraQuick® ADVANCE rapid HIV-1/2 antibody test, which has all of the above claims, was commercially launched in late October and initial shipments of this product are expected to begin in early November 2004.

Sales to the substance abuse testing market increased 40% to approximately $7.3 million in the nine months ended September 2004, primarily as a result of increased sales of our Intercept® oral fluid drug testing service in the U.S. workplace and criminal justice markets and sales of our UP*link*® drug detection system to Dräger Safety. Sales of Intercept® into the U.S. workplace and criminal justice markets increased 83% and 61% to approximately $2.1 million and $1.2 million, respectively, in the nine months ended September 2004, compared to 2003. Partially offsetting these increases were lower than expected sales of our drug assays into the forensic toxicology market, which were down 16% compared to the same period in 2003.

In April 2004, we launched our UP*link*® rapid oral fluid drug detection system, including assays for the detection of drugs of abuse commonly known as the NIDA-5 (i.e. cocaine, opiates, amphetamines/methamphetamines, PCP and marijuana) with our partner, Dräger Safety. This product is being initially sold to the roadside testing market in Europe. Revenues from this product were approximately $542,000 for the nine months ended September 2004.

Sales of our products in the cryosurgical systems market (which includes both the physicians' office and OTC markets) increased 126% to approximately $15.2 million in the nine months ended September 2004, compared to 2003. This increase was primarily the result of $10.3 million in sales of our OTC cryosurgical system, called Freeze Off™, to Medtech, the owner of the Compound W® line of wart removal products. In 2003, we entered into a distribution agreement with Medtech following receipt of FDA 510(k) clearance for the sale of our cryosurgical system in the OTC market in the U.S. The Freeze Off™ product was launched by Medtech in the third quarter of 2003, and there were $2.9 million of sales to Medtech during the nine-months ended September 30, 2003.

The Freeze Off™ product is being sold under Medtech's Compound W® trademark. Our five-year distribution agreement with Medtech requires minimum purchases of at least $2.0 million each year over the life of the contract in order for Medtech to maintain its exclusive distribution rights to the OTC market in the U.S. Based on purchase orders received to date, we expect sales of Freeze Off™ to Medtech to total at least $12.5 million for the full year 2004.

Sales of our Histofreezer® product to physicians' offices in the U.S. increased 33% to approximately $3.7 million in the nine months ended September 2004, when compared to the same period in 2003, primarily as a result of higher distributor sales. We are investing in promotional programs to raise the brand awareness of Histofreezer® in the U.S. professional marketplace and expect our 2004 full-year revenues for this product to increase by approximately $1.0 million over 2003. Sales of Histofreezer® in the international market increased by 7% to approximately $1.2 million, but on an annual basis are expected to remain at approximately 2003 levels until we are able to secure additional distributors in countries where this product is currently not sold.

It is possible that sales of the Freeze Off™ product in the U.S. OTC market 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. To date, we have not seen evidence of this and it is not possible at this time to estimate the timing or financial impact of such a change, if it occurs at all.

Licensing and product development revenues decreased by 47% to $302,000 during the nine months ended September 30, 2004, compared to the same period in 2003, primarily as a result of lower payments for our

collaborative UP*link*® and oral fluid research project with The University of Pennsylvania, under a grant awarded by the National Institutes of Health. The current annual phase of this grant expires in June 2005 and our share of funding is expected to be approximately $308,000 for that period.

Gross margin for the nine months ended September 30, 2004 was approximately 59%, a decrease from the gross margin of 60% recorded in the comparable period in 2003. Gross margin was positively affected by more efficient utilization of our manufacturing capacity and the favorable resolution of an outstanding royalty obligation, offset by a less favorable product sales mix, higher production costs associated with our recently-launched UP*link*® oral fluid drug detection system and higher scrap and spoilage charges.

Research and development expenses decreased 24% to approximately $4.7 million in the nine months ended September 30, 2004 from approximately $6.2 million in the same period in 2003, primarily as a result of a decrease in expenses related to the transfer of manufacturing operations to our Bethlehem, Pennsylvania facilities and lower clinical trial and staffing related expenses. We expect research and development expenses during the remainder of 2004 to be slightly higher than the level incurred during the third quarter of 2004.

Sales and marketing expenses increased 52% to approximately $11.4 million in the nine months ended September 30, 2004 from approximately $7.5 million in the same period in 2003. This increase was primarily the result of higher product advertising expenditures, costs associated with the deployment of our hospital sales force, increased staffing related expenses, higher consulting fees, and higher travel and entertainment expenses. Partially offsetting these increases was a reduction of our bad debt expense.

Included in advertising expenses for the first nine months of 2004 and 2003 were amounts payable to Medtech as reimbursement for marketing expenses incurred for the Freeze Off™ product totaling approximately $2.2 million and $602,000, respectively. Pursuant to our agreement with Medtech, we will continue to co-invest in Medtech's marketing activities for the Freeze Off™ product, and we will reimburse Medtech, on a declining basis over the first four years of the agreement, for a portion of Medtech's out-of-pocket costs of advertising and promoting this product in the OTC market.

We expect sales and marketing expenses to remain at the current quarterly level for the remainder of 2004.

General and administrative expenses increased 58% to approximately $8.1 million in the nine months ended September 30, 2004 from approximately $5.1 million in the same period in 2003. This increase was primarily attributable to increased legal fees associated with the Schering-Plough litigation and our arbitration proceedings with Abbott, transition costs for the retirement of our former Chief Executive Officer, the additional costs of hiring our new Chief Executive Officer, consulting fees for strategic planning, increased staffing related expenses and increased professional fees related to compliance with the requirements of the Sarbanes-Oxley Act of 2002. General and administrative expenses are expected to increase further in 2004 as a result of significantly higher legal fees associated with the Schering-Plough patent litigation, additional strategic planning consulting fees, and costs associated with complying with the requirements of the Sarbanes-Oxley Act of 2002.

In July 2004, we filed a lawsuit against Schering-Plough for infringement of several patents that cover our Histofreezer® and Freeze Off™ products. This suit relates to the Dr. Scholls® Freeze Away™ wart removal product sold by Schering-Plough in the United States OTC market, which competes with our Freeze Off™ product. This litigation is expected to result in a significant increase in legal fees during the term of the litigation. We expect to incur a minimum of $300,000 in incremental legal fees for this matter in the fourth quarter of 2004 and an additional $200,000 to $400,000 during the first quarter of 2005, when compared to the level of legal fees incurred in the third quarter of 2004.

Interest expense decreased to $104,000 in the first nine months of 2004 from $140,000 in the same period in 2003 primarily as a result of lower outstanding debt balances. Interest income increased to $665,000 in the first nine months of 2004 from $247,000 in the same period in 2003, as a result of substantially larger balances available for investment.

During the first nine months of 2004 and 2003, we recorded provisions for foreign income taxes of approximately $14,000 and $18,000, respectively.

Liquidity and Capital Resources

	September 30, 2004	December 31, 2003
	(In thousands)	
Cash and cash equivalents	$ 13,315	$ 30,695
Short-term investments	52,141	33,329
Working capital	68,217	67,171

Our cash, cash equivalents and short-term investments increased approximately $1.4 million during the first nine months of 2004 to approximately $65.5 million at September 30, 2004, primarily as a result of positive cash flow from operations of approximately $2.2 million and proceeds from the exercise of stock options of approximately $1.6 million, partially offset by debt repayments of $845,000, purchases of approximately $786,000 of capital equipment and our expenditure of $600,000 for patent license rights. At September 30, 2004, our working capital was approximately $68.2 million.

Net cash provided by operating activities was approximately $2.2 million in the first nine months of 2004. This resulted from a decrease of approximately $1.1 million in accounts receivable, primarily related to increased collection efforts, depreciation and amortization of approximately $1.8 million, non-cash charges of approximately $1.3 million related to stock-based compensation expense and provisions for excess and obsolete inventories, and a decrease in prepaid expense of $197,000, offset by inventory increases of $1.4 million, a reduction of accounts payable and accruals of $504,000 and the approximate $314,000 loss for the period. Accounts receivable are expected to grow as our sales increase and the proportion of sales increase to parties such as the CDC, hospitals and Medtech, which have 60-day payment terms.

Net cash used in investing activities during the first nine months of 2004 was approximately $20.3 million. We purchased a net amount of $18.9 million of short-term investments, expended $600,000 for patent license rights and purchased approximately $786,000 of capital equipment.

We do not expect to incur a significant amount of capital expenditures over the remaining months of 2004.

Net cash provided by financing activities was approximately $719,000, reflecting the proceeds of approximately $1.6 million received from the sale of common stock pursuant to the exercise of stock options, offset by approximately $845,000 of loan principal repayments.

In September 2002, we entered into a $10.9 million credit facility (the “Credit Facility”) with Comerica Bank. The Credit Facility, when originally executed, was comprised of an $887,000 mortgage loan, a $3.0 million term loan, a $3.0 million non-revolving equipment line of credit, and a $4.0 million revolving working capital line of credit.

In September 2003, we executed an amendment to the Credit Facility. Pursuant to this amendment, the $3.0 million non-revolving equipment line of credit (the “Original Non-Revolving Line”) was replaced with a new $4.0 million non-revolving line of credit for the purchase of both capital equipment and software (the “New Non-Revolving Line”). As a result, the Original Non-Revolving Line has expired and any new non-revolving borrowings for equipment or software will be made under the New Non-Revolving Line. Borrowings outstanding under the Original Non-Revolving Line at the time of the amendment will not be applied against the credit limit for the New Non-Revolving Line and will remain payable in accordance with their original terms. The amendment also extended the maturity date of the $4.0 million revolving working capital line of credit by one year, and provided for certain modifications to our financial covenants under the Credit Facility. The term loan and mortgage were not affected by the amendment. In September 2004, the Credit Facility was amended further to extend the maturity date of our revolving working capital line of credit to April 30, 2005.

The $887,000 mortgage loan matures in September 2012, bears interest at an annual floating rate equal to Comerica's prime rate (4.75% at September 30, 2004), and is repayable in fixed monthly principal and interest installments of $7,426 through September 2007, at which time the interest rate and fixed monthly repayment amount will be reset for the remaining 60 monthly installments. The outstanding balance of the loan at September 30, 2004 was $778,927.

The $3.0 million term loan matures in March 2006, bears interest at a fixed rate of 4.97% and is repayable in forty-two consecutive equal monthly principal payments of $71,429, plus interest. The outstanding balance of the loan at September 30, 2004 was $1,285,714.

Under the New Non-Revolving Line, we can borrow up to $4.0 million to finance eligible equipment and software purchases through December 31, 2004. Interest on outstanding borrowings accrues at a rate, selected at our option, equal to Comerica's prime rate, 180-day or 360-day LIBOR plus 2.625%, or the 4-year Treasury Note Rate plus 2.30%, determined at the time of each borrowing. Borrowings are repayable in 48 (for equipment purchases) or 36 (for software purchases) consecutive, equal monthly principal installments, plus interest. We had no outstanding borrowings under this facility at September 30, 2004.

As of September 30, 2004, we had an outstanding balance of $371,740 under the Original Non-Revolving Line consisting of four individual loans of (i) $95,886 with a fixed annual interest rate of 5.07%, (ii) $137,178 with a floating annual interest rate equal to Comerica's prime rate of 4.75% at September 30, 2004, (iii) $67,927 with a floating annual interest rate equal to Comerica's prime rate of 4.75% at September 30, 2004, and (iv) $70,749 with a floating annual interest rate equal to Comerica's prime rate of 4.75% at September 30, 2004.

Under the revolving working capital line of credit, we can borrow up to $4.0 million to finance working capital and other needs. Interest on outstanding borrowings accrues at a rate, selected at our option, equal to Comerica's prime rate less 0.25%, or 30-day LIBOR plus 2.55%, determined at the time of the initial borrowing. Borrowings are repayable by April 30, 2005, with interest payable monthly. We had no outstanding borrowings under this facility at September 30, 2004.

All borrowings under the Credit Facility are collateralized by a first priority security interest in all of our assets, including present and future accounts receivable, chattel paper, contracts and contract rights, equipment and accessories, general intangibles, investments, instruments, inventories, and a mortgage on our manufacturing facility in Bethlehem, Pennsylvania. Borrowings under the equipment and software non-revolving line and the revolving working capital line are limited to commercially standard percentages of equipment and software purchases and accounts receivable, respectively. 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, 2004 and expect to remain in compliance with all covenants during 2004. 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.

We have entered into a ten-year facility lease with Tech III Partners, LLC ("Tech Partners"), an entity owned and controlled by two of our former executive officers. Under the terms of this operating lease, we began leasing a 48,000 square-foot facility in October 2002 at a base rent of $780,000 per year, increasing to $858,240 per year, during the initial ten-year term. The base rental may be increased after the fifth year of the initial term in order to reflect changes in the interest rate on debt incurred by Tech Partners to finance construction of the leased facilities. We have not guaranteed any debt incurred by Tech Partners. The lease also provides us with options to renew the lease for an additional five years at a rental rate of $975,360 per year, and to purchase the facility at any time during the initial ten-year term based on a formula set forth in the lease. We are evaluating whether to exercise our option under the lease to purchase the facility.

The combination of our current cash position 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, the potential exercise of our options to purchase one, or both, of our leased facilities in Bethlehem, Pennsylvania, and other factors.

Certain Relationships and Related Transactions

In connection with the announcement that Mike Gausling, our former President and Chief Executive Officer, intended to retire from the Company by the end of 2004, in March 2004, we entered into a transition agreement with Mr. Gausling, which replaced and terminated his employment agreement. In June 2004, Mr. Gausling resigned from his position as President, Chief Executive Officer and a member of the Board, and his successor was named.

Pursuant to his transition agreement, Mr. Gausling will continue to be employed by our Company until December 31, 2004, unless his employment is terminated for cause (as defined therein). During 2004, Mr. Gausling will receive an annual base salary of $333,864, will be entitled to full executive benefits under our group health and other benefit arrangements, and will be entitled to a cash bonus under our 2004 Self-Funding Annual Bonus Plan payable, if at all, at the same time as other executives participating in the plan receive bonuses. Mr. Gausling was also granted a non-qualified option to purchase 100,000 shares of common stock, pursuant to our 2000 Stock Award Plan.

During 2005, Mr. Gausling will receive salary continuation payments in an aggregate amount of $333,864, payable in four equal installments at the end of each fiscal quarter during 2005. If Mr. Gausling elects to obtain continuing coverage under our health benefit plan pursuant to COBRA beginning January 1, 2005, we will reimburse Mr. Gausling for the cost of his COBRA premiums for the 12-month period ending December 31, 2005.

Contractual Obligations and Commercial Commitments

The following sets forth our approximate aggregate obligations at September 30, 2004 for future payments under contracts and other contingent commitments, for the years ending December 31, 2004 and beyond:

		Payments due by December 31,					
Contractual Obligations	**Total**	**2004**	**2005**	**2006**	**2007**	**2008**	**Thereafter**
Long-term debt[1]	$ 2,737,600	$ 281,124	$1,126,309	$ 475,161	$ 134,554	$ 118,898	$ 601,554
Operating leases[2]	6,803,746	373,449	888,641	780,000	783,108	798,854	3,179,694
Employment contracts[3]	3,374,332	448,752	1,795,008	930,572	200,000	—	—
Purchase obligations[4]	3,243,686	1,843,674	1,400,012	—	—	—	—
Minimum commitments under contracts[5]	7,762,500	12,500	325,000	525,000	725,000	725,000	5,450,000
Total contractual obligations	$23,921,864	$2,959,499	$5,534,970	$2,710,733	$1,842,662	$1,642,752	$ 9,231,248

1 Represents principal repayments required under notes payable to our lenders.
2 Represents payments required under our operating leases.
3 Represents salary, retention bonus or severance payments payable under the terms of employment agreements executed by us with certain officers.
4 Represents payments required by non-cancelable purchase orders related to inventory, capital expenditures and other goods or services.
S Represents payments required pursuant to certain research, licensing and royalty agreements executed by the Company.

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, 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 2003 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 U.S. Securities and Exchange Commission Staff Accounting Bulletin No. 104, "Revenue Recognition in Financial Statements" ("SAB 104"). This bulletin draws on existing accounting rules and provides specific guidance on revenue recognition for up-front non-refundable licensing and development fees. We license certain products or technology to outside third parties, in return for which we receive up-front licensing fees. Some of these fees can be significant. In accordance with SAB 104, we are required to defer immediate recognition of these fees as revenue and instead 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 $292,614 at

September 30, 2004. While credit losses have been within our expectations and the allowance provided, these losses can vary from period to period (approximately $89,000, $213,000, and $5,000 for the years ended December 31, 2003, 2002 and 2001, respectively). Furthermore, there is no assurance that we will experience credit losses at the same rates as we have in the past. Also, at September 30, 2004, approximately $2.6 million, or 36% of our net accounts receivable, was due from two 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 the years ended December 31, 2003, 2002 and 2001, we wrote-off inventory which had a cost of approximately $500,000, $1.4 million, and $600,000, respectively, as a result of manufacturing scrap levels and product expiration issues. Forecasting product demand can be a complex process, especially for a new product such as our OraQuick® ADVANCE rapid HIV-1/2 antibody test. 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 have a net book value of approximately $8.8 million or 10.1% of our total assets at September 30, 2004. Our investment in a 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 investee 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 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, 2004. 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, 2003, we have federal net operating loss ("NOL") carryforwards of approximately $76.6 million. The deferred tax asset associated with these NOLs and other temporary differences is approximately $31.7 million at December 31, 2003. In assessing the realizability of deferred tax assets, we consider whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the period in which those temporary differences become deductible or the NOL can be utilized. We consider the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. Based upon our cumulative and recent history of losses and projections for future taxable income over the periods in which the deferred tax assets are deductible or able to be utilized, we believe that a full valuation allowance is necessary at this time. Our level of future profitability could cause us to conclude that all or a portion of the deferred tax asset will be realizable. Upon reaching such a conclusion, we would immediately record the estimated net realizable value of the deferred tax asset and would begin to provide for income taxes at a rate equal to our combined federal and state effective rates, which we believe would approximate 40%. 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.

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 Statement of Financial Accounting Standards No. 5, "Accounting for Contingencies" ("SFAS No. 5"). 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 derivative financial instruments or derivative commodity instruments, and accordingly, we have no material derivative risk to report under this Item.

Our holdings of financial instruments are comprised of certificates of deposit, commercial paper, U.S. government and agency obligations, state and local government agency obligations, corporate bonds, and asset-backed obligations, with purchased maturities greater than ninety days. 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 approximately $467,000 and $1,291,000 or 3.3% and 3.2% of the Company's total revenues for the three months and nine months ended September 30, 2004, 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 of September 30, 2004. Based on that evaluation, the Company's management, including such officers, concluded that the Company's disclosure controls and procedures were effective in timely alerting them to material information relating to the Company, which is required to be included in its periodic filings with the Securities and Exchange Commission.

(b) Changes in Internal Controls Over Financial Reporting. The evaluation referred to in paragraph (a) of this Item did not identify any change in the Company's internal controls over financial reporting that occurred during the quarter ended September 30, 2004 that has materially affected, or is reasonably likely to materially affect, the Company's internal controls over financial reporting.

PART II. OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

On July 23, 2004, we filed a lawsuit against Schering-Plough for infringement of several of our patents relating to 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. Scholls® Freeze Away™ cryosurgical wart removal product in the United States over-the-counter market infringes the following United States patents: Nos. 5,738,682; 6,092,527 and 4,865,028. We are requesting injunctive relief and the payment of damages. In September 2004, the Court scheduled an early trial in this matter, which will include a final determination of our request for permanent injunctive relief in lieu of our previously filed request for a preliminary injunction. As a result of the Court's action, we withdrew our request for a preliminary injunction and expect a final trial on the merits to occur in February 2005.

Item 6. EXHIBITS.

Exhibits are listed on the attached 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 2, 2004

Ronald H. Spair
Executive Vice President and
Chief Financial Officer
(Principal Financial Officer)

/s/ Mark L. Kuna

Date: November 2, 2004

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

EXHIBIT INDEX

Exhibit	
10.1	Letter Agreement, dated September 8, 2004, between OraSure Technologies, Inc. and Comerica Bank, is incorporated herein by reference to Exhibit 10 to the Company's Current Report on Form 8-K, dated September 10, 2004.
10.2	Letter Agreement, executed September 27, 2004, between OraSure Technologies, Inc. and Comerica Bank, is incorporated herein by reference to Exhibit 10 to the Company's Current Report on Form 8-K, dated September 28, 2004.
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 15a-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 15a-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Exhibit 31.1

Certification

I, Douglas A. Michels, certify that:

1. I have reviewed this report on Form 10-Q of OraSure Technologies, Inc;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d –15(e)) 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, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b) 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
    c) 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.
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
    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 2, 2004

/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)) 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, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b) 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
    c) 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.
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
    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 2, 2004

/s/ Ronald H. Spair

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

Exhibit 32.1

Certification

In connection with the Quarterly Report of OraSure Technologies, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2004 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 § 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 2, 2004

Exhibit 32.2

Certification

In connection with the Quarterly Report of OraSure Technologies, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ronald H. Spair, Executive Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 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
Executive Vice President and
Chief Financial Officer

November 2, 2004