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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2005.

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 ☐

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

Number of shares of Common Stock, par value $.000001 per share, outstanding as of November 4, 2005: 45,525,325

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PART I. FINANCIAL INFORMATION

PART II. OTHER INFORMATION

Item 1. FINANCIAL STATEMENTS

ORASURE TECHNOLOGIES, INC.
BALANCE SHEETS
(Unaudited)

	September 30, 2005	December 31, 2004
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 16,220,113	$ 10,121,208
Short-term investments	59,076,818	56,602,248
Accounts receivable, net of allowance for doubtful accounts of $271,895 and $345,257	10,232,475	7,073,988
Inventories	4,666,425	4,951,979
Prepaid expenses and other	1,188,251	1,195,085
Total current assets	91,384,082	79,944,508
PROPERTY AND EQUIPMENT, net	5,536,273	5,551,261
PATENTS AND PRODUCT RIGHTS, net	3,013,388	2,080,363
OTHER ASSETS	505,427	488,192
	$ 100,439,170	$ 88,064,324
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	$ 685,698	$ 1,122,455
Accounts payable	1,973,865	2,360,214
Accrued expenses	8,725,844	7,552,279
Total current liabilities	11,385,407	11,034,948
LONG-TERM DEBT	932,855	1,334,236
OTHER LIABILITIES	228,482	118,135
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Preferred stock, par value $.000001, 25,000,000 shares authorized, none issued	—	—
Common stock, par value $.000001, 120,000,000 shares authorized, 45,507,808 and 44,631,731 shares issued and outstanding	46	45
Additional paid-in capital	216,157,633	209,948,075
Deferred compensation	(3,656,493)	(2,916,503)
Accumulated other comprehensive loss	(290,932)	(324,669)
Accumulated deficit	(124,317,828)	(131,129,943)
Total stockholders' equity	87,892,426	75,577,005
	$ 100,439,170	$ 88,064,324

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.
STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
REVENUES:				
Product	$ 18,049,479	$ 14,086,266	$ 51,097,873	$ 39,497,173
Licensing and product development	27,313	89,746	237,391	302,160
	18,076,792	14,176,012	51,335,264	39,799,333
COSTS OF PRODUCTS SOLD	6,432,218	5,721,750	20,772,981	16,437,016
Gross profit	11,644,574	8,454,262	30,562,283	23,362,317
COSTS AND EXPENSES:				
Research and development	1,297,900	1,464,918	3,750,534	4,745,692
Sales and marketing	3,965,284	3,956,266	12,289,073	11,387,748
General and administrative	3,167,760	3,513,828	9,131,967	8,085,973
	8,430,944	8,935,012	25,171,574	24,219,413
Operating income (loss)	3,213,630	(480,750)	5,390,709	(857,096)
INTEREST EXPENSE	(23,210)	(32,157)	(75,809)	(103,551)
INTEREST INCOME	618,940	228,877	1,458,204	664,659
FOREIGN CURRENCY GAIN (LOSS)	(1,259)	(5,057)	39,011	(3,726)
Income (loss) before income taxes	3,808,101	(289,087)	6,812,115	(299,714)
INCOME TAXES	—	4,987	—	14,448
NET INCOME (LOSS)	$ 3,808,101	$ (294,074)	$ 6,812,115	$ (314,162)
EARNINGS (LOSS) PER SHARE:				
BASIC AND DILUTED	$ 0.08	$ (0.01)	$ 0.15	$ (0.01)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING:				
BASIC	45,372,065	44,538,745	44,936,111	44,425,625
DILUTED	46,676,379	44,538,745	45,850,378	44,425,625

The accompanying notes are an integral part of these statements.

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

	Nine Months Ended September 30,	
	2005	**2004**
OPERATING ACTIVITIES:		
Net income (loss)	$ 6,812,115	$ (314,162)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Stock-based compensation expense	1,270,980	536,057
Depreciation and amortization	1,808,772	1,824,782
Provision for loss on property and equipment	196,011	4,339
Provision for excess and obsolete inventories	1,792,775	737,396
Changes in assets and liabilities:		
Accounts receivable	(3,158,487)	1,135,530
Inventories	(1,507,221)	(1,397,377)
Prepaid expenses and other current assets	6,834	196,846
Accounts payable, accrued expenses, and other liabilities	1,242,257	(503,534)
Net cash provided by operating activities	8,464,036	2,219,877
INVESTING ACTIVITIES:		
Purchases of short-term investments	(44,685,183)	(48,535,983)
Proceeds from maturities and redemptions of short-term investments	42,279,373	29,613,090
Purchases of property and equipment	(1,394,749)	(785,618)
Proceeds from the sale of property and equipment	—	2,260
Expenditures for patents and product rights	(1,800,000)	(600,000)
(Increase) decrease in other assets	(90,000)	847
Net cash used in investing activities	(5,690,559)	(20,305,404)
FINANCING ACTIVITIES:		
Repayments of long-term debt	(838,138)	(845,277)
Proceeds from issuance of common stock	4,649,442	1,564,520
Purchase and retirement of common stock	(450,853)	—
Net cash provided by financing activities	3,360,451	719,243
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	(35,023)	(14,138)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	6,098,905	(17,380,422)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	10,121,208	30,695,177
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 16,220,113	$ 13,314,755

The accompanying notes are an integral part of these statements.

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

1. The Company

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

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, 2004. Results of operations for the three-month and nine-month periods ended September 30, 2005 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, 2005 and December 31, 2004, cash equivalents consisted of commercial paper, U.S. government agency obligations, state and local government agency obligations, and corporate bonds.

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

The following is a summary of our available-for-sale securities at September 30, 2005 and December 31, 2004:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
September 30, 2005				
Certificates of deposit	$ 15,232,000	$ —	$ (379)	$ 15,231,621
Commercial paper	9,506,217	41,256	(2,708)	9,544,765
Government agency bonds	20,684,954	—	(60,117)	20,624,837
State and local government agency obligations	619,787	—	(321)	619,466
Corporate bonds	13,090,837	252	(34,960)	13,056,129
Total available-for-sale securities	$ 59,133,795	$ 41,508	$ (98,485)	$ 59,076,818
December 31, 2004				
Certificates of deposit	$ 18,702,211	$ 56	$ (29,411)	$ 18,672,856
Commercial paper	4,281,910	185	—	4,282,095
Government agency bonds	21,112,676	113	(61,631)	21,051,158
State and local government agency obligations	629,322	162	(1,059)	628,425
Asset-backed obligations	1,002,116	—	(866)	1,001,250
Corporate bonds	10,999,750	431	(33,717)	10,966,464
Total available-for-sale securities	$ 56,727,985	$ 947	$ (126,684)	$ 56,602,248

At September 30, 2005, all investments had maturities of less than one year.

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, 2005	December 31, 2004
Raw materials	$ 2,440,335	$ 3,405,578
Work-in-process	931,311	659,304
Finished goods	1,294,779	887,097
	$ 4,666,425	$ 4,951,979

Revenue Recognition. We recognize product revenues when there is persuasive evidence that an arrangement exists, the price is fixed or determinable, title has passed and collection is reasonably assured. Product revenues are net of allowances for any discounts or rebates. We do not grant price protection or product return rights to our customers, except for warranty returns. Historically, returns arising from warranty issues have been infrequent and immaterial. Accordingly, we expense warranty returns as incurred.

Up-front licensing fees are deferred and recognized ratably over the related license period. Product development revenues are recognized over the period in which the related product development efforts are performed. Amounts received prior to the performance of product development efforts are recorded as deferred revenues. Grant revenue is recognized as the related work is performed and costs are incurred. We record shipping and handling charges billed to our customers as product revenue and the related expense as cost of products sold.

Significant Customer Concentration. For the three-month period ended September 30, 2005, three individual customers accounted for 17, 10, and 11 percent of total revenues as compared to 28, 10, and 3 percent for the same period of 2004. For the nine-month period ended September 30, 2005, these customers accounted for 19, 11, and 7 percent of total revenues as compared to 26, 12, and 4 percent for the same period of 2004. The same customers also accounted for approximately 24, 7, and 12 percent of accounts receivable as of September 30, 2005 and 23, 8, and 4 percent of accounts receivable as of December 31, 2004.

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

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

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Net income (loss)	$ 3,808,101	$ (294,074)	$ 6,812,115	$ (314,162)
Weighted average shares of common stock outstanding:				
Basic	45,372,065	44,538,745	44,936,111	44,425,625
Dilutive effect of stock options, warrants and restricted shares	1,304,314	—	914,267	—
Diluted	46,676,379	44,538,745	45,850,378	44,425,625
Earnings (loss) per share:				
Basic	$ 0.08	$ (0.01)	$ 0.15	$ (0.01)
Diluted	$ 0.08	$ (0.01)	$ 0.15	$ (0.01)

For the three-month and nine-month periods ended September 30, 2005 and 2004, outstanding common stock options, warrants, and unvested restricted stock, representing 39,980, 5,630,221, 558,417 and 5,630,221 shares, respectively, were excluded from the computation of diluted earnings (loss) per share, 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-based 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 stock-based 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, 2005 and 2004 would have been impacted as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2005	2004	2005	2004
Net income (loss):				
As reported	$ 3,808,101	$ (294,074)	$ 6,812,115	$ (314,162)
Add: stock-based employee compensation expense included in net income (loss)	294,474	338,105	1,178,354	536,057
Deduct: total stock-based employee compensation expense determined under the fair value-based method for all awards	(1,153,229)	(1,585,296)	(4,210,973)	(4,225,985)
Pro forma	$ 2,949,346	$ (1,541,265)	$ 3,779,496	$ (4,004,090)
Basic and diluted earnings (loss) per share:				
As reported	$ 0.08	$ (0.01)	$ 0.15	$ (0.01)
Pro forma	$ 0.06	$ (0.03)	$ 0.08	$ (0.09)

In May 2005, we modified the term of two individual stock option grants. As a result, compensation expense of $58,635 and $92,626 was recorded during the three-month and nine-month periods ended September 30, 2005. No such expense was recorded for the comparable periods in 2004.

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.

Recent Accounting Pronouncements. In November 2004, the Financial Accounting Standards Board (“FASB”) issued SFAS No. 151, “Inventory Costs.” SFAS No. 151 clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material and requires such costs to be recognized as current-period charges. Additionally, SFAS No. 151 requires that allocation of fixed production overhead costs be based on normal capacity. SFAS No. 151 is effective for years beginning after June 15, 2005, with early adoption permitted. The implementation of SFAS No. 151 is not expected to have a material effect on our financial position, results of operations or cash flows.

In December 2004, the FASB issued SFAS No. 123 Revised, “Share-Based Payment” (“SFAS No. 123R”). SFAS No. 123R requires employee stock options to be accounted for in the statement of operations based on their fair values on the date of grant, and eliminates the ability to account for these instruments under the intrinsic value method prescribed by APB Opinion No. 25. SFAS No. 123R requires the use of an option pricing model for estimating fair value, which is amortized to expense over the service period. The requirements of SFAS No. 123R are effective for annual periods beginning after June 15, 2005. SFAS No. 123R allows for either modified prospective recognition of compensation expense or retrospective recognition. The Company is considering the potential implementation of different valuation models to determine the fair value of stock-based compensation and, therefore, has not yet completed evaluating the impact of adopting SFAS No. 123R on its results of operations.

3. Accrued Expenses:

	September 30, 2005	December 31, 2004
Payroll and related benefits	$ 2,658,914	$ 2,069,309
Royalties	1,719,709	1,069,932
Deferred revenue	1,613,249	1,353,711
Advertising	883,287	603,009
Professional fees	1,019,564	1,227,087
Laboratory testing fees	253,019	249,041
License fees	—	300,000
Other	578,102	680,190
	$ 8,725,844	$ 7,552,279

At September 30, 2005, accrued payroll and related benefits increased primarily as a result of an increase in accrued commissions and payroll, partially offset by the payment of annual bonuses during the first quarter. Accrued royalties and advertising expenses at September 30, 2005 and December 31, 2004 are primarily related to the OraQuick® and Freeze Off™ products. Deferred revenue at September 30, 2005 and December 31, 2004 consisted primarily of customer prepayments, totaling $1,203,364 and $1,041,711, respectively. Professional fees at September 30, 2005 decreased primarily as a result of the payment of legal fees related to current litigation. License fees at December 31, 2004 were related to a sublicense agreement for certain HIV-2 patents held by a third party, which were paid in June 2005.

4. Stockholders' Equity

During the nine-month period ended September 30, 2005, we granted 332,188 restricted shares of our common stock to certain key officers and members of management. These shares are nontransferable and vest over a three-year period. Upon granting of these restricted shares, we recorded deferred compensation of $1,918,343, which was the market value of the shares at the date of grant and is being amortized over the three-year vesting period of the awards. Amortization of deferred compensation related to these and previous grants was $1,178,354 and $536,057 during the nine-month periods ended September 30, 2005 and 2004, respectively.

In connection with the vesting of restricted shares during the nine-month period ended September 30, 2005, we repurchased and immediately retired 49,177 shares with an aggregate value of $450,853 to satisfy minimum statutory tax withholding requirements.

5. Geographic Area 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 all of our revenues outside the United States are export sales.

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

	Three months ended September 30,		Nine months ended September 30,	
	2005	2004	2005	2004
United States	$15,912	$12,416	$46,233	$35,138
Europe	1,610	1,132	3,896	3,116
Other regions	555	628	1,206	1,545
	$18,077	$14,176	$51,335	$39,799

6. Patents and Product Rights

In August 2005, the Company entered into a license agreement with third parties, pursuant to which we have been granted a limited, personal, non-transferrable, non-exclusive license to certain patents related to the Hepatitis C Virus (“HCV”) held by such parties. The agreement required us to pay the third parties a one-time non-refundable license fee of $1.5 million, which was paid in August 2005. We may also be required to pay additional license fees, up to an additional $8.5 million, upon the achievement of specific development and/or commercial milestones.

Management’s intent in executing the license agreement is to provide for various alternatives for use of the licensed patents. Some of these uses require additional research and development expense and regulatory approvals, while others, specifically in the international market, do not require additional research and development expense or regulatory approvals. Based on management’s estimate of the cash flows to be received from future product sales in these international markets, we capitalized the $1.5 million license fee as patents and product rights in the accompanying balance sheet at September 30, 2005. We are amortizing this amount to cost of products sold on a straight line basis over a ten-year period, which represents management’s estimate of the useful life of the licensed patents.

Under the terms of the license agreement, we are also obligated to pay royalties based on a percentage of our net sales of certain products which incorporate the technology covered by the licensed patents. Royalties under the license agreement vary based upon the geographical territory where the product is sold. No sales have been made under the terms of this license agreement through September 30, 2005.

7. Provision for Loss on Assets

During the first six months of 2005, the Company explored options with respect to one of its products, including transitioning the manufacturing of the product to the Company’s distribution partner. The Company was not able to determine an outlet for this product and as a result, recorded a $1.5 million charge in June 2005 to reflect the provision for loss on inventory and fixed assets related to this product.

Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Statements below regarding future events or performance are "forward-looking statements" within the meaning of the Federal securities laws. These may include statements about our expected revenues, earnings, expenses, cash flow or other financial performance or development, expected regulatory filings and approvals, planned business transactions, views of future industry, competitive or market conditions, and other factors that could affect our future operations, results of operations or financial position. These statements often include the words "believes," "expects," "anticipates," "intends," "plans," "estimates," "may," "will," "should," "could," or similar expressions. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include: 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 other new products or technology; 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; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally; loss or impairment of sources of capital; ability to meet financial covenants in agreements with financial institutions; ability to retain qualified personnel; exposure to product liability, patent infringement, and other types of litigation; changes in international, federal or state laws and regulations; changes in relationships with strategic partners and reliance on strategic partners for the performance of critical activities under collaborative arrangements; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks, war and civil unrest; ability to identify, complete and realize the full benefits of potential acquisitions; and general political, business and economic conditions. These and other factors that could cause the forward-looking statements to be materially different are described in greater detail in our filings with the Securities and Exchange Commission, including our registration statements and our Annual Report on Form 10-K for the year ended December 31, 2004. Although forward-looking statements help to provide complete information about future prospects, they may not be reliable. The forward-looking statements are made as of the date of this Report and we undertake no duty to update these statements.

The following discussion should be read in conjunction with the financial statements contained herein and the notes thereto, along with the Section entitled "Critical Accounting Policies and Estimates," set forth below.

Overview

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 is designed for use at the point-of-care. Our cryosurgical products are also used at the point-of-care.

In vitro diagnostics have traditionally used blood or urine as the 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 and, when combined with their ease of use, non-invasive and dignified nature, and cost effectiveness, represent a competitive alternative to the more traditional testing methods in the diagnostic space.

During the first nine months of 2005, we continued to increase sales and gain market acceptance for our products, and as a result, reported strong financial results. Our total revenues were $51.3 million, or an increase of 29% over the comparable period in 2004, and our net income was $6.8 million ($0.15 per share), representing an improvement of more than $7.1 million over the first nine months of 2004. Our liquidity also improved, as we reported $8.5 million in cash flow from operations during the first nine months of 2005 and had $75.3 million in cash, cash equivalents and short-term investments as of September 30, 2005.

Sales into the infectious disease testing market increased significantly during the first nine months of 2005 due to the continued market acceptance of our OraQuick® device. This resulted largely from sales directly to various public health organizations, sales both directly and through Abbott Laboratories into the hospital market, sales to the Substance Abuse and Mental Health Services Administration ("SAMHSA") for further distribution to drug treatment centers and other clinics, and sales to the Centers for Disease Control and Prevention ("CDC") for further distribution in the public health market.

In 2004, the CDC and SAMHSA placed purchase orders totaling $6.3 million for OraQuick® devices and related testing materials, of which $0 and $1.4 million, respectively, remain to be shipped under the purchase orders at September 30, 2005. Both of these orders were for the OraQuick® *ADVANCE*™ rapid HIV-1/2 antibody test only. Although we are working to secure additional bulk purchases by federal governmental agencies of the OraQuick® ADVANCE™ test for further distribution to the public health and other markets throughout the United States, it cannot be predicted precisely if or when such bulk purchases will occur. In light of these circumstances, we are focusing our efforts on increasing direct sales of OraQuick® *ADVANCE*™.

In February 2005, we entered into a new agreement for the distribution of OraQuick® *ADVANCE*™ with Abbott Laboratories. Under this agreement, Abbott was appointed as our exclusive distributor in the U.S. hospital market and as a non-exclusive distributor in the U.S. physicians' office marketplace. As our exclusive distributor to hospitals, Abbott sells OraQuick® *ADVANCE*™ to federal hospitals under the terms and conditions of our Federal Supply Schedule that is filed with the U.S. General Services Administration. We have retained exclusive rights to all other markets, including the public health and criminal justice markets, the military, the CDC, SAMHSA and other government agencies. We have deployed a small sales force that provides direct access to and marketing support for the sales of our OraQuick® test into the hospital market. This sales force supports Abbott and works together with Abbott sales representatives to maximize the penetration of OraQuick® ADVANCE™ in the hospital market.

The markets for rapid HIV testing are very competitive and the level of competition is expected to increase, which could affect sales of our OraQuick® tests. For example, the Ortho Diagnostics division of Johnson & Johnson and Bio-Rad Laboratories each sell competing laboratory-based HIV-1 enzyme immunoassays, and Calypte, Inc. sells an HIV-1 screening test for urine in the United States. In addition, MedMira and Trinity Biotech have each received U.S. Food and Drug Administration ("FDA") approval to sell competing rapid HIV-1 blood tests and Bio-Rad received FDA approval for a rapid HIV-1/2 blood test. Under their current FDA approvals, these tests compete with our OraQuick® tests in the hospital or other laboratory settings. In addition, Trinity Biotech has received a waiver under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, for its rapid finger stick HIV-1 blood test, and we believe that this test will compete with our OraQuick® tests in the public health and other markets outside of the traditional hospital and laboratory settings. These companies, or others, may continue to expand the bodily fluids with which a rapid HIV test may be performed or develop and commercialize new rapid tests, either of which would provide further competition for our OraQuick® tests.

Sales to the substance abuse testing market also increased during the first nine months of 2005, 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.

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 our Intercept® drugs of abuse testing product. Modifications may be required to bring our Intercept® product into compliance with the guidelines when finally adopted. Compliance with the guidelines will be required in order for us to sell our drug testing products to federal agencies and possibly other industries that are influenced by the federal guidelines in structuring their drug testing programs.

As part of the strategic business review we completed in late 2004, we concluded that the roadside drugs of abuse testing market for UP*link*® may not be as attractive as a number of other opportunities we are pursuing. During the first six months of 2005, we explored our options with respect to the UP*link*® product, including transitioning the manufacturing of the product to our distribution partner, Dräger Safety. Throughout this period, we were not able to reach an agreement with Dräger Safety or determine an alternative outlet for this product. In addition, we were advised that Dräger will no longer promote the sale of the UP*link*® product. As a result, we recorded a $1.5 million charge in June 2005 to reflect a provision for loss on inventory and fixed assets related to our UP*link*® product. We expect to terminate our existing research, development and distribution agreements with Dräger for the UP*link*® product.

Sales to the cryosurgical systems market during the third quarter of 2005 have increased slightly. The cryosurgical systems market represents sales of Histofreezer® into both the domestic and international physicians' office markets and sales of the over-the-counter ("OTC") formulation of this product to our domestic distributor, Medtech Holdings, Inc. ("Medtech"), and our international distributor, SSL International plc ("SSL"). Medtech, a wholly-owned subsidiary of Prestige Brands Holdings, Inc., distributes Freeze Off™ to consumers under its Compound W® trademark in the OTC market in the United States and Canada, and is the owner of both tradenames. In June 2005, we entered into an agreement with SSL under which we manufacture and supply, and SSL distributes on an exclusive basis, the Company's cryosurgical wart removal product in the OTC footcare market in Europe, Australia and New Zealand. The product is manufactured and sold under SSL's Scholl and Dr. Scholl trademarks. This product is now available for retail purchase in pharmacies and retail outlets in Germany and France and is expected to be made available for retail purchase in Spain, Italy, the United Kingdom and other European countries, Australia and New Zealand, beginning in 2006.

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. We are seeking injunctive relief and the payment of damages, and Schering-Plough has raised several defenses, including that their Freeze Away™ device does not infringe our patents and that one or more of our patents are either invalid or unenforceable. On November 2, 2005, a pretrial conference was held in this matter, at which the Court heard oral argument on motions for summary judgment filed by the parties. We expect the Court to rule on these and other motions and to set a new trial schedule in the near future.

Sales to the insurance risk assessment market decreased in the third quarter of 2005. We anticipate little growth 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.

Because of the regulatory approvals needed for most of our products, we often are required to rely on sole source providers for critical components and materials and on related products supplied by third parties. This is particularly true for our OraQuick® tests, our OraSure® oral fluid collection device and our oral fluid Western blot HIV-1 confirmatory product. If we are unable to obtain necessary components or materials from these sole sources, the time required to develop replacements and obtain the required FDA approvals could disrupt our ability to sell the affected products. Any delay or interruption in our ability to manufacture the oral fluid Western blot HIV-1 confirmatory test would adversely affect sales of our OraSure® oral fluid collection device, as our customers are not expected to purchase OraSure® devices if an oral fluid Western blot HIV-1 confirmatory test is not readily available. In addition, if the HIV-1 enzyme immunoassay approved by the FDA for use with our OraSure® collection device, which is

manufactured by a third party, is either unavailable or experiences quality or performance problems, sales of our OraSure® device could be adversely affected.

Results of Operations

Three months ended September 30, 2005 compared to September 30, 2004

Total revenues increased 28% to approximately $18.1 million in the third quarter of 2005 from approximately $14.2 million in the comparable quarter in 2004, primarily as a result of increased sales of our OraQuick® *ADVANCE*™ rapid HIV-1/2 antibody test and our Intercept® oral fluid drug test. International sales accounted for 12% of total revenues in the third quarter of 2005.

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	
	2005	2004	Percent Change Inc. (Dec.)	2005	2004
Market revenues					
Infectious disease testing	$ 7,037	$ 3,702	90%	39%	26%
Substance abuse testing	3,595	2,745	31	20	19
Cryosurgical systems	6,143	5,831	5	34	41
Insurance risk assessment	1,275	1,808	(29)	7	13
Product revenues	18,050	14,086	28	100	99
Licensing and product development	27	90	(70)	—	1
Total revenues	$18,077	$14,176	28%	100%	100%

Sales to the infectious disease testing market increased 90% to approximately $7.0 million in the third quarter of 2005, primarily as a result of the increasing strength of our OraQuick® *ADVANCE*™ rapid HIV-1/2 antibody test. OraQuick® sales totaled approximately $5.9 million and $2.6 million in the third quarters of 2005 and 2004, respectively. OraSure® sales totaled approximately $1.1 million in the third quarters of both 2005 and 2004.

In the third quarters of 2005 and 2004, we recorded approximately $2.1 million and $909,000, respectively, in direct sales of OraQuick® to the U.S. public health market and approximately $606,000 and $611,000, respectively, to the CDC. We also had OraQuick® sales of approximately $867,000 and $0 to SAMHSA, approximately $2.0 million and $354,000 to Abbott, approximately $377,000 and $495,000 to the international marketplace, and approximately $2,000 and $229,000 directly to hospital customers, in the third quarters of 2005 and 2004, respectively. Sales of OraQuick® *ADVANCE*™ in the United States totaled approximately $4.9 million, or 88% of total U.S. OraQuick® sales in the third quarter of 2005.

We believe that our OraQuick® *ADVANCE*™ device, which is FDA-approved for detecting antibodies to both HIV-1 and 2 in oral fluid, fingerstick and venous whole blood, and plasma samples, and is CLIA-waived for use with all sample types except plasma, provides a significant competitive advantage and will allow us to more fully implement a strategy to sell OraQuick® internationally. We are currently pursuing CE marking for our OraQuick® ADVANCE™ product which would allow us to sell our product in Europe. Our goal is to obtain a CE mark for OraQuick® *ADVANCE*™ in the next several months, and then obtain several country-specific registrations in order to permit the launch of this product in Europe in 2006.

Although sales of OraQuick® are expected to increase, such sales may 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® tests. It is not possible at this time, however, to estimate the extent of such change in purchasing patterns or the financial impact of replacing OraSure® sales with sales of our OraQuick® tests.

Sales to the substance abuse testing market increased 31% to approximately $3.6 million in the third quarter of 2005, primarily as a result of increased sales of our Intercept® oral fluid drug testing service in the U.S. workplace, criminal justice and international markets. Sales into the U.S. workplace, criminal justice and international markets increased 66%, 74% and 29% to approximately $1.5 million, $625,000 and $536,000, respectively, in the third quarter of 2005. We expect continued growth in Intercept® sales through the remainder of 2005 as customers continue to shift from urine-based to oral fluid-based drug testing methods.

Revenues from our UP*link*® rapid point-of-care oral fluid drug detection system were approximately $10,000 and $269,000 in the third quarter of 2005 and 2004, respectively. As part of the strategic business review we completed in late 2004, we concluded that the roadside drugs of abuse testing market for UP*link*® may not be as attractive as a number of other opportunities we are pursuing. During the first half of 2005, we explored our options with respect to the UP*link*® product, including transitioning the manufacturing of the product to our distribution partner, Dräger Safety. Throughout this period, we were not able to reach an agreement with Dräger Safety or determine an alternative outlet for this product. In addition, we were advised that Dräger will no longer promote the sale of the UP*link*® product. As a result, we recorded a $1.5 million charge in June 2005 to reflect a provision for loss on inventory and fixed assets related to our UP*link*® product. We expect to terminate our existing research, development and distribution agreements with Dräger for the UP*link*® product.

Sales of our products in the cryosurgical systems market (which includes both the physicians' office and OTC markets) increased 5% to approximately $6.1 million in the third quarter of 2005. This increase was primarily due to the initial stocking purchases of our international OTC cryosurgical product pursuant to our agreement with SSL, the launch of the Freeze Off™ product by Medtech in Canada, and an increase in sales of Histofreezer® to United States physicians' offices. This increase was partially offset by a reduction in sales of the Freeze Off™ product to Medtech for distribution in the United States, to $2.6 million in the third quarter of 2005, compared to $3.9 million during the comparable period in 2004.

The Freeze Off™ product is being sold under Medtech's Compound W® trademark. The 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 United States.

In June 2005, we entered into an agreement with SSL under which SSL will distribute, on an exclusive basis, the Company's cryosurgical wart removal product in the OTC footcare market in Europe, Australia and New Zealand. The product is being manufactured and sold under SSL's Scholl and Dr. Scholl trademarks, and is now available for retail purchase in pharmacies and retail outlets in Germany and France and is expected to be launched by SSL in several other countries beginning in early 2006. We expect international sales of OTC cryosurgery products to our distributors to approximate $3.3 million in the fourth quarter of 2005.

Sales of our Histofreezer® product to physicians' offices in the U.S. and international markets increased 40% and 35% to $2.1 million and $553,000, respectively, in the third quarter of 2005. We anticipate that U.S. and international sales of Histofreezer® in the professional market will continue to increase slightly during 2005, as compared to 2004, particularly as we secure additional distributors in countries where the product is currently not sold.

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

Sales to the insurance risk assessment market in the third quarter of 2005 decreased by 29% to approximately $1.3 million as compared to the third quarter of 2004, primarily as a result of decreased OraSure® device

purchases by our insurance lab testing partners. We believe this decrease is a result of an overall reduction in life insurance application activity in the United States. As a result, we currently expect that our 2005 full-year revenues in this market will fall below the levels attained in 2004.

Licensing and product development revenues decreased by 70% to $27,000 during the third quarter of 2005, from $90,000 in the comparable period in 2004. Licensing and product development revenues during the third quarter of 2004 were primarily related to our collaborative UP*link*® and oral fluid research project, under a grant awarded by the National Institutes of Health. The annual phase of this grant expired in June 2005 and, therefore, there were no related revenues during the third quarter of 2005. Further revenues under this grant will depend on progress achieved in the research and future funding awarded by the National Institutes of Health.

Medtech accounted for approximately 17% and 28% of total revenues for the third quarter of 2005 and 2004, respectively. Lab*One*, Inc. accounted for approximately 10% of total revenues for both the third quarter of 2005 and 2004. Abbott Laboratories accounted for approximately 11% and 3% of total revenues for the third quarter of 2005 and 2004, respectively.

Gross margin in the third quarter of 2005 was approximately 64%, compared to 60% for the third quarter of 2004. Gross margin was positively affected by more efficient utilization of the Company's manufacturing facilities and lower inventory scrap expense, partially offset by the absence in 2005 of a favorable resolution of an estimated prior period royalty obligation, that occurred in the third quarter of 2004.

Research and development expenses decreased 11% to approximately $1.3 million in the third quarter of 2005 from approximately $1.5 million in the same period in 2004, primarily as a result of lower overall staffing costs and lower expenses for clinical trials, partially offset by fees paid to recruit and relocate the Company's new Chief Science Officer and Senior Vice President, Regulatory Affairs/Quality Assurance.

Sales and marketing expenses remained consistent at approximately $4.0 million in both the third quarter of 2005 and 2004. Within the sales and marketing expense category, lower advertising and bad debt expense were offset by increased market research, compensation and related expenses as a result of higher staffing levels. Included in advertising expenses for the third quarters of 2005 and 2004 were $497,000 and $918,000, respectively, related to reimbursements to Medtech for marketing expenses incurred for the Freeze Off™ product. 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.

General and administrative expenses decreased 10% to approximately $3.2 million in the third quarter of 2005 from approximately $3.5 million in the same period in 2004. This decrease was primarily attributable to a reduction in consulting expenses, a reduction in rent expense and moving expenses due to the transfer of manufacturing operations to Bethlehem and the expiration of the lease for our Oregon facilities in January 2005, and a reduction in transition expenses related to the Company's former Chief Executive Officer. This decrease was partially offset by an increase in legal fees associated with the Schering-Plough patent litigation and increased staffing related expenses. Legal fees associated with the Schering-Plough patent litigation were $653,000 and $459,000 in the three months ended September 30, 2005 and 2004, respectively. General and administrative expenses are expected to increase in 2005 compared to 2004, primarily as a result of higher legal fees associated with the Schering-Plough litigation.

Interest expense decreased to $23,000 in the third quarter of 2005 from $32,000 in the same period in 2004, primarily as a result of lower outstanding debt balances. Interest income increased to $619,000 in the third quarter of 2005 from $229,000 in the same period in 2004, as a result of higher yields on our investment portfolio.

Although there was income before income taxes during the third quarter of 2005, there was no provision for income taxes due to the utilization of previously unused net operating loss ("NOL") carryforwards. The utilization of such NOL carryforwards results in a corresponding decrease in deferred tax assets and the related valuation allowance.

There also was no provision for foreign income taxes recorded during the third quarter of 2005. During the third quarter of 2004, a provision for foreign income taxes of $5,000 was recorded.

At December 31, 2004, we had federal NOL carryforwards of approximately $74.9 million. Our ability to use our NOL carryforwards and credit carryforwards to offset income tax obligations may be limited by changes in the ownership of our stock. Internal Revenue Code ("IRC") Section 382 and related sections ("Section 382") contain provisions that limit the amount of NOL carryforwards and credit carryforwards that can be used in any given year in the event of specified occurrences, including significant ownership changes. In the fourth quarter of 2005, we expect to complete an analysis to determine if any Section 382 ownership changes have occurred. Provided that we can demonstrate actual and forecasted sustained profitability, we expect to release a portion of our deferred tax valuation allowance during the fourth quarter of 2005 to reflect the realizability of the deferred tax asset including the carryforwards that are not limited by Section 382. At this time, however, the precise impact of the release of the deferred tax valuation allowance cannot be determined, but could be material to both our financial position and results of operations.

Results of Operations

Nine months ended September 30, 2005 compared to September 30, 2004

Total revenues increased 29% to approximately $51.3 million for the nine months ended September 30, 2005 from approximately $39.8 million in the comparable period in 2004, primarily as a result of increased sales of our OraQuick® *ADVANCE*™ rapid HIV-1/2 antibody test, our Intercept® oral fluid drug test, and our Histofreezer® cryosurgical product. International sales accounted for 10% of total revenues during the first nine months of 2005.

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	
	2005	2004	Percent Change Inc. (Dec.)	2005	2004
Market revenues					
Infectious disease testing	$19,672	$11,009	79%	38%	28%
Substance abuse testing	10,060	7,329	37	20	18
Cryosurgical systems	16,002	15,162	6	31	38
Insurance risk assessment	5,364	5,997	(11)	11	15
Product revenues	51,098	39,497	29	100	99
Licensing and product development	237	302	(22)	—	1
Total revenues	$51,335	$39,799	29%	100%	100%

Sales to the infectious disease testing market increased 79% to approximately $19.7 million in the first nine months of 2005, primarily as a result of the increasing strength of our OraQuick® *ADVANCE*™ rapid HIV-1/2 antibody test. OraQuick® sales totaled approximately $16.2 million and $7.1 million in the first nine months of 2005 and 2004, respectively. OraSure® sales totaled approximately $3.4 million and $3.9 million in the first nine months of 2005 and 2004, respectively.

In the first nine months of 2005 and 2004, we recorded approximately $6.0 million and $2.1 million, respectively, in direct sales of OraQuick® to the U.S. public health market and approximately $2.3 million during each period to the CDC. We also had OraQuick® sales of approximately $3.5 million and $1.5 million to Abbott, approximately $2.6 million and $0 to SAMHSA, approximately $1.1 million and $944,000 to the international marketplace, and approximately $736,000 and $296,000 directly to hospital customers, in the first nine months of 2005 and 2004,

respectively. Sales of OraQuick® *ADVANCE*™ in the United States totaled $11.5 million, or 76% of total U.S. OraQuick® sales in the first nine months of 2005.

We believe that our OraQuick® *ADVANCE*™ device, which is FDA-approved for detecting antibodies to both HIV-1 and 2 in oral fluid, fingerstick and venous whole blood, and plasma samples, and is CLIA-waived for use with all sample types except plasma, provides a significant competitive advantage and will allow us to more fully implement a strategy to sell OraQuick® internationally. We are currently pursuing CE marking for our OraQuick® *ADVANCE*™ product which would allow us to sell our product in Europe. Our goal is to obtain a CE mark for OraQuick® *ADVANCE*™ in the next several months, and then obtain several country-specific registrations in order to permit the launch of this product in Europe in 2006.

Although sales of OraQuick® are expected to increase, such sales may 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® tests. It is not possible at this time, however, to estimate the extent of such change in purchasing patterns or the financial impact of replacing OraSure® sales with sales of our OraQuick® tests.

Sales to the substance abuse testing market increased 37% to approximately $10.1 million in the first nine months of 2005, primarily as a result of increased sales of our Intercept® oral fluid drug testing service in the U.S. workplace and criminal justice markets. Sales into the U.S. workplace and criminal justice markets increased 101% and 62% to approximately $4.3 million and $1.9 million, respectively, in the first nine months of 2005. We expect continued growth in Intercept® sales through the remainder of 2005 as customers continue to shift from urine-based to oral fluid-based drug testing methods.

Revenues from our UP*link*® rapid point-of-care oral fluid drug detection system were approximately $277,000 and $542,000 in the first nine months of 2005 and 2004, respectively. As part of the strategic business review we completed in late 2004, we concluded that the roadside drugs of abuse testing market for UP*link*® may not be as attractive as a number of other opportunities we are pursuing. During the first half of 2005, we explored our options with respect to the UP*link*® product, including transitioning the manufacturing of the product to our distribution partner, Dräger Safety. Throughout this period, we were not able to reach an agreement with Dräger Safety or determine an alternative outlet for this product. In addition, we were advised that Dräger will no longer promote the sale of the UP*link*® product. As a result, we recorded a $1.5 million charge in June 2005 to reflect a provision for loss on inventory and fixed assets related to our UP*link*® product. We expect to terminate our existing research, development and distribution agreements with Dräger for the UP*link*® product.

Sales of our products in the cryosurgical systems market (which includes both the physicians' office and OTC markets) increased 6% to approximately $16.0 million in the first nine months of 2005. This increase was primarily due to the initial stocking purchases of our international OTC cryosurgical product pursuant to our agreement with SSL, the launch of the Freeze Off™ product by Medtech in Canada, and an increase in Histofreezer® sales to both United States and international physicians' offices. This increase was partially offset by a reduction in sales of the Freeze Off™ product to Medtech for distribution in the United States, to $9.4 million in the first nine months of 2005, compared to $10.3 million during the comparable period in 2004.

The Freeze Off™ product is being sold under Medtech's Compound W® trademark. The 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 United States.

In June 2005, we entered into an agreement with SSL under which SSL will distribute, on an exclusive basis, the Company's cryosurgical wart removal product in the OTC footcare market in Europe, Australia and New Zealand. The product is being manufactured and sold under SSL's Scholl and Dr. Scholl trademarks, and is now available for retail purchase in pharmacies and retail outlets in Germany and France and is expected to be launched by SSL in several other countries beginning in early 2006. We expect international sales of OTC cryosurgery products to our distributors to approximate $3.3 million in the fourth quarter of 2005.

Sales of our Histofreezer® product to physicians' offices in the U.S. and international market increased 15% and 25% to $4.2 million and $1.4 million, respectively, in the first nine months of 2005. We anticipate that U.S. and international sales of Histofreezer® in the professional market will continue to increase slightly for fiscal year 2005, as compared to 2004, particularly as we secure additional distributors in countries where the product is currently not sold.

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

Sales to the insurance risk assessment market decreased in the first nine months of 2005 by 11% to approximately $5.4 million, compared to the first nine months of 2004, primarily as a result of decreased OraSure® device purchases by our insurance lab testing partners. We believe this decrease is a result of an overall reduction in life insurance application activity in the United States. As a result, we currently expect that our 2005 full-year revenues in this market will fall below the levels attained in 2004.

Licensing and product development revenues during the first nine months of 2005 decreased 22% to $237,000 as compared to $302,000 in 2004. Licensing and product development revenues during the first nine months of 2005 and the first nine months of 2004 were primarily related to our collaborative UP*link*® and oral fluid research project, under a grant awarded by the National Institutes of Health. The annual phase of this grant expired in June 2005 and, therefore, there were no related revenues during the third quarter of 2005. Further revenues under this grant will depend on progress achieved in the research and future funding awarded by the National Institutes of Health.

Medtech accounted for approximately 19% and 26% of total revenues for the first nine months of 2005 and 2004, respectively. Lab*One* accounted for approximately 11% and 12% of total revenues for the first nine months of 2005 and 2004, respectively.

Gross margin for the first nine months of 2005 was approximately 60%, compared to 59% for the first nine months of 2004. Gross margin was positively affected by more efficient utilization of the Company's manufacturing facilities, partially offset by the $1.5 million charge in June 2005 associated with the UP*link*® assets.

Research and development expenses decreased 21% to approximately $3.8 million in the first nine months of 2005 from approximately $4.7 million in the same period in 2004, primarily as a result of lower overall staffing costs and lower costs associated with clinical trials.

Sales and marketing expenses increased 8% to approximately $12.3 million in the first nine months of 2005 from approximately $11.4 million in the same period in 2004. This increase was primarily the result of increased levels of market research, staffing, compensation, and commissions, partially offset by lower advertising expenses. Included in advertising expenses for the first nine months of 2005 and 2004 were $1.5 million and $2.2 million, respectively, related to reimbursements to Medtech for marketing expenses incurred for the Freeze Off™ product. 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.

General and administrative expenses increased 13% to approximately $9.1 million in the first nine months of 2005 from approximately $8.1 million in the same period in 2004. This increase was primarily attributable to increased legal fees associated with the Schering-Plough patent litigation, increased amortization of restricted stock grants to management, and increased staffing related expenses. This increase was partially offset by a reduction in consulting expenses, a reduction in transition expenses related to the Company's former Chief Executive Officer, and a reduction in rent expense due to the transfer of manufacturing operations to Bethlehem and the expiration of the lease for our Oregon facilities in January 2005. Legal fees associated with the Schering-Plough patent litigation were $1.7 million and $496,000 in the nine months ended September 30, 2005 and 2004, respectively. General and administrative expenses are expected to increase further in 2005 compared to 2004 as a result of higher legal fees associated with the Schering-Plough litigation.

Interest expense decreased to $76,000 in the first nine months of 2005 from $104,000 in the same period in 2004, primarily as a result of lower outstanding debt balances. Interest income increased to $1.5 million in the first nine months of 2005 from $665,000 in the same period in 2004, as a result of higher yields on our investment portfolio.

Although there was income before income taxes during the first nine months of 2005, there was no provision for income taxes primarily due to the utilization of previously unused NOL carryforwards. The utilization of such NOL carryforwards results in a corresponding decrease in deferred tax assets and the related valuation allowance. There also was no provision for foreign income taxes recorded during the first nine months of 2005. During the first nine months of 2004, a provision for foreign income taxes of approximately $14,000 was recorded.

At December 31, 2004, we had federal NOL carryforwards of approximately $74.9 million. Our ability to use our NOL carryforwards and credit carryforwards to offset income tax obligations may be limited by changes in the ownership of our stock. Internal Revenue Code (“IRC”) Section 382 and related sections (“Section 382”) contain provisions that limit the amount of NOL carryforwards and credit carryforwards that can be used in any given year in the event of specified occurrences, including significant ownership changes. In the fourth quarter of 2005, we expect to complete an analysis to determine if any Section 382 ownership changes have occurred. Provided that we can demonstrate actual and forecasted sustained profitability, we expect to release a portion of our deferred tax valuation allowance during the fourth quarter of 2005 to reflect the realizability of the deferred tax asset including the carryforwards that are not limited by Section 382. At this time, however, the precise impact of the release of the deferred tax valuation allowance cannot be determined, but could be material to both our financial position and results of operations.

Liquidity and Capital Resources

	September 30, 2004	December 31, 2005
	(In thousands)	
Cash and cash equivalents	$ 16,220	$ 10,121
Short-term investments	59,077	56,602
Working capital	79,999	68,910

Our cash, cash equivalents, and short-term investments increased approximately $8.6 million during the first nine months of 2005 to approximately $75.3 million at September 30, 2005, primarily as a result of $8.5 million in positive cash flow from operations and approximately $4.7 million in proceeds from the exercise of stock options, partially offset by the purchase of approximately $1.4 million of property and equipment, approximately $838,000 of loan principal repayments, approximately $451,000 of payments related to the purchase and retirement of common stock, expenditures of $1.8 million for patent license rights, and an increase of $90,000 in other assets. At September 30, 2005, our working capital was approximately $80.0 million.

Net cash provided by operating activities was approximately $8.5 million in the first nine months of 2005. This resulted from net income of approximately $6.8 million, depreciation and amortization of approximately $1.8 million, non-cash charges of approximately $3.3 million related to stock-based compensation expense and provisions for excess and obsolete inventories and for loss on property and equipment, a decrease of approximately $7,000 in prepaid expenses and other current assets, and an increase of $1.3 million in accounts payable and accrued expenses, partially offset by an increase of approximately $3.2 million in accounts receivable and an increase of $1.5 million in inventory. Accounts receivable are expected to continue to grow as our sales increase and as the proportion of sales increase to parties such as the CDC and Medtech, which have 60-day payment terms.

Net cash used in investing activities during the first nine months of 2005 was approximately $5.7 million. We purchased approximately $1.4 million of property and equipment, sold a net amount of $2.4 million of short-term investments, paid $1.8 million for patent license rights, and had an increase of $90,000 in other assets.

Capital expenditures are anticipated to increase during 2005 to approximately $3.9 million for the year, as a result of additional commitments we have made for the purchase and installation of manufacturing and research and

development equipment. We also expect to purchase additional information systems equipment and to upgrade certain older equipment in 2005.

Net cash provided by financing activities was approximately $3.4 million, reflecting the proceeds of $4.7 million received from the issuance of common stock pursuant to stock option exercises, offset by approximately $838,000 of loan principal repayments and approximately $451,000 of payments related to the purchase and retirement of common stock.

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 April 2005, the Credit Facility was amended further to extend the maturity date of our revolving working capital line of credit to April 29, 2006.

The $887,000 mortgage loan matures in September 2012, bears interest at an annual floating rate equal to Comerica’s prime rate (6.75% at September 30, 2005), 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, 2005 was $732,023.

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, 2005 was $428,571.

As of September 30, 2005, we had an outstanding balance of $209,930 under the Original Non-Revolving Line consisting of four individual loans of (i) $47,943 with a fixed annual interest rate of 5.07%, (ii) $76,209 with a floating annual interest rate equal to Comerica’s prime rate (6.75% at September 30, 2005), (iii) $45,022 with a floating annual interest rate equal to Comerica’s prime rate (6.75% at September 30, 2005), and (iv) $40,756 with a floating annual interest rate equal to Comerica’s prime rate (6.75% at September 30, 2005).

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 29, 2006, with interest payable monthly. We had no outstanding borrowings under this facility at September 30, 2005.

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 revolving working capital line are limited to commercially standard percentages of accounts receivable. The Credit Facility contains certain covenants that set forth minimum requirements for our quick ratio, liquidity, and tangible net worth. We were in full compliance with all covenants at September 30, 2005 and expect to remain in compliance with all covenants during the remainder of 2005. 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.

As of September 30, 2005, we also had a $248,029 note payable to the Pennsylvania Industrial Development Authority related to the purchase of one of our facilities in Bethlehem, Pennsylvania in 1998. This note is secured by a second lien on our building, bears interest at 2% per year, and requires monthly installments of principal and interest of $4,893 through March 2010.

The combination of our current cash position, cash flow from operations, and available borrowings under our Credit Facility is expected to be sufficient to fund our operating, licensing, 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 of defending patent infringement or other types of litigation, 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.

Recent Accounting Pronouncements

In November 2004, the Financial Accounting Standards Board (“FASB”) issued Statement of Financial Accounting Standards (“SFAS”) No. 151, “Inventory Costs,” which amends the guidance in Accounting Research Bulletin No. 43. SFAS No. 151 clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material and requires such costs to be recognized as current-period charges. Additionally, SFAS No. 151 requires that allocation of fixed production overhead costs be based on normal capacity. SFAS No. 151 is effective for years beginning after June 15, 2005, with early adoption permitted. The implementation of SFAS No. 151 is not expected to have a material effect on our financial position, results of operations or cash flows.

In December 2004, the FASB issued SFAS No. 123 Revised, “Share-Based Payment” (“SFAS No. 123R”). SFAS No. 123R requires employee stock options to be accounted for in the statement of operations based on their fair values on the date of the grant, and eliminates the ability to account for these instruments under the intrinsic value method prescribed by Accounting Principles Board Opinion No. 25. SFAS No. 123R requires the use of an option pricing model for estimating fair value, which is amortized to expense over the service period. The requirements of SFAS No. 123R are effective for annual periods beginning after June 15, 2005. SFAS No. 123R allows for either modified prospective recognition of compensation expense or retrospective recognition. The Company is considering the potential implementation of different valuation models to determine the fair value of stock-based compensation and, therefore, has not yet completed evaluating the impact of adopting SFAS No. 123R on its results of operations.

Summary of Contractual Obligations and Commercial Commitments

The following sets forth our approximate aggregate obligations at September 30, 2005 for future payments under contracts and other contingent commitments, for the years 2005 and beyond:

Contractual Obligations	Total	Payments due by December 31, 2005	2006	2007	2008	2009	Thereafter
Long-term debt[1]	$ 1,618,553	$ 278,280	$ 460,297	$ 119,847	$ 104,416	$ 108,880	$ 546,833
Operating leases[2]	5,940,315	295,559	880,836	783,062	798,810	814,262	2,367,786
Employment contracts[3]	2,297,670	659,409	1,245,761	392,500	—	—	—
Purchase obligations[4]	2,956,196	2,956,196	—	—	—	—	—
Minimum commitments under contracts[5]	8,322,917	106,250	625,000	725,000	725,000	650,000	5,491,667
Total contractual obligations	$ 21,135,651	$ 4,295,694	$ 3,211,894	$ 2,020,409	$ 1,628,226	$ 1,573,142	$ 8,406,286

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

2 Represents payments required under our operating leases.

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

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

5 Represents payments required pursuant to certain research, licensing and royalty agreements executed by the Company.

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 2004 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" ("SAB No. 104"). This bulletin draws on existing accounting rules and provides specific guidance on revenue recognition of up-front non-refundable licensing and development fees. We license certain products or technology to outside third parties, in return for which we receive up-front licensing fees. Some of these fees can be significant. In accordance with SAB No. 104, we ratably recognize this revenue over the related license period.

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

We recognize product revenues when there is persuasive evidence that an arrangement exists, the price is fixed or determinable, title has passed and collection is reasonably assured. Product revenues are net of allowances for any discounts or rebates. We do not grant price protection or product return rights to our customers, except for warranty returns. Where a product fails to comply with its limited warranty, we can either replace the product or provide the customer with a refund of the purchase price or credit against future purchases. Historically, returns arising from warranty issues have been infrequent and immaterial. Accordingly, we expense warranty returns as incurred. While such returns have been immaterial in the past, we cannot guarantee that we will continue to experience the same rate of warranty claims as we have in the past. Any significant increase in product warranty claims could have a material adverse impact on our operating results for the period in which the claims occur.

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

Based upon historical experience and any specific customer collection issues that are identified, we use our judgment to establish and evaluate the adequacy of our allowance for estimated credit losses, which was $271,895 at September 30, 2005. While credit losses have been within our expectations and the allowance provided, these losses

can vary from period to period (approximately $3,541, $88,659, and $213,188 in 2004, 2003 and 2002, 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, 2005, approximately $4.4 million, or 43% of our accounts receivable, were due from three major customers. Any significant changes in the liquidity or financial position of these customers, or others, could have a material adverse impact on the collectibility of our accounts receivable and future operating results.

Inventories. Our inventories are valued at the lower of cost or market, determined on a first-in, first-out basis, and include the cost of raw materials, labor, and overhead. The majority of our inventories are subject to expiration dating. We continually evaluate the carrying value of our inventories and when, in the opinion of management, factors indicate that impairment has occurred, either the inventories' carrying value is reduced or the inventories are completely written off. We base these decisions on the level of inventories on hand in relation to our estimated forecast of product demand, production requirements over the next twelve months and the expiration dates of raw materials and finished goods. During 2004, 2003, and 2002, we wrote-off inventory which had a cost of approximately $839,000, $540,000, and $1.4 million, respectively, as a result of scrap levels and product expiration issues. During the nine months ended September 30, 2005, we wrote-off inventory which had a cost of approximately $1.8 million, of which the majority related to a provision for loss on our UP*link*® product. During the first half of 2005, we explored options with respect to the UP*link*® product, however, we were not able to determine an outlet for this product. As a result, we recorded a $1.3 million charge in June 2005 to reflect a provision for loss on the UP*link*® inventory. 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 $8.9 million or 9% of our total assets at September 30, 2005. Our investment in the privately-held nonaffiliated company is recorded under the cost method of accounting, because we do not have a controlling interest in this company nor do we have the ability to exert significant influence over the operating and financial policies of this 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. In August 2005, we recorded a $1.5 million intangible asset related to a payment under a license agreement to certain patents related to the Hepatitis C Virus. Management's intent in executing this license is to provide for various alternatives for use, including uses in the international market that would not require additional research and development expense or regulatory approvals. This $1.5 million asset was capitalized based on management's estimate of the cash flows to be received from future product sales in these international markets. A similar analysis of estimated future cash flows will be prepared upon payment of additional license fees under this agreement, or upon changes in circumstances, to determine the appropriate accounting treatment for payments under this license agreement. An impairment of long-lived or intangible assets could occur whenever events or changes in circumstances indicate that the net book value of these assets may not be recoverable. Events which could trigger an asset impairment include significant underperformance relative to expected historical or projected future operating results, significant changes in the manner of our use of an asset or in our strategy for our overall business, significant negative industry or economic trends, shortening of product life-cycles or changes in technology, and negative financial performance of our nonaffiliated investee company. If we believe impairment of an asset has occurred, we measure the amount of such impairment by comparing the net book value of the affected assets to the fair value of these assets, which is generally determined based upon the present value of the expected cash flows associated with the use and ultimate disposition of these assets. If the net book value exceeds the fair value of the impaired assets, we would incur an impairment expense equal to this difference. In June 2005, we recorded a $196,000 provision for loss on our UP*link*® fixed assets as a result of our inability to reach an agreement to transfer these assets to our distribution partner or determine an alternative outlet for these assets. We currently believe the future cash flows to be received from all other long-lived and intangible assets will exceed their book value and, as such, we have not recognized any additional impairment losses through September 30, 2005. 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, 2004, we had federal NOL carryforwards of approximately $74.9 million. The deferred tax asset associated with these NOLs and other temporary differences was approximately $31.5 million at December 31, 2004. 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. 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, 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, at that time. 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.

Our ability to use our NOL carryforwards and credit carryforwards to offset income tax obligations may be limited by changes in the ownership of our stock. Internal Revenue Code ("IRC") Section 382 and related sections ("Section 382") contain provisions that limit the amount of NOL carryforwards and credit carryforwards that can be used in any given year in the event of specified occurrences, including significant ownership changes. In the fourth quarter of 2005, we expect to complete an analysis to determine if any Section 382 ownership changes have occurred. Provided that we can demonstrate actual and forecasted sustained profitability, we expect to release a portion of our deferred tax valuation allowance during the fourth quarter of 2005 to reflect the realizability of the deferred tax asset including the carryforwards that are not limited by Section 382. At this time, however, the precise impact of the release of the deferred tax valuation allowance cannot be determined, but could be material to both our financial position and results of operations.

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

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

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

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

exposed to the risks of changes in the credit quality of issuers. We typically invest in the shorter end of the maturity spectrum.

We do not currently have any foreign currency exchange contracts or 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 $643,000 and $1.5 million or 4% and 3% of our total revenues for the three months and nine months ended September 30, 2005, respectively. We do not expect the risk of foreign currency fluctuations to be material.

Item 4. CONTROLS AND PROCEDURES.

(a) Evaluation of Disclosure Controls and Procedures. The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) as of September 30, 2005. Based on that evaluation, the Company's management, including such officers, concluded that the Company's disclosure controls and procedures are adequate and effective to ensure that information required to be disclosed by the Company in the reports that we file or submit under the Securities Exchange Act of 1934 is accumulated and communicated to the Company's management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure and is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission.

(b) Changes in Internal Control Over Financial Reporting. There was no change in the Company's internal control over financial reporting identified in connection with the evaluation referred to in paragraph (a) above that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

On July 23, 2004, we filed a lawsuit against Schering-Plough Healthcare Products, Inc. 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 permanent injunctive relief and the payment of damages. Schering-Plough has asserted various defenses in this matter, including that its Dr. Scholls® Freeze Away™ product does not infringe our patents and that one or more of our patents are invalid or unenforceable.

On November 2, 2005, a pretrial conference was held on this matter, at which the Court heard oral argument on motions for summary judgment filed by the parties. We expect the Court to rule on these and other motions and to set a new trial schedule in the near future.

Item 6. EXHIBITS

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

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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.

Date: November 9, 2005

/s/ RONALD H. SPAIR

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

Date: November 9, 2005

/s/ MARK L. KUNA

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

EXHIBIT INDEX

Exhibit	
10.1	Employment Agreement, dated September 23, 2005, between OraSure Technologies, Inc. and Stephen R. Lee, Ph.D, is incorporated herein by reference to Exhibit 99 to the Company's Current Report on Form 8-K filed September 28, 2005.*
31.1	Certification of Douglas A. Michels required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Ronald H. Spair required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
32.1	Certification of Douglas A. Michels required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Ronald H. Spair required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Management contract or compensatory plan or arrangement.

Exhibit 31.1

Certification

I, Douglas A. Michels, certify that:

1. I have reviewed this report on Form 10-Q of OraSure Technologies, Inc;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d -15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within the entity, particularly during the period in which this report is being prepared;
   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors:
   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2005

/s/ DOUGLAS A. MICHELS

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

Exhibit 31.2

Certification

I, Ronald H. Spair, certify that:

1. I have reviewed this report on Form 10-Q of OraSure Technologies, Inc;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d -15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within the entity, particularly during the period in which this report is being prepared;
   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors:
   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2005

/s/ RONALD H. SPAIR

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

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. §1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of OraSure Technologies, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2005 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Douglas A. Michels, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ DOUGLAS A. MICHELS

Douglas A. Michels
President and Chief Executive Officer

November 9, 2005

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. §1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of OraSure Technologies, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2005 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 Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ RONALD H. SPAIR

Ronald H. Spair
Executive Vice President and
Chief Financial Officer

November 9, 2005