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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 March 31, 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 ☐

Number of shares of Common Stock, par value $.000001 per share, outstanding as of May 2, 2005: 44,692,555

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PART I. FINANCIAL INFORMATION

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Item 1. FINANCIAL STATEMENTS

ORASURE TECHNOLOGIES, INC.
BALANCE SHEETS
(Unaudited)

	March 31, 2005	December 31, 2004
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 14,482,273	$ 10,121,208
Short-term investments	52,322,106	56,602,248
Accounts receivable, net of allowance for doubtful accounts of $327,889 and $345,257	8,742,276	7,073,988
Inventories	4,803,633	4,951,979
Prepaid expenses and other	1,178,086	1,195,085
Total current assets	81,528,374	79,944,508
PROPERTY AND EQUIPMENT, net	5,313,059	5,551,261
PATENTS AND PRODUCT RIGHTS, net	1,893,599	2,080,363
OTHER ASSETS	453,519	488,192
	$ 89,188,551	$ 88,064,324
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	$ 1,119,660	$ 1,122,455
Accounts payable	2,726,284	2,360,214
Accrued expenses	6,443,808	7,552,279
Total current liabilities	10,289,752	11,034,948
LONG-TERM DEBT	1,056,828	1,334,236
OTHER LIABILITIES	271,373	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, 44,672,974 and 44,631,731 shares issued and outstanding	45	45
Additional paid-in capital	211,532,895	209,948,075
Deferred compensation	(4,042,824)	(2,916,503)
Accumulated other comprehensive loss	(350,913)	(324,669)
Accumulated deficit	(129,568,605)	(131,129,943)
Total stockholders' equity	77,570,598	75,577,005
	$ 89,188,551	$ 88,064,324

The accompanying notes are an integral part of these statements.

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ORASURE TECHNOLOGIES, INC.
STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31,	
	2005	2004
REVENUES:		
Product	$15,743,975	$12,288,868
Licensing and product development	84,314	119,740
	15,828,289	12,408,608
COST OF PRODUCTS SOLD	6,370,622	5,190,530
Gross profit	9,457,667	7,218,078
OPERATING EXPENSES:		
Research and development	1,198,534	1,767,157
Sales and marketing	3,867,479	3,650,716
General and administrative	3,176,581	2,125,972
	8,242,594	7,543,845
Operating income (loss)	1,215,073	(325,767)
INTEREST EXPENSE	(27,324)	(31,413)
INTEREST INCOME	372,061	205,759
OTHER, NET	420	—
FOREIGN CURRENCY GAIN (LOSS)	1,108	(6,293)
Income (loss) before income taxes	1,561,338	(157,714)
INCOME TAXES	—	4,500
NET INCOME (LOSS)	$ 1,561,338	$ (162,214)
BASIC AND DILUTED EARNINGS (LOSS) PER SHARE	$ 0.03	$ (0.00)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING:		
BASIC	44,644,729	44,270,845
DILUTED	45,045,555	44,270,845

The accompanying notes are an integral part of these statements.

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

	Three Months Ended March 31,	
	2005	**2004**
OPERATING ACTIVITIES:		
Net income (loss)	$ 1,561,338	$ (162,214)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Stock-based compensation expense	433,422	63,772
Depreciation and amortization	630,514	597,487
Provision for excess and obsolete inventories	289,165	140,014
Changes in assets and liabilities:		
Accounts receivable	(1,668,288)	803,459
Inventories	(140,819)	(463,688)
Prepaid expenses and other current assets	23,224	(146,279)
Accounts payable, accrued expenses, and other liabilities	(607,832)	(693,574)
Net cash provided by operating activities	520,724	138,977
INVESTING ACTIVITIES:		
Purchases of short-term investments	(12,937,323)	(27,106,355)
Proceeds from maturities and redemptions of short-term investments	17,199,281	7,733,157
Purchases of property and equipment	(152,229)	(345,904)
(Increase) decrease in other assets	23	(16)
Net cash provided by (used in) investing activities	4,109,752	(19,719,118)
FINANCING ACTIVITIES:		
Repayments of long-term debt	(280,203)	(281,762)
Proceeds from issuance of common stock	38,827	228,641
Withholding and retirement of common stock	(19,975)	—
Net cash used in financing activities	(261,351)	(53,121)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	(8,060)	(11,125)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	4,361,065	(19,644,387)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	10,121,208	30,695,177
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 14,482,273	$ 11,050,790

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 over-the-counter or consumer retail market.

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 period ended March 31, 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 March 31, 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, corporate bonds, and asset-backed obligations, all with purchased maturities greater than ninety days. Available-for-sale securities are carried at fair value, based upon quoted market prices, with unrealized gains and losses reported in stockholders' equity as a component of accumulated other comprehensive loss.

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

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
March 31, 2005				
Certificates of deposit	$16,489,287	$ —	$ (3,517)	$16,485,770
Commercial paper	994,500	—	(750)	993,750
Government agency bonds	20,287,917	120	(88,042)	20,199,995
State and local government agency obligations	844,986	—	(1,827)	843,159
Corporate bonds	13,849,337	595	(50,500)	13,799,432
Total available-for-sale securities	$52,466,027	$ 715	$(144,636)	$52,322,106
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 March 31, 2005, maturities of investments were as follows:				
Less than one year	$50,465,098	$ 512	$(133,835)	$50,331,775
1 – 2 years	2,000,929	203	(10,801)	1,990,331
Total available-for-sale securities	$52,466,027	$ 715	$(144,636)	$52,322,106

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:

	March 31, 2005	December 31, 2004
Raw materials	$3,307,846	$3,405,578
Work-in-process	686,947	659,304
Finished goods	808,840	887,097
	$4,803,633	$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. In the first quarter of 2005, one customer accounted for 12 percent of total revenues as compared to 16 percent for the same quarter of 2004. The same customer accounted for approximately 7 percent and 8 percent of accounts receivable as of March 31, 2005 and December 31, 2004, respectively.

In the first quarter of 2005 and 2004, another customer accounted for 25 percent of total revenues. This customer accounted for approximately 36 percent and 23 percent of accounts receivable as of March 31, 2005 and December 31, 2004, respectively.

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

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

Earnings (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 (loss) per share is computed in a manner similar to basic earnings (loss) per share except that the weighted average number of shares outstanding is increased to include incremental shares from the assumed vesting or exercise of all dilutive securities, such as common stock options, warrants, and unvested restricted stock. The number of incremental shares is calculated by assuming that outstanding stock options and warrants were exercised and unvested restricted shares were vested, and the proceeds from such exercises or 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 March 31,	
	2005	2004
Net income (loss)	$ 1,561,338	$ (162,214)
Weighted average shares of common stock outstanding:		
Basic	44,644,729	44,270,845
Dilutive effect of stock options, warrants and restricted shares	400,826	—
Diluted	45,045,555	44,270,845
Earnings (loss) per share:		
Basic	$ 0.03	$ (0.00)
Diluted	$ 0.03	$ (0.00)

For the three-month periods ended March 31, 2005 and March 31, 2004, outstanding common stock options, warrants, and unvested restricted stock, representing 3,306,089 and 5,213,765 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 periods ended March 31, 2005 and 2004 would have been impacted as follows:

	Three months ended March 31,	
	2005	2004
Net income (loss):		
As reported	$ 1,561,338	$ (162,214)
Add: stock-based employee compensation expense included in net income (loss):	433,422	63,772
Deduct: total stock-based employee compensation expense determined under the fair value- based method for all awards	(1,301,018)	(1,248,388)
Pro forma	$ 693,742	$(1,346,830)
Basic and diluted earnings (loss) per share:		
As reported	$ 0.03	$ (0.00)
Pro forma	$ 0.02	$ (0.03)

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 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. If the Company had applied the provisions of SFAS No. 123R to the financial statements for the period ending March 31, 2005, net income would have been reduced by $867,596.

3. Accrued Expenses:

	March 31, 2005	December 31, 2004
Deferred revenue	$1,517,114	$1,353,711
Payroll and related benefits	1,415,209	2,069,309
Royalties	1,184,370	1,069,932
Advertising	738,099	603,009
Professional fees	358,762	1,227,087
Laboratory testing fees	306,110	249,041
License fees	300,000	300,000
Other	624,144	680,190
	$6,443,808	$7,552,279

At March 31, 2005, accrued payroll and related benefits decreased primarily as a result of the payment of annual bonuses during the first quarter, partially offset by an increase in commissions. Deferred revenue at March 31, 2005 and December 31, 2004 consisted primarily of customer prepayments, totaling $1,142,414 and $1,041,711, respectively. Professional fees at March 31, 2005 decreased primarily as a result of the payment of legal fees related to current litigation. Accrued royalties and advertising expenses at March 31, 2005 and December 31, 2004 are primarily related to our OraQuick® products. License fees at March 31, 2005 and December 31, 2004 are related to a sublicense agreement to certain HIV-2 patents held by a third party, which we entered into in June 2004.

4. Stockholders' Equity

During the three-month period ended March 31, 2005, we granted 292,188 restricted shares of our common stock to certain key officers and members of management. These shares are nontransferable and are subject to three-year vesting requirements. Upon granting of these restricted shares, deferred compensation expense equivalent to the market value at the date of grant was charged to stockholders' equity and is subsequently being amortized over the three-year period during which the restrictions lapse. In connection with these restricted share grants, we initially recorded $1,635,668 of deferred compensation, which was subsequently reduced by $75,925 due to restricted stock forfeitures, during the three-month period ended March 31, 2005. Amortization of deferred compensation related to these and previous grants was $433,422 and $63,772 during the three months ended March 31, 2005 and 2004, respectively.

In connection with the vesting of restricted shares during the three-month period ended March 31, 2005, we withheld and immediately retired 3,052 shares with an aggregate value of $19,975.

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 (amounts in thousands):

	Three months ended March 31,	
	2005	2004
United States	$14,140	$10,926
Europe	1,313	1,076
Other regions	375	407
	$15,828	$12,409

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 our 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 and UP*link*® oral fluid rapid drug detection system are designed for use at the point-of-care. Our cryosurgical product, which is sold under the names Histofreezer® and Freeze Off™, is 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 quarter of 2005, we continued to increase sales and gain market acceptance for our products. As a result, we reported strong financial results for the first quarter 2005. Our total revenues were $15.8 million, or an increase of 28% over the comparable period in 2004, and our net income was $1.6 million, representing an improvement of more than $1.7 million over the first quarter of 2004. Our liquidity also improved, as we reported $521,000 in cash flow from operations during the first quarter of 2005 and had $66.8 million in cash, cash equivalents and short-term investments as of March 31, 2005.

Sales into the infectious disease testing market during the first quarter of 2005 increased significantly due to the continued market acceptance of our OraQuick® device. This resulted largely from sales directly to various public health organizations, sales to the Centers for Disease Control and Prevention (“CDC”) for further distribution in the public health market, and sales both directly and through Abbott Laboratories into the hospital market.

During the period March 2004 through June 2004, we received FDA approval of our new OraQuick® *ADVANCE*™ test to detect antibodies to both HIV-1 and HIV-2 in oral fluid, finger stick whole blood, venous whole blood, and plasma samples. In June 2004, we also obtained a CLIA waiver for the OraQuick® *ADVANCE*™ HIV-1/2 test for all specimen types except plasma. This new product was officially launched commercially in October 2004. Since that time, the demand for OraQuick® *ADVANCE*™ has grown quickly, and we are working to convert all OraQuick® customers to this new product and expect eventually to cease selling our original OraQuick® HIV-1 test.

In June 2004, we received a nonexclusive, worldwide sublicense to certain HIV-2 patents held by Bio-Rad Laboratories. We believe that the recently approved OraQuick® *ADVANCE*™ test, together with the sublicense from Bio-Rad, will provide a significant competitive advantage by allowing us to sell a versatile rapid HIV test that is capable of detecting antibodies to both the HIV-1 and HIV-2 strains of the virus in oral fluids, finger stick whole blood, venous whole blood, and plasma.

In 2004, the CDC and the Substance Abuse and Mental Health Services Administration (“SAMHSA”) placed purchase orders totaling $6.3 million for OraQuick® devices and related testing materials. Both of these orders were for OraQuick® *ADVANCE*™ only. We expect that federal governmental agencies will make future bulk purchases of OraQuick® *ADVANCE*™ for further distribution to the public health and other markets throughout the United States.

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 will sell 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. In 2004, we deployed a small sales force that provided direct access to and marketing support for the sales of our OraQuick® test into the hospital market. This sales force will now support Abbott and will work together with them to maximize the penetration of OraQuick® *ADVANCE*™ in the hospital market.

The markets for rapid HIV testing are very competitive and the level of competition is expected to increase, which could affect sales of our OraQuick® 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 FDA approval to sell competing rapid HIV-1 blood tests and Bio-Rad recently received FDA approval for a rapid HIV-1/2 blood test. We believe these tests, under their current FDA approvals, will compete with our OraQuick® tests in the hospital or other laboratory settings. In addition, Trinity Biotech has received CLIA waiver 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 quarter 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 March 2004, the FDA responded to our application for 510(k) clearance of the UP*link*® rapid oral fluid drugs of abuse detection system, by indicating that additional performance data would be needed in order to obtain clearance. We are evaluating the FDA's requirements and whether any modifications to our UP*link*® system will be required in order to provide that data. At this time, we cannot predict if or when we will resubmit an application for 510(k) clearance of the UP*link*® system. However, the absence of 510(k) clearance will not affect our ability to sell the UP*link*® system internationally. In April 2004, we launched our UP*link*® system in Germany and other European countries, primarily in the roadside testing market, with our partner, Dräger Safety.

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

Sales to the cryosurgical systems market during the first quarter of 2005 have continued to grow. The cryosurgical systems market represents sales of Histofreezer® into both the domestic and international physicians' office markets and sales of the over-the-counter ("OTC") formulation of this product, called Freeze Off™, to our partner, Medtech Holdings, Inc. ("Medtech"), a wholly-owned subsidiary of Prestige Brands Holdings, Inc. Medtech distributes Freeze Off™ to consumers under its Compound W® trademark in the OTC market in the United States.

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. We currently expect that a final trial on the merits in this matter will occur during 2005.

Sales to the insurance risk assessment market continued to decline in the first quarter of 2005, primarily as a result of lower assay sales to our largest customer in that market, Lab*One*, Inc. The assays have experienced substantial competitive pressure from "home-brew" assays internally developed by this customer. Sales of these products are not expected to recover. We anticipate little growth in the insurance risk assessment market until we are successful in developing new oral fluid based diagnostic tests for additional predictive health markers desired by the insurance industry.

In January 2005, the lease on our Oregon facility expired and all operations at that location have now ceased. The absence of this lease will reduce our operating expenses.

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

Total revenues increased 28% to approximately $15.8 million in the first quarter of 2005 from approximately $12.4 million in the comparable quarter in 2004, primarily as a result of increased sales of our OraQuick®*ADVANCE*™ rapid HIV-1/2 antibody test, our Freeze Off™ and Histofreezer® cryosurgical products, and our Intercept® oral fluid drug test, partially offset by lower sales in the insurance risk assessment market. Product revenues for the first quarter of 2005 also increased 28% to approximately $15.7 million compared to approximately $12.3 million for the first quarter of 2004. International sales accounted for 11% of total revenues in the first 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 March 31,				
	Dollars		Percent Change Inc. (Dec.)	Percentage of Total Revenues	
	2005	2004		2005	2004
Market revenues					
Insurance risk assessment	$ 2,115	$ 2,284	(7)%	13%	18%
Infectious disease testing	5,126	3,338	54	32	27
Substance abuse testing	2,925	2,194	33	19	18
Cryosurgical systems	5,578	4,473	25	35	36
Product revenues	15,744	12,289	28	99	99
Licensing and product development	84	120	(30)	1	1
Total revenues	$15,828	$12,409	28%	100%	100%

Sales to the insurance risk assessment market decreased 7% to approximately $2.1 million in the first quarter of 2005 as a result of lower insurance testing assay sales. Our laboratory customers have stopped or reduced their purchases of these products and instead use lower cost, internally-developed (i.e., “home-brew’) assays or reagents or testing products purchased from our competitors. We currently expect that our 2005 revenues in this market segment will remain at approximately the levels attained in 2004.

Sales to the infectious disease testing market increased 54% to approximately $5.1 million in the first 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 $4.0 million and $2.2 million in the first quarters of 2005 and 2004, respectively. OraSure® sales totaled approximately $1.1 million in the first quarters of 2005 and 2004.

In the first quarters of 2005 and 2004, we recorded approximately $1.6 million and $486,000, respectively, in direct sales of OraQuick® to the U.S. public health market and approximately $837,000 and $721,000, respectively, to the CDC. We also had OraQuick® sales of approximately $682,000 and $751,000 to Abbott, approximately $531,000 and $0 directly to hospital customers, and approximately $343,000 and $222,000 to the international marketplace, in the first quarter of 2005 and 2004, respectively. Sales of OraQuick® *ADVANCE*™ in the United States totaled $2.0 million, or 59% of total U.S. OraQuick® sales in the first quarter of 2005.

We believe that our OraQuick® *ADVANCE*™ device, which is 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*™ by the summer of 2005, and obtain several country-specific registrations thereafter allowing us to launch the product in Europe later this year.

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 timing or extent of such change in purchasing patterns or the financial impact of replacing OraSure® sales with sales of our OraQuick® tests, if it occurs at all.

Sales to the substance abuse testing market increased 33% to approximately $2.9 million in the first quarter 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 testing markets. Sales into the U.S. workplace and criminal justice markets increased approximately 90% and 28% to approximately $1.1 million and $600,000, respectively, in the first quarter of 2005. We expect continued growth in Intercept® sales in 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 approximated $237,000 and $144,000 in the first quarter of 2005 and 2004, respectively. As part of our strategic review of our business conducted in the later part of 2004, we concluded that the roadside drugs of abuse market may not be as attractive as a number of other opportunities. Consequently, we are exploring our options with respect to the UP*link*® product including transitioning the manufacturing of the product to our partner, Dräger Safety, which is permitted under our agreement with Dräger. In exchange, we would expect to receive a royalty on future sales by Dräger while retaining the right to sell UP*link*® in the workplace testing and other markets.

Sales of our products in the cryosurgical systems market (which includes both the physicians' office and OTC markets) increased 25% to approximately $5.6 million in the first quarter of 2005. This increase was primarily the result of $4.0 million in sales of our OTC cryosurgical system, called Freeze Off™, to MedTech, the owner of the Compound W® line of wart removal products, in the first quarter of 2005 versus $3.1 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. Based on additional purchase orders received to date, we expect sales of Freeze Off™ to Medtech to approximate $3.25 million in the second quarter of 2005. We have concluded a review of the market potential for an over-the-counter cryosurgical product in the European Union and have entered into negotiations with a distribution partner. We expect to announce a distributor in the near future and intend to launch an OTC product in selected European countries later in 2005.

Sales of our Histofreezer® product to physicians' offices in the U.S. market remained flat at approximately $1.0 million in the first quarter of 2005, when compared to the same period in 2004. We anticipate that U.S. sales of Histofreezer® in the professional market will increase during 2005. Sales of Histofreezer® in the international market increased by 43% to approximately $554,000 and are expected to continue to increase above 2004 levels as we secure additional distributors in countries where the product is currently not sold.

Although it is not our experience to date in the U.S. professional marketplace, it is possible that sales of the Freeze Off™ product in the U.S. OTC market may reduce the number of individuals that will seek to obtain treatment of their warts by a physician, which in turn could negatively affect sales of our Histofreezer® product in the professional market. However, it is not possible at this time to estimate the timing or financial impact of such a change, if it occurs at all.

Medtech, our largest customer, accounted for approximately 25% of total revenues for the first quarter of 2005 and 2004. Lab*One* accounted for approximately 12% and 16% of total revenues for the first quarter of 2005 and 2004, respectively.

Licensing and product development revenues decreased by 30% to $84,000 during the first quarter of 2005, from $120,000 in the comparable period in 2004. Licensing and product development revenues are primarily related to our collaborative UP*link*™ and oral fluid research project with The University of Pennsylvania, under a grant awarded by the National Institutes of Health. The current annual phase of this grant expires in June 2005. Further revenues under this grant beyond June 2005 will depend on progress achieved in the research and future funding awarded by the National Institutes of Health.

Gross margin in the first quarter of 2005 was approximately 60%, compared to 58% for the first quarter of 2004. Gross margin was positively affected by a reduction in the production cost for our Freeze Off™ product and more efficient utilization of the Company's manufacturing capacity, partially offset by a less favorable sales mix.

Research and development expenses decreased 32% to approximately $1.2 million in the first quarter of 2005 from approximately $1.8 million in the same period in 2004, primarily as a result of lower overall staffing costs and lower costs associated with transferring our manufacturing operations from Oregon to Bethlehem, Pennsylvania. Research and development costs are expected to increase for the full year during 2005, as compared to 2004, primarily as a result of costs associated with the development of new product offerings and product enhancements for the infectious disease and substance abuse testing markets.

Sales and marketing expenses increased 6% to approximately $3.9 million in the first quarter of 2005 from approximately $3.7 million in the same period in 2004. This increase was primarily the result of higher staffing, increased commission, compensation, and travel expenses due to the deployment of the hospital sales force, and increased consulting fees, partially offset by the elimination of recruiting fees that were incurred during the first quarter of 2004 for the hospital sales team. Included in advertising expenses for the first quarter of 2005 and 2004 were $569,000 and $551,000, respectively, payable to Medtech as reimbursement 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 49% to approximately $3.2 million in the first quarter of 2005 from approximately $2.1 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 rent expense due to the transfer of manufacturing operations to Bethlehem and the expiration of the lease for our Oregon facilities in January 2005. General and administrative expenses are expected to increase further in 2005 versus 2004 as a result of legal fees associated with the Schering-Plough litigation.

Interest expense decreased to $27,000 in the first quarter of 2005 from $31,000 in the same period in 2004, primarily as a result of lower outstanding debt balances. Interest income increased to $372,000 in the first quarter of 2005 from $206,000 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 quarter of 2005, there was no provision for income taxes primarily due to the utilization of previously unbenefitted net operating loss carryforwards. The utilization of such tax attributes 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 quarter of 2005. During the first quarter of 2004, a provision for foreign income taxes of approximately $5,000 was recorded.

Liquidity and Capital Resources

	March 31, 2005	December 31, 2004
	(In thousands)	
Cash and cash equivalents	$ 14,482	$ 10,121
Short-term investments	52,322	56,602
Working capital	71,239	68,910

Our cash, cash equivalents, and short-term investments increased approximately $81,000 during the first quarter of 2005 to approximately $66.8 million at March 31, 2005, primarily as a result of the Company's $521,000 in positive cash flow from operations and approximately $39,000 in proceeds from the exercise of stock options during the quarter, partially offset by the purchase of approximately $152,000 of equipment, approximately $280,000 of debt repayments, and approximately $20,000 in withholding and retirement of common stock. At March 31, 2005, the Company's working capital was approximately $71.2 million.

Net cash provided by operating activities was approximately $521,000 in the first quarter of 2005. The $521,000 of cash provided by operating activities resulted from net income of approximately $1.6 million, depreciation and amortization of approximately $631,000 and non-cash charges of approximately $723,000 related to stock-based compensation expense and provisions for excess and obsolete inventories and a decrease of $23,000 in prepaid expenses and other current assets, offset by inventory increases of $141,000, an increase of approximately $1.7 million in accounts receivable and a reduction of accounts payable and accruals of $608,000. Accounts receivable are expected to grow as our sales increase and the proportion of sales increase to parties such as the CDC and Medtech, which have 60-day payment terms.

Net cash provided by investing activities during the first quarter of 2005 was approximately $4.1 million. We purchased approximately $152,000 of property and equipment and sold a net amount of $4.3 million of short-term investments.

Capital expenditures are anticipated to increase during 2005 to approximately $3.2 million 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 used in financing activities was approximately $261,000, reflecting the proceeds of $39,000 received from the issuance of common stock, offset by approximately $280,000 of loan principal repayments and approximately $20,000 in withholding 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 (5.75% at March 31, 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 March 31, 2005 was $753,750.

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 March 31, 2005 was $857,143.

Under the New Non-Revolving Line, we could borrow up to $4.0 million to finance eligible equipment and software purchases through December 31, 2004. We had no outstanding borrowings under this facility, which expired at December 31, 2004 and was not renewed.

As of March 31, 2005, we had an outstanding balance of $290,834 under the Original Non-Revolving Line consisting of four individual loans of (i) $71,914 with a fixed annual interest rate of 5.07%, (ii) $106,694 with a floating annual interest rate equal to Comerica's prime rate (5.75% at March 31, 2005), (iii) $57,885 with a floating annual interest rate equal to Comerica's prime rate (5.75% at March 31, 2005), and (iv) $54,341 with a floating annual interest rate equal to Comerica's prime rate (5.75% at March 31, 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 March 31, 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 March 31, 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 March 31, 2005, we also have a $274,761 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%, 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 and capital needs for at least the next twelve months. However, our cash requirements may vary materially from those now planned due to many factors, including, but not limited to, the scope and timing of strategic acquisitions, the cost and timing of the expansion of our manufacturing capacity, the progress of our research and development programs, the scope and results of clinical testing, the magnitude of capital expenditures, changes in existing and potential relationships with business partners, the time and cost of obtaining regulatory approvals, the costs involved in obtaining and enforcing patents, proprietary rights and any necessary licenses, the cost and timing of expansion of sales and marketing activities, the timing of market launch of new products, market acceptance of new products, competing technological and market developments, the potential exercise of our options to purchase one, or both, of our leased facilities in Bethlehem, Pennsylvania, and other factors.

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 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. If the Company had applied the provisions of SFAS No. 123R to the financial statements for the period ending March 31, 2005, net income would have been reduced by approximately $900,000.

Summary of Contractual Obligations

A summary of our obligations to make future payments under contracts existing at December 31, 2004 is included in Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations, of our Annual Report on Form 10-K for the year ended December 31, 2004. As of March 31, 2005, there were no significant changes to this information.

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 $327,889 at March 31, 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 March 31, 2005, approximately $3.8 million, or 43% of our accounts receivable, were due from two major customers. Any significant changes in the liquidity or financial position of these customers, or others, could have a material adverse impact on the collectibility of our accounts receivable and future operating results.

Inventories. Our inventories are valued at the lower of cost or market, determined on a first-in, first-out basis, and include the cost of raw materials, labor, and overhead. The majority of our inventories are subject to expiration dating. We continually evaluate the carrying value of our inventories and when, in the opinion of management, factors indicate that impairment has occurred, either the inventories' carrying value is reduced or the inventories are completely written off. We base these decisions on the level of inventories on hand in relation to our estimated forecast of product demand, production requirements over the next twelve months and the expiration dates of raw materials and finished goods. During 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. 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 $7.5 million or 8% of our total assets at March 31, 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. An impairment of long-lived or intangible assets could occur whenever events or changes in circumstances indicate that the net book value of these assets may not be recoverable. Events which could trigger an asset impairment include significant underperformance relative to expected historical or projected future operating results, significant changes in the manner of our use of an asset or in our strategy for our overall business, significant negative industry or economic trends, shortening of product life-cycles or changes in technology, and negative financial performance of our nonaffiliated investee company. If we believe impairment of an asset has occurred, we measure the amount of such impairment by comparing the net book value of the affected assets to the fair value of these assets, which is generally determined based upon the present value of the expected cash flows associated with the use of these assets. If the net book value exceeds the fair value of the impaired assets, we would incur an impairment expense equal to this difference. We currently believe the future cash flows to be received from our long-lived and intangible assets will exceed their book value and, as such, we have not recognized any impairment losses through March 31, 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 net operating loss ("NOL") carryforwards of approximately $74.9 million. The deferred tax asset associated with these NOLs and other temporary differences is 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.

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

We do not currently have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. We have operations in The Netherlands which are subject to foreign currency fluctuations. As currency rates change, translation of the statement of operations for this operation from euros to U.S. dollars affects year-to-year comparability of operating results. Sales denominated in a foreign currency represented approximately $554,000 or 3% of our total revenues for the three months ended March 31, 2005. 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 March 31, 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 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 6. EXHIBITS

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

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned thereunto duly authorized.

ORASURE TECHNOLOGIES, INC.

/s/ Ronald H. Spair

Date: May 5, 2005

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

/s/ Mark L. Kuna

Date: May 5, 2005

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

EXHIBIT INDEX

Exhibit	
10.1	Fourth Amendment to Commercial Lease, dated as of March 4, 2005, between OraSure Technologies, Inc. and Northampton County New Jobs Corp., is incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K filed March 11, 2005.
10.2	Amendment No. 3 to Production Agreement, dated as of March 9, 2005, between OraSure Technologies, Inc. and Koninklijke Utermöhlen N.V.*
10.3	Third Amendment to Loan and Security Agreement, dated as of April 21, 2005, between OraSure Technologies, Inc. and Comerica Bank, is incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K filed April 27, 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.

* Portions of this exhibit were omitted pursuant to an application for confidential treatment and filed separately with the Securities and Exchange Commission.

EXHIBIT 10.2

Portions of this exhibit were omitted and filed separately with the Secretary of the Commission pursuant to an application for confidential treatment filed with the Commission pursuant to Rule 406 under the Securities Act of 1933. Such omissions are designated as **.

Execution Copy

AMENDMENT NO. 3 TO PRODUCTION AGREEMENT

This Amendment No. 3 to Production Agreement (this "Amendment") is made and entered into this 9th day of March, 2005 by and between OraSure Technologies, Inc., a Delaware corporation, with its registered offices at Bethlehem, Pennsylvania 18015 U.S.A. (the "Purchaser"), and Koninklijke Utermöhlen N.V., a limited liability company organized under the laws of The Netherlands, with its registered offices at Wolvega, the Netherlands (the "Seller"). Seller and Purchaser are each referred to herein as a "Party" and collectively as the "Parties."

BACKGROUND

Seller and Purchaser are parties to a Production Agreement, dated June 8, 1998, as amended by Amendment No. 1 to Production Agreement ("Amendment No. 1"), dated as of December 11, 2001, and Amendment No. 2 to Production Agreement, dated as of April 28, 2003 (collectively, the "Original Agreement"), pursuant to which Seller agreed to produce certain products related to the Histofreezer Business for the Purchaser. The Parties desire to amend further the Original Agreement as set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing, and of the mutual promises and covenants contained in this Amendment, Seller and Purchaser, intending to be legally bound, hereby agree as follows:

1. Definitions. Capitalized terms not otherwise defined in this Amendment shall have the meanings set forth in the Original Agreement.

2. Professional Products. The Products, other than the OTC Product, that are supplied hereunder are listed in Exhibit 1 to this Amendment and are to be marketed, sold and distributed by Purchaser to physicians and other medical professionals (the "Professional Products").

3. Duration and Termination. The first sentence of Section 13.1 of the Original Agreement is hereby amended and restated in its entirety, as follows:

"This Agreement shall be in force on June 1, 1998 and shall terminate (i) with respect to the Professional Products, on December 31, 2008 and (ii) with respect to the OTC Product, on December 31, 2006."

4. Minimum Purchases.

4.1 Professional Products. During the period January 1, 2005 through December 31, 2008, Purchaser shall purchase an aggregate of at least **** units of the Professional Products. For purposes of this Section 4.1, a unit of a Professional Product shall consist of one canister of any size containing the applicable number of applicators, in each case as indicated in Exhibit 1 attached to this Amendment, which is manufactured, assembled and packaged in accordance with the Specifications and the Original Agreement. Notwithstanding the foregoing, to the extent Purchaser purchases the H-105 unit of Product (with 5 applicators), the purchase of such units shall not count towards the foregoing minimum aggregate purchase commitment.

4.2 OTC Product. During the period January 1, 2005 through December 31, 2006, Purchaser shall purchase an aggregate of at least **** units of the OTC Product. For purposes of this Section 4.2 and Section 5, the number of units shall be determined by the number of canisters purchased and a unit of the OTC Product shall be defined as a 110 ml. canister filled with 80 ml. of refrigerant and a 12-count set of 5 mm. foam tip applicators (which number may vary from time to time based on customer needs), manufactured, assembled and packaged in accordance with the OTC Product Specifications and the Original Agreement for distribution by Purchaser in the United States and Canada.

4.3 Adjustments to Minimums. The parties acknowledge that factors beyond the Purchaser's control may affect its ability to sell and distribute the Professional Products and the OTC Product. Accordingly, in the event that either (i) Purchaser loses, or otherwise suffers an adverse result in, the patent infringement litigation against Schering-Plough Healthcare Corporation pending as of the date of this Amendment in the United States, or (ii) there is a change in the professional market in the United States or internationally or in the over-the-counter market in the United States, and in the case of both (i) and (ii) such event adversely affects Purchaser's ability to market, sell or distribute the Professional Products or OTC Product into the markets for such Products, then the Parties shall negotiate in good faith appropriate reductions to the purchase minimums set forth in Sections 4.1 and 4.2.

5. Purchase Price – OTC Product. Effective for all purchases on or after January 1, 2005, the price of the OTC Product shall be € **** per unit. The Seller shall retroactively adjust the price for any purchases of OTC Product occurring after January 1, 2005 and prior to the execution of this Amendment, and shall provide Purchaser with a credit or refund for the excess of the price paid for such purchases over € **** per unit.

6. Purchase Price Adjustments – Professional Products. The current prices for the Professional Products are set forth in Exhibit 2 attached to this Amendment (the "Base Professional Prices"). The Parties agree that such prices shall be adjusted to reflect the Euro/U.S. Dollar (€/U.S. $) exchange rate fluctuations as provided in this Section 6. For purposes of such adjustments, the Parties have agreed upon a pegged exchange rate of € **/U.S. $ (the "Agreed Upon Rate"). At the end of each six-month period ending June 30 and December 31, with the first such period ending June 30, 2005, the current Euro/U.S. Dollar exchange rate shall be determined by calculating the average of the Euro/U.S. Dollar exchange rates, as published in the Wall Street Journal, for the last business day of each month during such six-month period (the "Current Rate"). To the extent the Current Rate for any six-month period is higher than the Agreed Upon Rate (such difference is referred to herein as the "Differential"), the Base Professional Prices shall be increased to reflect ** percent (**%) of the Differential pursuant to the following formula (the "Adjusted Price"), and such increased prices shall be in effect for the next succeeding six (6) month period:

(Differential x **% x Base Professional Price) + Base Professional Price = Adjusted Price

In the event that the Current Rate for any six (6) month period is less than or equal to the Agreed Upon Rate, there shall be no adjustment under this Section 6 and the Base Professional Prices shall remain in effect. The Parties shall determine whether an Adjusted Price should apply, using the Base Professional Prices as set forth in Exhibit 2 hereto, pursuant to the procedures set forth above at the end of each six (6) month period.

Example No. 1. For example, **

Example No. 2. **

Notwithstanding the foregoing, if either of the events described in Section 4.3 (i) or (ii) shall occur and such event adversely affects Purchaser's ability to market, sell or distribute the Professional Products, then the Parties shall meet to discuss whether the price adjustment procedures in this Section 4 are reasonable and to negotiate appropriate amendments to such procedures or the elimination of such procedures.

7. No Other Changes. Except as set forth in this Amendment, the Original Agreement remains in full force and effect without any other changes. The Original Agreement, together with this Amendment, constitute the entire agreement between the Seller and the Purchaser with respect to the subject matter hereof and thereof and supersede and cancel all previous negotiations, agreements, and commitments, whether oral or in writing, with respect to such subject matter. All references to the Original Agreement shall be deemed to mean the Original Agreement as amended by this Amendment.

8. Counterparts. This Amendment may be executed in two or more counterparts, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument. A facsimile transmission of a signed original shall be deemed to be the same as delivery of a signed original.

9. Governing Law. This Amendment and any controversy, claim or dispute arising under this Amendment shall be governed by, and construed in accordance with, the laws of the Netherlands.

IN WITNESS WHEREOF, the undersigned duly authorized officers of the Seller and the Purchaser have executed this Amendment as of the date first above written.

ORASURE TECHNOLOGIES, INC.

By: */s/ P. Michael Formica*

Name: P. Michael Formica
Title: Executive VP, Operations

KONINKLIJKE UTERMÖHLEN N.V.

By: */s/ D.T. Van der Vat*

Name: D.T. Van der Vat
Title: President

EXHIBIT 1

The Professional Products

Art.nr.	Description
123070	Histofreezer Dutch/French 5mm (40 applicators)
123082	Histofreezer English 5mm (40 applicators)
123086	Histofreezer English 2mm (50 applicators)
9381406	Histofreezer Askina French 5mm (50 applicators)
9381457	Histofreezer Askina French 2mm (60 applicators)
9381309	Histofreezer Askina Spanish 5mm (50 applicators)
9381350	Histofreezer Askina Spanish 2mm (60 applicators)
9381201	Histofreezer Askina German 5mm (50 applicators)
8381252	Histofreezer Askina German 2mm (60 applicators)
H-170	Histofreezer Paladin Mix (60 applicators)
H-60	Histofreezer OraSure USA Mix (60 applicators)
H-140	Histofreezer Mexico Mix (60 applicators)
H-150	Histofreezer English Mix (50 applicators)
H-505	Histofreezer OraSure USA 5mm (50 applicators)
H-105	Histofreezer Sample Mix (5 applicators)
H-30	Histofreezer OraSure USA Mix (30 applicators)

Exhibit 2

Prices – Professional Products

The Prices

Table A

Product	Price per Unit
Unit with aerosol can and 30 applicators	€ **
Unit with aerosol can and 40 applicators	€ **
Unit with aerosol can and 50 applicators	€ **
Unit with aerosol can and 60 applicators	€ **

Other Professional Products that are part of this Agreement are defined and priced as follows:

Table B

Product	Price per Unit
Sample packaging with aerosol can and 5 applicators (3 Medium/5mm and 2 Small/2mm)	€ **

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: May 5, 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: May 5, 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 March 31, 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

May 5, 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 March 31, 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

May 5, 2005