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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2003.

OR

o **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 x No o

Indicate by check mark whether the Registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).Yes x No o

Number of shares of Common Stock, par value $.000001 per share, outstanding as of May 7, 2003: 38,405,924

Item 1. FINANCIAL STATEMENTS

ORASURE TECHNOLOGIES, INC.
BALANCE SHEETS
(Unaudited)

	March 31, 2003	December 31, 2002
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 2,732,080	$ 4,364,308
Short-term investments	12,531,587	10,543,876
Accounts receivable, net of allowance for doubtful accounts of $292,831 and $292,146	5,498,599	5,197,787
Inventories	4,049,098	4,088,474
Prepaid expenses and other	915,526	925,707
Total current assets	25,726,890	25,120,152
PROPERTY AND EQUIPMENT, net	7,321,147	7,427,950
PATENTS AND PRODUCT RIGHTS, net	2,379,100	2,543,519
OTHER ASSETS	636,518	645,626
	$ 36,063,655	$ 35,737,247
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	$ 1,098,388	$ 1,065,966
Accounts payable	2,068,168	1,801,952
Accrued expenses	3,538,621	3,321,509
Total current liabilities	6,705,177	6,189,427
LONG-TERM DEBT	3,215,078	3,409,362
OTHER LIABILITIES	186,411	119,546
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, 38,363,618 and 38,100,557 shares issued and outstanding	38	38
Additional paid-in capital	156,673,278	155,638,314
Accumulated other comprehensive loss	(188,703)	(184,676)
Accumulated deficit	(130,527,624)	(129,434,764)
Total stockholders' equity	25,956,989	26,018,912
	$ 36,063,655	$ 35,737,247

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.
STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31,	
	2003	2002
REVENUES:		
Product	$ 8,342,964	$ 7,468,621
Licensing and product development	267,672	256,853
	8,610,636	7,725,474
COST OF PRODUCTS SOLD	3,580,116	2,894,230
Gross profit	5,030,520	4,831,244
OPERATING EXPENSES:		
Research and development	2,054,711	2,420,263
Sales and marketing	2,235,137	1,988,181
General and administrative	1,865,621	2,084,301
	6,155,469	6,492,745
Operating loss	(1,124,949)	(1,661,501)
INTEREST EXPENSE	(48,605)	(84,249)
INTEREST INCOME	85,573	153,235
FOREIGN CURRENCY LOSS	—	(182)
Loss before income taxes	(1,087,981)	(1,592,697)
INCOME TAXES	4,879	—
NET LOSS	$ (1,092,860)	$ (1,592,697)
BASIC AND DILUTED NET LOSS PER SHARE	$ (0.03)	$ (0.04)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	38,248,521	37,434,075

The accompanying notes are an integral part of these statements.

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

	Three Months Ended March 31,	
	2003	2002
OPERATING ACTIVITIES:		
Net loss	$ (1,092,860)	$ (1,592,697)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Stock-based compensation expense	33,900	—
Amortization of deferred revenue	—	(53,750)
Depreciation and amortization	626,847	542,626
Loss on disposition of assets	—	2,137
Provision for excess and obsolete inventories	111,284	104,817
Changes in assets and liabilities:		
Accounts receivable	(300,812)	318,983
Inventories	(71,908)	(543,986)
Prepaid expenses and other assets	10,181	25,151
Accounts payable and accrued expenses	855,274	(877,415)
Net cash provided by (used in) operating activities	171,906	(2,074,134)
INVESTING ACTIVITIES:		
Purchases of short-term investments	(6,790,725)	(1,989,774)
Proceeds from the sale of short-term investments	4,803,559	3,269,044
Purchases of property and equipment	(411,798)	(396,773)
Proceeds from the sale of property and equipment	—	2,393
Purchases of patents and product rights	(250,000)	—
Increase in other assets	(1,287)	(8,949)
Net cash provided by (used in) investing activities	(2,650,251)	875,941
FINANCING ACTIVITIES:		
Borrowings of term debt	108,683	—
Repayments of term debt	(270,545)	(296,199)
Proceeds from issuance of common stock	1,001,064	108,372
Net cash provided by (used in) financing activities	839,202	(187,827)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	6,915	(12,024)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(1,632,228)	(1,398,044)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	4,364,308	2,426,346
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 2,732,080	$ 1,028,302

The accompanying notes are an integral part of these statements.

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 certain foreign countries to various distributors, government agencies, clinical laboratories, physicians' offices, hospitals, and commercial and industrial entities.

2. Summary of Significant Accounting Policies

Basis of Presentation. The accompanying financial statements are unaudited and, in the opinion of management, include all adjustments (consisting only of normal and recurring adjustments) necessary for a fair presentation of the results for these interim periods. These financial statements should be read in conjunction with the financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2002. Results of operations for the three-month period ended March 31, 2003 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 certain 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.

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, 2002	December 31, 2003
Raw materials	$ 2,915,059	$ 2,787,967
Work-in-process	528,366	430,977
Finished goods	605,673	869,530
	$ 4,049,098	$ 4,088,474

Revenue Recognition. We recognize product revenues when products are shipped. 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.

We follow U.S. Securities and Exchange Commission Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" ("SAB 101"). The bulletin draws on existing accounting rules and provides specific guidance on revenue recognition of up-front non-refundable licensing and development fees. In accordance with SAB 101, 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.

In accordance with Emerging Issues Task Force ("EITF") Issue No. 00-10, "Accounting for Shipping and Handling Fees and Costs," 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 2003, one customer accounted for 20 percent of total revenues as compared to 23 percent for the same quarter of 2002. The same customer accounted for approximately 21 percent and 19 percent of accounts receivable as of March 31, 2003 and December 31, 2002, respectively.

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

Foreign Currency Translation. Pursuant to Statement of Financial Accounting Standards ("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 separate component of stockholders' equity.

Net Loss Per Common Share. We have presented basic and diluted net loss per common share pursuant to SFAS No. 128, "Earnings per Share" ("SFAS No. 128"). In accordance with SFAS No. 128, basic and diluted net loss per common share has been computed using the weighted-average number of shares of common stock outstanding during the period. Diluted loss per common share is generally computed assuming the conversion or exercise of all dilutive securities such as common stock options and warrants; however, outstanding common stock options and warrants to purchase 4,691,969 and 4,815,984 shares were excluded from the computation of diluted net loss per common share for the three-month periods ended March 31, 2003 and 2002, respectively, because they were anti-dilutive due to our losses.

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" ("SFAS No. 123") and EITF 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 options granted to employees and directors is computed based on the fair value of the stock option at the date of grant using an option valuation methodology, typically the Black-Scholes option pricing model. Pursuant to the disclosure requirements of SFAS No. 123, had compensation expense for our common stock option plan been determined based upon the fair value of the options at the date of grant, our net loss for three-month periods ended March 31, 2003 and 2002 would have increased as follows:

	Three months ended March 31,	
	2003	2002
Net loss:		
As reported	$ (1,092,860)	$ (1,592,697)
Add: stock-based employee compensation expense included in net loss	33,900	—
Deduct: total stock-based employee compensation expense determined under the fair value-based method for all awards	(1,119,921)	(777,712)
Pro forma	$ (2,178,881)	$ (2,370,409)
Basic and diluted net loss per share:		
As reported	$ (0.03)	$ (0.04)
Pro forma	$ (0.06)	$ (0.06)

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 retained earnings and additional paid-in capital in the equity section of our balance sheet.

3. Geographic Area Information

Under the disclosure requirements of SFAS No. 131, "Segment Disclosures and Related Information," we operate within one segment, medical devices and products. 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,	
	2002	2003
United States	$ 7,520	$ 6,796
Europe	624	665
Other regions	467	264
	$ 8,611	$ 7,725

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

Statements below regarding future events or performance are "forward-looking statements" within the meaning of the Federal securities laws. These include statements about expected revenues, earnings, expenses, cash flow or other financial performance, products, markets, and regulatory filings and approvals. Forward-looking statements are not guarantees of future performance or results. Factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include: ability to market products; impact of competitors, competing products and technology changes; ability to develop, commercialize and market new products; market acceptance of oral fluid testing products and up-converting phosphor technology products; ability to fund research and development and other projects and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical product components; availability of related products produced by third parties; ability to obtain and timing of obtaining necessary regulatory approvals; ability to comply with applicable regulatory requirements; history of losses and ability to achieve sustained profitability; volatility of our stock price; uncertainty relating to patent protection and potential patent infringement claims; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; loss or impairment of sources of capital; ability to meet financial covenants in agreements with financial institutions; ability to retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; changes in relationships with strategic partners and reliance on strategic partners for the performance of critical activities under collaborative arrangements; changes in accounting practices or interpretation of accounting requirements; customer inventory practices and consolidations; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks, war and civil unrest; ability to complete consolidation or restructuring activities; ability to identify, complete and realize the full benefits of potential acquisitions; and general business, political and economic conditions. These and other factors that could cause the forward-looking statements to be materially different are described in greater detail in our filings with the Securities and Exchange Commission, including our registration statements and our Annual Report on Form 10-K for the year ended December 31, 2002. Although forward-looking statements help to provide information about future prospects, they may not be reliable. The forward-looking statements are made as of the date of this Report and we undertake no duty to update these statements.

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

Results of Operations

Total revenues increased 11% to approximately $8.6 million in the first quarter of 2003 from approximately $7.7 million in the comparable quarter in 2002, primarily as a result of increased sales of our new OraQuick® rapid HIV-1 antibody test, partially offset by substantially lower sales of our Histofreezer® wart removal system. Product revenues for the first quarter of 2003 increased 12% to approximately $8.3 million compared to $7.5 million for the first quarter of 2002.

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			Percentage of Total Revenues	
	2003	2002	Percent Change Inc. (Dec.)	2003	2002
Market revenues					
Insurance risk assessment	$ 3,000	$ 2,792	7%	35%	36%
Infectious disease testing	2,768	1,510	83	32	20
Substance abuse testing	1,598	1,187	35	19	15
Physicians' office therapies	977	1,979	(51)	11	26
	8,343	7,468	12	97	97
Licensing and product development	268	257	4	3	3
Total revenues	$ 8,611	$ 7,725	11%	100%	100%

Sales to the insurance risk assessment market increased by 7% to approximately $3.0 million in the first quarter of 2003 as a result of increased OraSure® oral fluid collection device sales, partially offset by lower urine assay and reagent sales. We expect that sales of our insurance assays and reagents will continue to come under competitive pressure. Our laboratory customers have reduced and are expected to continue to reduce their purchases of these products and instead use lower cost, internally-developed assays or reagents or testing products purchased from our competitors. Although we will make every effort to retain this business, our revenues are expected to be negatively impacted by as much as $1.5 million in 2003 and $2.0 million in 2004, when compared to 2002 revenues in the insurance risk assessment market.

Sales to the infectious disease testing market increased 83% to approximately $2.8 million in the first quarter of 2003, primarily as a result of the launch of our OraQuick® rapid HIV-1 antibody test. The OraQuick® test received U.S. Food and Drug Administration ("FDA") approval in November 2002 for detecting HIV-1 antibodies in finger-stick whole blood samples and a CLIA (Clinical Laboratory Improvement Amendments of 1988) waiver in January 2003. OraQuick® sales totaled $1.4 million in the first quarter of 2003.

Approximately 70% of the OraQuick® devices shipped in the first quarter were shipped to Abbott Laboratories, Inc., our co-exclusive distribution partner in the U.S. marketplace. Of the devices shipped to Abbott in the first quarter, over 80% were shipped in March and most of these devices were held in Abbott's inventory at the beginning of the second quarter. This inventory buildup will likely result in Abbott purchasing fewer OraQuick® devices in the second quarter of 2003 than it purchased in the first quarter of 2003. Additionally, we are completing necessary trials to support additional FDA-approved claims for OraQuick® that would allow the test to be used with oral fluid, venous whole blood and plasma samples, in addition to its approved usage with finger-stick whole blood. We believe the venous whole blood and plasma claims will be needed by Abbott in order to fully penetrate the hospital market in the U.S. Until such additional claims are secured, we will likely not see optimal sales penetration for OraQuick® in the hospital market.

Sales to the substance abuse testing market increased 35% to approximately $1.6 million, primarily as a result of increased sales of our Intercept® oral fluid drug testing service. During the first quarter of 2003, Quest Laboratories, one of our newest Intercept® distributors, closed 84 new accounts for this product. Although most of these new accounts are expected to purchase small annual volumes of Intercept® devices and assays, we believe this is an indication of increased product acceptance that should help Intercept® sales grow in 2003.

Sales of our Histofreezer® wart removal system in the physicians' office therapies market declined 51% to approximately $1.0 million in the first quarter of 2003. This decline was primarily the result of our U.S. distributors increasing their inventory levels in the fourth quarter of 2002 in advance of an announced price increase effective December 2002. Additionally, our U.S. distributors increased their inventory levels in the first quarter of 2002 in advance of an announced price increase effective April 2002, further contributing to the revenue variance between

the first quarters of 2003 and 2002. We anticipate that U.S. sales of Histofreezer® in the professional market will increase in the second quarter of 2003 and return to levels previously experienced.

In March 2003, we secured FDA 510(k) clearance for the sale of Histofreezer® in the over-the-counter ("OTC") market in the U.S. Following this clearance, we entered into an agreement with Medtech Holdings, Inc., the owner of the Compound W® line of wart removal products, to distribute this product in the OTC market. The product will be called Freeze Off™ and will be sold under Medtech's Compound W® tradename. We expect to record revenues totaling in excess of $2.0 million over the second and third quarters of 2003 for this product, as Medtech fulfills its minimum contractual purchase obligations for 2003. The five-year distribution agreement provides for comparable annual minimum purchases by Medtech over the life of the contract.

Licensing and product development revenues increased by 4% to $268,000 during the first quarter of 2003, compared to 2002. Licensing and product development revenues for the quarter were primarily related to our collaborative UP*link*™ and oral fluid research project with The University of Pennsylvania, under a grant recently awarded by the National Institutes of Health.

Our gross margin decreased to approximately 58% in the first quarter of 2003 from 63% in the first quarter of 2002. This decrease was primarily attributable to the $1.0 million decrease in higher-margin Histofreezer® sales in the U.S. and additional start-up costs associated with the initial production of our OraQuick® test. The decrease in Histofreezer® sales accounted for four percentage points of the gross margin reduction.

Research and development expenses decreased 15% to approximately $2.1 million in the first quarter of 2003 from approximately $2.4 million in 2002, primarily as a result of lower staffing and related charges together with lower clinical testing costs, partially offset by higher consulting fees related to the transfer of manufacturing operations to our Bethlehem, Pennsylvania facilities.

Sales and marketing expenses increased 12% to approximately $2.2 million in the first quarter of 2003 from approximately $2.0 million in 2002. This increase was primarily the result of increased expenses related to the launch of OraQuick® in the U.S. We expect sales and marketing expenses to increase in 2003 as we attempt to increase market awareness for our OraQuick® and Intercept® products. In addition, pursuant to our agreement with Medtech, we will co-invest in Medtech's marketing activities for the Freeze Off™ product. As a result, 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 the Freeze Off™ product in the OTC market.

General and administrative expenses decreased 10% to approximately $1.9 million in the first quarter of 2003 from approximately $2.1 million in 2002. This decrease was primarily attributable to the absence of an approximate $480,000 severance charge related to the departure of our former Chief Executive Officer recorded in the first quarter of 2002, partially offset by higher facility-related expenses incurred in 2003 associated with our new corporate headquarters in Bethlehem, Pennsylvania.

Interest expense decreased to $49,000 in the first quarter of 2003 from $84,000 in 2002 as a result of lower effective interest rates. Interest income decreased to $86,000 in the first quarter of 2003 from $153,000 in 2002, as a result of lower interest rates on investments.

During the first quarter of 2003, a provision for foreign income taxes of $5,000 was recorded.

Liquidity and Capital Resources

	March 31, 2003	December 31, 2002
	(In thousands)	
Cash and cash equivalents	$ 2,732	$ 4,364
Short-term investments	12,532	10,544
Working capital	19,022	18,931

Our cash, cash equivalent and short-term investment position increased approximately $350,000 during the first quarter of 2003 to approximately $15.3 million at March 31, 2003, primarily as a result of the receipt of approximately $1.0 million in stock option exercise proceeds, partially offset by capital equipment expenditures, a $250,000 payment under our distribution agreement with bioMerieux, Inc., debt reduction payments and the net loss for the quarter. At March 31, 2003, our working capital was approximately $19.0 million.

Net cash provided by operating activities was approximately $172,000 for the first quarter of 2003, primarily as a result of the net loss of approximately $1.1 million for the quarter and an increase in accounts receivable of approximately $300,000, offset by non-cash items of approximately $145,000 related to inventory reserves and stock-based compensation, depreciation and amortization of approximately $0.6 million and increases of approximately $0.8 million in accounts payable and accruals.

Net cash used in investing activities during the first quarter of 2003 was approximately $2.7 million, primarily as a result of an approximate $2.0 million increase in short-term investments, the purchase of approximately $400,000 of capital equipment and the payment of $250,000 pursuant to our distribution agreement with bioMerieux.

Net cash provided by financing activities was approximately $0.8 million during the first quarter of 2003 as a result of approximately $1.0 million in proceeds from the exercise of stock options, partially offset by approximately $200,000 of net term debt repayments.

In September 2002, we entered into a new $10.9 million credit facility (“New Credit Facility”) with Comerica Bank, pursuant to which we refinanced substantially all of our previously outstanding mortgage and term debt and increased our equipment and working capital lines of credit. The New Credit Facility is 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.

The $887,000 mortgage loan matures in September 2012, bears interest at an annual floating rate equal to Comerica’s prime rate, 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, 2003 was $861,154.

The $3.0 million term loan matures in March 2006, bears interest at a fixed rate of 4.99% 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, 2003 was $2,571,429.

Under the non-revolving equipment line of credit, we can borrow up to $3.0 million to finance eligible equipment purchases through September 9, 2003. Interest on outstanding borrowings accrues at a rate, selected at our option, equal to Comerica’s prime rate, 180-day or 360-day LIBOR plus 2.625%, or the 4-year Treasury Note Rate plus 2.30%, determined at the time of each borrowing. Borrowings are repayable in 48 consecutive, equal monthly principal installments, plus interest. As of March 31, 2003, we had an outstanding balance of approximately $501,857 under this facility consisting of three individual loans of (i) $179,786 with a fixed annual interest rate of 5.07% and (ii) $243,872 with a floating annual interest rate equal to Comerica’s prime rate of 4.25% at March 31, 2003 and (iii) $108,683 with a floating annual interest rate equal to Comerica’s prime rate of 4.25% at March 31, 2003. We had $2,455,673 available for future borrowings under this facility as of March 31, 2003.

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 September 9, 2003, with interest payable monthly. We had no outstanding borrowings under this facility at March 31, 2003.

All borrowings under the New Credit Facility are collateralized by a first priority security interest in all of our assets, including present and future accounts receivable, chattel paper, contracts and contract rights, equipment and accessories, general intangibles, investments, instruments, inventories, and a mortgage on our manufacturing facility in Bethlehem, Pennsylvania. Borrowings under the equipment and working capital lines of credit are limited to

commercially standard percentages of equipment purchases and accounts receivable, respectively. The New Credit Facility contains certain covenants that set forth minimum requirements for our quick ratio, liquidity, and tangible net worth and require that we achieve positive net income for the year ending December 31, 2003 and for each year thereafter. The New Credit Facility also restricts our ability to pay dividends, to make certain investments, to incur additional indebtedness, to sell or otherwise dispose of a substantial portion of assets, and to merge or consolidate operations with an unaffiliated entity, without the consent of Comerica.

We have entered into a ten-year facility lease with Tech III Partners, LLC ("Tech Partners"), an entity owned and controlled by two of our executive officers. Under the terms of this operating lease, we began leasing a 48,000 square-foot facility in October 2002 at a base rent of $780,000 per year, increasing to $852,240 per year, during the initial 10-year term. The base rental may be increased after the fifth year of the initial term in order to reflect changes in the interest rate on debt incurred by Tech Partners to finance construction of the leased facilities. We have not guaranteed any debt incurred by Tech Partners. The lease also provides us with options to renew the lease for an additional five years at a rental rate of $975,360 per year, and to purchase the facility at any time during the initial ten-year term based on a formula set forth in the lease.

The combination of our current cash position and available borrowings under our New Credit Facility is expected to be sufficient to fund our foreseeable operating and capital needs. However, our cash requirements may vary materially from those now planned due to many factors, including, but not limited to, 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 commercial launch of new products, market acceptance of new products, competing technological and market developments, the scope and timing of strategic acquisitions, and other factors.

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, 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 2002 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. 101, "Revenue Recognition in Financial Statements" ("SAB 101"). 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 101, we are required to defer immediate recognition of these fees as revenue and instead ratably recognize this revenue over the related license period.

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

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

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

Based upon historical experience and any specific customer collection issues that are identified, we use our judgment to establish and evaluate the adequacy of our allowance for estimated credit losses, which was $292,831 at March 31, 2003. While credit losses have been within our expectations and the allowance provided, these losses can vary from period to period ($213,188, $5,193 and $4,269 for the years ended December 31, 2002, 2001 and 2000, 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, 2003, approximately $1.2 million or 21% of our accounts receivable were due from one major customer. Any significant changes in the liquidity or financial position of this customer, or others, could have a material adverse impact on the collectibility of our accounts receivable and future operating results.

Inventories. Our inventories are valued at the lower of cost or market, determined on a first-in, first-out basis, and include the cost of raw materials, labor and overhead. The majority of our inventories are subject to expiration dating. We continually evaluate the carrying value of our inventories and when, in the opinion of management, factors indicate that impairment has occurred, either a reserve is established against the inventories' carrying value or the inventories are completely written off. We base these decisions on the level of inventories on hand in relation to our estimated forecast of product demand, production requirements over the next twelve months and the expiration dates of raw materials and finished goods. During the years ended December 31, 2002, 2001 and 2000, we wrote-off inventory which had a cost of approximately $1.4 million, $0.6 million and $1.1 million, respectively, as a result of increased scrap levels and product expiration issues. Forecasting product demand can be a complex process, especially for a new product such as our OraQuick® rapid HIV-1 antibody test, which was launched in the United States in November 2002. 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 $10.3 million or 29% of our total assets at March 31, 2003. Our investment in a privately-held nonaffiliated company is recorded under the cost method of accounting, because we do not have a controlling interest in this company nor do we have the ability to exert significant influence over the operating and financial policies of this investee company. Property and equipment, patents and product rights are amortized on a straight-line basis over their useful lives, which we determine based upon our estimate of the period of time over which each asset will generate revenues. An impairment of long-lived or intangible assets could occur

whenever events or changes in circumstances indicate that the net book value of these assets may not be recoverable. Events which could trigger an asset impairment include significant underperformance relative to expected historical or projected future operating results, significant changes in the manner of our use of an asset or in our strategy for our overall business, significant negative industry or economic trends, shortening of product life-cycles or changes in technology, and negative financial performance of our nonaffiliated investee company. If we believe impairment of an asset has occurred, we measure the amount of such impairment by comparing the net book value of the affected assets to the fair value of these assets, which is generally determined based upon the present value of the expected cash flows associated with the use of these assets. If the net book value exceeds the fair value of the impaired assets, we would incur an impairment expense equal to this difference. We currently believe the future cash flows to be received from our long-lived and intangible assets will exceed their book value and, as such, we have not recognized any impairment losses through March 31, 2003. 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. We have a history of losses, which has generated a sizeable federal tax net operating loss ("NOL") carryforward of approximately $79.6 million as of December 31, 2002. The deferred tax asset associated with these NOLs and other temporary differences is approximately $31.8 million at December 31, 2002. Under generally accepted accounting principles, we are required to record a valuation allowance against our deferred tax asset associated with this NOL carryforward if it is more likely than not that some portion or all of the deferred tax asset will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of taxable income in the future. Due to the size of the NOL carryforward in relation to our history of unprofitable operations, we have not recognized any of our net deferred tax asset. It is possible that we could be profitable in the future at levels which would cause us to conclude that it is more likely than not that we will realize all or a portion of the deferred tax asset. Upon reaching such a conclusion, we would immediately record the estimated net realizable value of the deferred tax asset at that time and would then begin to provide for income taxes at a rate equal to our combined federal and state effective rates, which we believe would approximate 40%. Subsequent revisions to the estimated net realizable value of the deferred tax asset could cause our provision for income taxes to vary significantly from period to period.

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

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We do not hold any 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 U.S. corporate debt, certificates of deposit, government securities and commercial paper. All such instruments are classified as securities available for sale. 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 income statements of these operations from Euros to U.S. dollars affects year-to-year comparability of operating results. Sales denominated in a foreign currency represented approximately $0.4 million or 4.6% of our revenues for the three months ended March 31, 2003. 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. Within the 90 days preceding the filing of this Report, an evaluation was performed under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures. Based on that evaluation, the Company's management, including such officers, concluded that the Company's disclosure controls and procedures were effective in timely alerting them to material information relating to the Company, which is required to be included in its periodic filings with the Securities and Exchange Commission.

(b) Changes in Internal Controls. There have been no significant changes in the Company's internal controls or in other factors that could significantly affect internal controls (including any corrective actions with regard to significant deficiencies or material weaknesses) subsequent to the date of the evaluation referred to in paragraph (a) of this Item.

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PART II. OTHER INFORMATION

Item 6. EXHIBITS AND REPORTS ON FORM 8-K.

(a) Exhibits.

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

(b) Reports on Form 8-K.

Current Report on Form 8-K, dated January 31, 2003, reporting the Company's issuance of press releases announcing that the Company had applied for a waiver of its OraQuick® Rapid HIV-1 Antibody Test under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA") and had received approval of such CLIA waiver by the U.S. Food and Drug Administration.

Current Report on Form 8-K, dated February 6, 2003, reporting the Company's announcement of final financial results for the year ended December 31, 2002, and certain other matters.

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 15, 2003

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

/s/ MARK L. KUNA

Date: May 15, 2003

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

Certification

I, Michael J. Gausling, certify that:

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

2. Based on my knowledge, this quarterly 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 quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly 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-14 and 15d –14) for the registrant and we have:

    a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

    b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and

    c) Presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 15, 2003

/s/ MICHAEL J. GAUSLING

Michael J. Gausling
President and Chief Executive Officer
(Principal Executive Officer)

Certification

I, Ronald H. Spair, certify that:

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

2. Based on my knowledge, this quarterly 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 quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly 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-14 and 15d –14) for the registrant and we have:

   a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

   b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and

c) Presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses

Date: May 15, 2003

/s/ RONALD H. SPAIR

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

EXHIBIT INDEX

Exhibit	
99.1	Certification pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
99.2	Certification pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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, 2003 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael J. Gausling, 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/ MICHAEL J. GAUSLING

Michael J. Gausling
President and Chief Executive Officer

May 15, 2003

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to OraSure Technologies, Inc. and will be retained by OraSure Technologies, Inc. and furnished to the Securities and Exchange Commission or its Staff upon request.

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, 2003 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 15, 2003

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to OraSure Technologies, Inc. and will be retained by OraSure Technologies, Inc. and furnished to the Securities and Exchange Commission or its Staff upon request.