Table of Contents

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 June 30, 2003.

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 July 28, 2003: 38,518,540

Table of Contents

PART I. FINANCIAL INFORMATION

PART II. OTHER INFORMATION

Item 1. FINANCIAL STATEMENTS

ORASURE TECHNOLOGIES, INC.
BALANCE SHEETS
(Unaudited)

	June 30, 2003	December 31, 2002
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 1,730,494	$ 4,364,308
Short-term investments	13,677,720	10,543,876
Accounts receivable, net of allowance for doubtful accounts of $302,317 and $292,146	6,314,562	5,197,787
Inventories	4,170,251	4,088,474
Prepaid expenses and other	691,619	925,707
Total current assets	26,584,646	25,120,152
PROPERTY AND EQUIPMENT, net	7,103,241	7,427,950
PATENTS AND PRODUCT RIGHTS, net	2,217,372	2,543,519
OTHER ASSETS	625,286	645,626
	$ 36,530,545	$ 35,737,247
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	$ 1,137,771	$ 1,065,966
Accounts payable	1,695,576	1,801,952
Accrued expenses	4,556,648	3,321,509
Total current liabilities	7,389,995	6,189,427
LONG-TERM DEBT	3,007,774	3,409,362
OTHER LIABILITIES	181,655	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, 38,470,426 and 38,100,557 shares issued and outstanding	38	38
Additional paid-in capital	157,191,210	155,638,314
Accumulated other comprehensive loss	(182,250)	(184,676)
Accumulated deficit	(131,057,877)	(129,434,764)
Total stockholders' equity	25,951,121	26,018,912
	$ 36,530,545	$ 35,737,247

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.
STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2003	2002	2003	2002
REVENUES:				
Product	$ 9,437,555	$ 7,874,076	$ 17,780,519	$ 15,342,697
Licensing and product development	191,303	55,956	458,975	312,809
	9,628,858	7,930,032	18,239,494	15,655,506
COST OF PRODUCTS SOLD	3,820,875	3,200,451	7,400,991	6,094,681
Gross profit	5,807,983	4,729,581	10,838,503	9,560,825
COSTS AND EXPENSES:				
Research and development	1,965,275	2,210,224	4,019,986	4,630,487
Sales and marketing	2,737,397	2,392,325	4,972,534	4,380,506
General and administrative	1,657,369	1,481,580	3,522,990	3,565,881
	6,360,041	6,084,129	12,515,510	12,576,874
Operating loss	(552,058)	(1,354,548)	(1,677,007)	(3,016,049)
INTEREST EXPENSE	(47,208)	(79,096)	(95,813)	(163,345)
INTEREST INCOME	83,373	150,749	168,946	303,984
FOREIGN CURRENCY GAIN (LOSS)	(3,796)	1,759	(3,796)	1,577
Loss before income taxes	(519,689)	(1,281,136)	(1,607,670)	(2,873,833)
INCOME TAXES	10,564	—	15,443	—
NET LOSS	$ (530,253)	$ (1,281,136)	$ (1,623,113)	$ (2,873,833)
BASIC AND DILUTED NET LOSS PER SHARE	$ (0.01)	$ (0.03)	$ (0.04)	$ (0.08)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	38,412,351	37,493,741	38,330,924	37,464,073

The accompanying notes are an integral part of these statements.

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

	Six Months Ended June 30,	
	2003	2002
OPERATING ACTIVITIES:		
Net loss	$ (1,623,113)	$ (2,873,833)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Stock based compensation expense	33,900	—
Amortization of deferred revenue	—	(107,500)
Depreciation and amortization	1,269,505	1,084,451
Loss on disposition of property and equipment	—	2,053
Write-off of inventory	328,412	482,056
Changes in assets and liabilities:		
Accounts receivable	(1,116,775)	1,188,078
Inventories	(410,189)	(1,026,641)
Prepaid expenses and other assets	234,088	159,802
Accounts payable and accrued expenses	1,557,330	(892,779)
Net cash provided by (used in) operating activities	273,158	(1,984,313)
INVESTING ACTIVITIES:		
Purchases of short-term investments	(10,181,924)	(3,710,389)
Proceeds from the sale of short-term investments	7,048,399	5,490,428
Purchases of property and equipment	(730,844)	(651,896)
Proceeds from the sale of property and equipment	—	2,393
Purchase of patent and product rights	(250,000)	—
Increase in other assets	(450)	(21,211)
Net cash provided by (used in) investing activities	(4,114,819)	1,109,325
FINANCING ACTIVITIES:		
Borrowings of term debt	211,590	—
Repayments of term debt	(541,373)	(500,156)
Proceeds from issuance of common stock	1,518,996	388,015
Net cash provided by (used in) financing activities	1,189,213	(112,141)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	18,634	(1,771)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(2,633,814)	(988,900)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	4,364,308	2,426,346
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 1,730,494	$ 1,437,446

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 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 and six-month periods ended June 30, 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 periods. 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:

	June 30, 2003	December 31, 2002
Raw materials	$2,810,498	$2,787,967
Work-in-process	538,321	430,977
Finished goods	821,432	869,530
	$4,170,251	$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 for 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. For both the three-month and six-month periods ended June 30, 2003, one customer accounted for 20 percent of total revenues, as compared to 26 percent and 25 percent for the same periods of 2002, respectively. The same customer accounted for approximately 10 percent and 19 percent of accounts receivable as of June 30, 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." 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 4,592,419 and 4,572,515 shares were excluded from the computation of diluted net loss per common share for the three-month and six-month periods ended June 30, 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 and six-month periods ended June 30, 2003 and 2002 would have increased as follows:

	Three months ended June 30,		Six months ended June 30,	
	2003	2002	2003	2002
Net loss:				
As reported	$ (530,253)	$ (1,281,136)	$ (1,623,113)	$ (2,873,833)
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	(1,070,225)	(879,214)	(2,224,046)	(1,656,926)
Pro forma	$ (1,600,478)	$ (2,160,350)	$ (3,813,259)	$ (4,530,759)
Basic and diluted net loss per share:				
As reported	$ (0.01)	$ (0.03)	$ (0.04)	$ (0.08)
Pro forma	$ (0.04)	$ (0.06)	$ (0.10)	$ (0.12)

Other Comprehensive Income (Loss). We follow SFAS No. 130, "Reporting Comprehensive Income." This statement requires the classification of items of other comprehensive income (loss) by their nature and disclosure of the accumulated balance of other comprehensive income (loss), separately from accumulated deficit and additional paid-in capital in the 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):

	For the three months ended June 30,		For the six months ended June 30,	
	2003	2002	2003	2002
United States	$ 8,385	$ 6,864	$15,904	$13,661
Europe	911	816	1,535	1,481
Other regions	333	250	800	514
	$ 9,629	$ 7,930	$18,239	$15,656

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 ("SEC"), including our registration statement, our Annual Report on Form 10-K for the year ended December 31, 2002, our Quarterly Reports on Form 10-Q, and our other filings with the SEC. 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

Three months ended June 30, 2003 compared to June 30, 2002

Total revenues increased 21% to approximately $9.6 million in the second quarter of 2003 from approximately $7.9 million in the comparable quarter in 2002, primarily as a result of increased sales of our OraQuick® rapid HIV-1 antibody test and initial sales to the distributor of our over-the-counter ("OTC") portable cryosurgical wart removal product under the Compound W® and Freeze Off™ trademarks. Offsetting these revenue increases was an anticipated decline in urine assay revenues in the insurance risk assessment market, as compared to the second quarter of 2002. Revenues derived from products sold in countries outside the U.S. were approximately $1.2 million and $1.1 million for the second quarters of 2003 and 2002, respectively, or 13% of total revenues for each period.

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

Market Revenues	Three Months ended June 30, Dollars 2003	Dollars 2002	% Change	Percentage of Total Revenues 2003	Percentage of Total Revenues 2002
Insurance risk assessment	$ 2,458	$ 3,120	(21)%	26%	39%
Infectious disease testing	2,703	1,564	73	28	20
Substance abuse testing	1,835	1,776	3	19	22
Cryosurgical systems	2,442	1,414	73	25	18
Product revenues	9,438	7,874	20	98	99
Licensing and product development	191	56	241	2	1
Total revenues	$ 9,629	$ 7,930	21	100%	100%

Sales to the insurance risk assessment market declined by 21% to approximately $2.5 million in the second quarter of 2003, primarily as a result of lower urine assay and reagent sales and lower OraSure® oral fluid collection device sales. We expect that sales of our insurance assays and reagents will continue to come under competitive pressure because of sluggish sales and competition in the life insurance market. As a result of these conditions, 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. For example, as of June 30, 2003, Lab*One*, Inc., our largest customer, stopped purchasing our urine assays. Our revenues are expected to be negatively impacted by the loss of this business 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 73% to approximately $2.7 million in the second quarter of 2003, primarily as a result of sales 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. In addition, the test received a CLIA (Clinical Laboratory Improvement Amendments of 1988) waiver in January 2003. OraQuick® and OraSure® sales in the second quarter of 2003 totaled approximately $1.1 million and $1.6 million, respectively, compared to $21,000 and $1.5 million, respectively, for the comparable quarter of 2002.

We shipped approximately 43,000 OraQuick® devices, or approximately 24% of total OraQuick device sales in the second quarter, to Abbott Laboratories, Inc. ("Abbott"), our co-exclusive distribution partner in the U.S. marketplace. This purchase level was less than the approximately 200,000 devices shipped to Abbott in the first quarter and was anticipated due to the build-up of inventory levels by Abbott at the end of the first quarter. We are working with Abbott to increase its future purchases of OraQuick® tests and to ensure Abbott meets its purchase obligations under our distribution agreement.

Sales to the infectious disease testing market are expected to increase as a result of the recently announced $2 million purchase order received from The Centers for Disease Control and Prevention ("CDC") for our OraQuick® test. Pursuant to the CDC's purchase order, we expect to sell 250,000 devices to the CDC by December 31, 2003. In addition to supplying the tests, we will provide training to prospective OraQuick® customers at various sites throughout the U.S. It is expected that the training will generally precede the purchase of the OraQuick® devices. Consequently, most of the CDC sales are expected to occur in the fourth quarter of 2003.

Although sales of our OraQuick® test 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® test. However,

it is not possible at this time to estimate the timing or extent of such change in purchasing patterns or the financial impact of replacing OraSure® sales with sales of our OraQuick® test, if it occurs at all.

We are currently seeking FDA approval for certain other claims for OraQuick®, in addition to its approved usage to detect HIV-1 antibodies in finger-stick whole blood. We have filed for FDA approval of a venous whole blood claim, and are performing the clinical trials for usage of the device with oral fluid and plasma. We expect to make the related FDA submissions for these claims in the third quarter of 2003. We believe the venous whole blood and plasma claims are needed in order to fully penetrate the hospital market in the U.S. with our OraQuick® product. Until such additional claims are secured, we will likely not see optimal sales penetration for OraQuick® in the hospital market.

We have also completed the necessary clinical trials and filed for FDA approval for use of the OraQuick® device to detect antibodies to HIV-2. We have taken this action in anticipation of obtaining access to an HIV-2 patent license, either through our distribution arrangement with Abbott or directly with the holder of the HIV-2 patents. Although we believe the addition of an FDA-approved HIV-2 claim would enhance the versatility of our OraQuick® test and allow us to more fully implement a strategy to sell OraQuick® internationally, there is no assurance that we will receive FDA approval of an HIV-2 claim or be able to obtain access to an HIV-2 patent license.

Sales to the substance abuse testing market increased 3% to approximately $1.8 million as a result of significantly higher sales of our Intercept® oral fluid collection device and related drug assays in the workplace, criminal justice and the international marketplaces, which more than offset the absence of over $250,000 in laboratory equipment sales to Quest Diagnostics included in our revenues for the second quarter of 2002. Sales of our Intercept® device and related drug assays during the second quarter increased 25% or by approximately $200,000 over the comparable period in 2002.

Sales of our products in the cryosurgical systems market (which includes both the physicians' office and OTC markets) increased 73% to approximately $2.4 million in the second quarter of 2003. This increase was primarily the result of $1.2 million of initial sales of our OTC cryosurgical system to Medtech Holdings, Inc. ("Medtech"), the owner of the Compound W® line of wart removal products. We entered into an agreement with Medtech following receipt of FDA 510(k) clearance for the sale of Histofreezer® in the OTC market in the U.S. The product, which is expected to be launched by Medtech in the third quarter of 2003, will be called Freeze Off™ and will be sold under Medtech's Compound W® trademark. We expect to ship the balance of the approximately $2.0 million of minimum contractual purchases of this product in the third quarter of 2003. The five-year distribution agreement provides for comparable annual minimum purchases by Medtech over the life of the contract in order for Medtech to maintain its exclusive distribution rights to the OTC market in the U.S.

Sales of our Histofreezer® product to physicians' offices in the U.S. and international markets declined 12% and 15% to approximately $0.8 million and $0.4 million, respectively, in the second quarter of 2003, when compared to 2002, as a result of lower end-user purchases and an effort by some of our distributors to reduce their inventory levels. We anticipate that U.S. sales of Histofreezer® in the professional market will increase in the third quarter of 2003 as a result of new sales initiatives involving the use of contract sales organizations and the replenishment of low inventory levels at our distributors. Sales in the international market are expected to remain at approximately the levels experienced in 2002 until we are able to secure additional distributors in countries where the product is currently not sold.

It is possible that sales of the Freeze Off™ product in the 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.

Licensing and product development revenue increased 241% to $191,000 in the second quarter of 2003 from $56,000 in 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 awarded by the National Institutes of Health.

The Company's gross margin remained at approximately 60% in the second quarter of 2003, as compared to 2002.

Research and development expenses decreased 11% to approximately $2.0 million in the second quarter of 2003 from approximately $2.2 million in 2002, primarily as a result of lower clinical trial expenses and staffing costs, partially offset by higher materials expense and consulting fees related to the transfer of manufacturing operations from Oregon to our Bethlehem, Pennsylvania facilities.

Sales and marketing expenses increased 14% to approximately $2.7 million in the second quarter of 2003 from approximately $2.4 million in 2002. This increase was primarily the result of higher advertising, travel and public relations fees related to our Intercept® and OraQuick® products, partially offset by lower consulting fees for the development of strategic marketing plans. We expect sales and marketing expenses to increase during the remainder of 2003 as we attempt to increase market awareness for our OraQuick® and Intercept® products. In addition, pursuant to our agreement with Medtech, we are required to co-invest in Medtech's marketing activities for the Compound W® Freeze Off™ product. As a result, we expect to 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 12% to approximately $1.7 million in the second quarter of 2003 from approximately $1.5 million in 2002. This increase was primarily attributable to higher facility-related expenses incurred in 2003, partially offset by lower payroll, financial advisory and legal fees.

Interest expense decreased to $47,000 in the first quarter of 2003 from $79,000 in 2002 as a result of lower effective interest rates. Interest income decreased to $83,000 in the second quarter of 2003 from $151,000 in 2002, as a result of lower interest rates on investments.

During the second quarter of 2003, a provision for foreign income taxes of approximately $11,000 was recorded.

Results of Operations

Six months ended June 30, 2003 compared to June 30, 2002

Total revenues increased 17% to approximately $18.2 million for the six months ended June 30, 2003 from approximately $15.7 million in the comparable six month period in 2002, primarily as a result of increased sales of our OraQuick® rapid HIV-1 antibody test and increased sales of our Intercept® oral fluid collection device and related drug assays, partially offset by a previously anticipated decline in urine assay revenues in the insurance risk assessment market, compared to the first six months of 2002. Revenues derived from products sold in countries outside the U.S. were approximately $2.3 million and $2.0 million for the six months ended June 30, 2003 and 2002, respectively, or 13% of total revenues for each period.

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

	Six months ended June 30,				
	Dollars			Percentage of Total Revenues	
Market Revenues	2003	2002	% Change	2003	2002
Insurance risk assessment	$ 5,458	$ 5,913	(8)%	30%	38%
Infectious disease testing	5,471	3,074	78	30	19
Substance abuse testing	3,433	2,963	16	19	19
Cryosurgical systems	3,419	3,393	1	19	22
Product revenues	17,781	15,343	16	98	98
Licensing and product development	459	313	47	2	2
Total revenues	$ 18,240	$ 15,656	17	100%	100%

Sales to the insurance risk assessment market declined by 8% to approximately $5.5 million for the six months ended June 30, 2003 from approximately $5.9 million in the comparable period in 2002, primarily as a result of lower urine assay and reagent sales. We expect that sales of our insurance assays and reagents will continue to come under competitive pressure because of sluggish sales and competitive conditions in the life insurance market. As a result of these conditions, 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. For example, as of June 30, 2003, Lab*One*, Inc., our largest customer, stopped purchasing our urine assays. Our revenues are expected to be negatively impacted by the loss of this business 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 78% to approximately $5.5 million for the six months ended June 30, 2003, primarily as a result of sales of our OraQuick® rapid HIV-1 antibody test. OraQuick® and OraSure® sales for the six months ended June 30, 2003 totaled approximately $2.5 million and $3.0 million, respectively, as compared to approximately $59,000 and $3.0 million, respectively, for the comparable period in 2002.

We shipped approximately 245,000 OraQuick® devices, or approximately 52% of total OraQuick® device sales for the six months ended June 30, 2003, to Abbott Laboratories, Inc. ("Abbott"), our co-exclusive distribution partner in the U.S. marketplace. We are working with Abbott to increase its future purchases of OraQuick® tests and to ensure Abbott meets its purchase obligations under our distribution agreement.

Sales to the infectious disease testing market are expected to increase as a result of the recently announced $2 million purchase order received from The Centers for Disease Control and Prevention ("CDC") for our OraQuick® rapid HIV-1 antibody test. Pursuant to the CDC's purchase order, we expect to sell 250,000 devices to the CDC by December 31, 2003. In addition to supplying the tests, we will provide training to prospective OraQuick® customers at various sites throughout the U.S. It is expected that the training will generally precede the purchase of the OraQuick® devices. Consequently, most of the CDC sales are expected to occur in the fourth quarter of 2003.

Although sales of our OraQuick® test 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® test. However, it is not possible at this time to estimate the timing or extent of such change in purchasing patterns or the financial impact of replacing OraSure® sales with sales of our OraQuick® test, if it occurs at all.

We are currently seeking FDA approval for certain other claims for OraQuick®, in addition to its approved usage to detect HIV-1 antibodies in finger-stick whole blood. We have filed for FDA approval of a venous whole blood

claim, and are performing the clinical trials for usage of the device with oral fluid and plasma. We expect to make the related FDA submissions for these claims in the third quarter of 2003. We believe the venous whole blood and plasma claims are needed in order to fully penetrate the hospital market in the U.S. with our OraQuick® product. Until such additional claims are secured, we will likely not see optimal sales penetration for OraQuick® in the hospital market.

We have also completed the necessary clinical trials and filed for FDA approval for use of the OraQuick® device to detect antibodies to HIV-2. We have taken this action in anticipation of obtaining access to an HIV-2 patent license, either through our distribution arrangement with Abbott or directly with the holder of the HIV-2 patents. Although we believe the addition of an FDA-approved HIV-2 claim would enhance the versatility of our OraQuick® test and allow us to more fully implement a strategy to sell OraQuick® internationally, there is no assurance that we will receive FDA approval of our HIV-2 claim or be able to obtain access to an HIV-2 patent license.

Sales to the substance abuse testing market increased 16% to approximately $3.4 million for the six months ended June 30, 2003 as a result of higher sales of our Intercept® oral fluid collection device and related drug assays in the workplace, criminal justice and the international marketplaces, which more than offset the absence of over $250,000 in laboratory equipment sales to Quest Diagnostics included in our revenues for the six months ended June 30, 2002. Sales of our Intercept® device and related drug assays for the six months ended June 30, 2002, increased 43% or by approximately $525,000 over the comparable period in 2002.

Sales of our products in the cryosurgical systems market (which includes both the physicians' office and over-the-counter ("OTC") markets) increased 1% to approximately $3.4 million for the six months ended June 30, 2003. This increase was primarily the result of $1.2 million of initial sales of our OTC cryosurgical system to Medtech Holdings, Inc. ("Medtech"), the owner of the Compound W® line of wart removal products, offset by lower sales of Histofreezer® in the professional markets in both the U.S. and international markets. We entered into an agreement with Medtech following receipt of FDA 510(k) clearance for the sale of Histofreezer® in the OTC market in the U.S.

The product, which is expected to be launched by Medtech in the third quarter of 2003, will be called Freeze Off™ and will be sold under Medtech's Compound W® trademark. We expect to ship the balance of the approximately $2.0 million of minimum contractual purchases of this product in the third quarter of 2003. The five-year distribution agreement provides for comparable annual minimum purchases by Medtech over the life of the contract in order for Medtech to maintain its exclusive distribution rights to the OTC market in the U.S.

Sales of our Histofreezer® product to physicians' offices in the U.S. and international markets declined 46% and 4% to approximately $1.4 million and $0.8 million, respectively, for the six months ended June 30, 2003, when compared to 2002 as a result of lower end-user purchases and an effort by some of our distributors to reduce their inventory levels. We anticipate that U.S. sales of Histofreezer® in the professional market will increase in the third quarter of 2003 as a result of new sales initiatives involving the use of contract sales organizations and the replenishment of low inventory levels at our distributors. Sales in the international market are expected to remain at approximately the levels experienced in 2002 until we are able to secure additional distributors in countries where the product is currently not sold.

It is possible that sales of the Freeze Off™ product in the 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.

Licensing and product development revenue increased 47% to approximately $459,000 for the six months ended June 30, 2003 from approximately $313,000 in the comparable period in 2002. Licensing and product development revenues for the six months ended June 30, 2003 were 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 Company's gross margin decreased to approximately 59% for the six months ended June 30, 2003 from 61% for the comparable period in 2002. This decrease was primarily attributable to the decrease in high-margin Histofreezer® sales in the U.S. professional market.

Research and development expenses decreased 13% to approximately $4.0 million for the six months ended June 30, 2003 from approximately $4.6 million for the comparable period in 2002, primarily as a result of lower clinical trial expenses and staffing costs, partially offset by higher materials expense and consulting fees related to the transfer of manufacturing operations from Oregon to our Bethlehem, Pennsylvania facilities.

Sales and marketing expenses increased 14% to approximately $5.0 million for the six months ended June 30, 2003 from approximately $4.4 million in the comparable period in 2002. This increase was primarily the result of higher advertising, travel, market research and public relations fees, partially offset by lower outside consulting fees for the development of strategic marketing plans. We expect sales and marketing expenses to increase during the remainder of 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 Compound W® 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 this product in the OTC market.

General and administrative expenses decreased 1% to approximately $3.5 million for the six months ended June 30, 2003 from approximately $3.6 million for the comparable period in 2002. This decrease was primarily attributable to the absence of a $0.5 million severance charge related to the departure of the Company's former Chief Executive Officer, partially offset by higher facility-related expenses.

Interest expense decreased to approximately $96,000 for the six months ended June 30, 2003 from approximately $163,000 for the comparable period in 2002, as a result of lower effective interest rates. Interest income decreased to approximately $169,000 for the six months ended June 30, 2003 from approximately $304,000 for the comparable period in 2002, as a result of as a result of lower interest rates on investments.

During the six months ended June 30, 2003, a provision for foreign income taxes of approximately $15,000 was recorded.

Liquidity and Capital Resources

	June 30, 2003	December 31, 2002
	(In thousands)	
Cash and cash equivalents	$ 1,730	$ 4,364
Short-term investments	13,678	10,544
Working capital	19,195	18,931

Our cash, cash equivalents and short-term investment position increased approximately $500,000 during the first six months of 2003 to approximately $15.4 million at June 30, 2003, primarily as a result of the receipt of approximately $1.5 million in proceeds from the exercise of stock options and cash provided by operations of approximately $270,000, partially offset by capital equipment expenditures of approximately $0.7 million, a $250,000 payment under our distribution agreement with bioMerieux, Inc., and net term debt repayments of approximately $330,000. At June 30, 2003, our working capital was approximately $19.2 million.

Net cash provided by operating activities was approximately $273,000 for the six months ended June 30, 2003, primarily as a result of the net loss of approximately $1.6 million for the six months ended June 30, 2003, an increase in accounts receivable of approximately $1.1 million and an increase in inventories of approximately $410,000, offset by non-cash items totaling approximately $360,000 related to inventory reserves and stock-based compensation, depreciation and amortization of approximately $1.3 million, decreases in prepaid expenses of approximately $235,000 and an aggregate increase of approximately $1.6 million in accounts payable and accruals.

Net cash used in investing activities during the six months ended June 30, 2003 was approximately $4.1 million, primarily as a result of an approximate $3.1 million net increase in short-term investments, the purchase of approximately $0.7 million of capital equipment and the payment of $250,000 pursuant to our distribution agreement with bioMerieux, Inc.

Net cash provided by financing activities was approximately $1.2 million during the six months ended June 30, 2003 as a result of approximately $1.5 million in proceeds from the exercise of stock options, partially offset by approximately $330,000 of net term debt repayments.

In September 2002, we entered into a $10.9 million credit facility ("Credit Facility") with Comerica Bank. The 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. We are currently in discussions with Comerica to renew and extend our credit facilities.

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 June 30, 2003 was $848,182.

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 June 30, 2003 was $2,357,143.

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 June 30, 2003, we had an outstanding balance of $574,000 under this facility consisting of four individual loans of (i) $155,814 with a fixed annual interest rate of 5.07%, (ii) $213,388 with a floating annual interest rate equal to Comerica's prime rate of 4.25% at June 30, 2003, (iii) $101,890 with a floating annual interest rate equal to Comerica's prime rate of 4.25% at June 30, 2003, and (iv) $102,908 with a floating annual interest rate equal to Comerica's prime rate of 4.25% at June 30, 2003. We had $2,352,766 available for future borrowings under this facility as of June 30, 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 June 30, 2003.

All borrowings under the Credit Facility are collateralized by a first priority security interest in all of our assets, including present and future accounts receivable, chattel paper, contracts and contract rights, equipment and accessories, general intangibles, investments, instruments, inventories, and a mortgage on our manufacturing facility in Bethlehem, Pennsylvania. Borrowings under the equipment and working capital lines of credit are limited to commercially standard percentages of equipment purchases and accounts receivable, respectively. The Credit Facility contains certain covenants that set forth minimum requirements for our quick ratio, liquidity, and tangible net worth and requires that we achieve positive net income for the year ending December 31, 2003 and for each year thereafter. The Credit Facility also restricts our ability to pay dividends, to make certain investments, to incur additional indebtedness, to sell or otherwise dispose of a substantial portion of assets, and to merge or consolidate operations with an unaffiliated entity, without the consent of Comerica.

We have entered into a ten-year facility lease with Tech III Partners, LLC ("Tech Partners"), an entity owned and controlled by two of our 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.

In July 2003, we filed a universal shelf registration statement on Form S-3 with the Securities and Exchange Commission for the registration and potential issuance of up to $75 million of securities. The securities covered by the universal shelf, which may include common stock, preferred stock or debt securities, are being registered on a delayed basis because we do not intend to sell securities immediately upon the effectiveness of the registration statement. The actual amount and type of securities, or combination of securities, to be issued and the terms of those securities, will be determined at the time of sale, if such sale occurs. Proceeds from any sale of securities covered by the shelf registration can be used for general corporate purposes, which may include ongoing research and development activities, commercialization of new products, potential acquisitions, capital expenditures, patent license fees, debt service and retirement, and general working capital.

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 these fees and 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 $302,317 at June 30, 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 credit losses will continue at the same rates as in the past. Also, at June 30, 2003, approximately $611,000 or 10% 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 $9.8 million or 27% of our total assets at June 30, 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 June 30, 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 NOL's 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 these NOL's and temporary differences 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 derivative 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 risk of change 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 revenues and expenses for these operations from Euros to U.S. dollars affects year-to-year comparability of operating results. Sales denominated in a foreign currency represented approximately $478,000 and $873,000 or 5.0% and 4.8% of the Company's total revenues for the three months and six months ended June 30, 2003, respectively. We do not expect the risk of foreign currency fluctuations to be material.

Item 4. CONTROLS AND PROCEDURES.

(a) Evaluation of Disclosure Controls and Procedures. The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures as of June 30, 2003. Based on that evaluation, the Company's management, including such officers, concluded that the Company's disclosure controls and procedures were effective in timely alerting them to material information relating to the Company, which is required to be included in its periodic filings with the Securities and Exchange Commission.

(b) Changes in Internal Controls Over Financial Reporting. The evaluation referred to in paragraph (a) of this Item did not identify any change in the Company's internal controls over financial reporting that occurred during the quarter ended June 30, 2003 that has materially affected, or is reasonably likely to materially affect, the Company's internal controls over financial reporting.

PART II. OTHER INFORMATION

Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

At our 2003 Annual Meeting of Stockholders (the "Annual Meeting") held on May 20, 2003, the following individuals were elected by the votes indicated as Class III directors of the Company for terms expiring at the 2006 Annual Meeting of Stockholders:

Nominee	Votes For	Votes Withheld
Michael J. Gausling	31,678,789	4,495,220
Gregory B. Lawless	35,501,225	672,784

Immediately following the Annual Meeting, Richard J. Lane retired from the Board and his service as a Director of our Company ended at that time. The other directors whose terms of office continued after the Annual Meeting are: Carter H. Eckert, Frank G. Hausmann, Ronny B. Lancaster, Roger L. Pringle and Douglas G. Watson.

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

(a) Exhibits.

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

(b) Reports on Form 8-K.

Current Report on Form 8-K, dated April 30, 2003, reporting our announcement of financial results for the quarter ended March 31, 2003, and certain other matters.

Current Report on Form 8-K, dated June 27, 2003, reporting our announcement that the Centers for Disease Control and Prevention has committed $2 million for the purchase of our OraQuick® Rapid HIV-1 Antibody Test.

SIGNATURES

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

ORASURE TECHNOLOGIES, INC.

Date: July 31, 2003

/s/ RONALD H. SPAIR

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

Date: July 31, 2003

/s/ MARK L. KUNA

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

EXHIBIT INDEX

Exhibit	
31.1	Certification of Michael J. Gausling 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 Michael J. Gausling required by Rule 13a-14(b) or Rule 15a-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Ronald H. Spair required by Rule 13a-14(b) or Rule 15a-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Exhibit 31.1

Certification

I, Michael J. Gausling, certify that:

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

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

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

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

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

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

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

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

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

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

Date: July 31, 2003

/s/ MICHAEL J. GAUSLING

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

Exhibit 31.2

Certification

I, Ronald H. Spair, certify that:

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

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

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

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

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

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

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

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

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

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

Date: July 31, 2003

/s/ RONALD H. SPAIR

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

Certification

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

July 31, 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

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

July 31, 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.