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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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 October 29, 2003: 43,917,397

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PART I. FINANCIAL INFORMATION

PART II. OTHER INFORMATION

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Item 1. FINANCIAL STATEMENTS

ORASURE TECHNOLOGIES, INC.
BALANCE SHEETS

	September 30, 2003 (Unaudited)	December 31, 2002
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 3,523,122	$ 4,364,308
Short-term investments	14,168,657	10,543,876
Accounts receivable, net of allowance for doubtful accounts of $316,982 and $292,146	7,024,798	5,197,787
Inventories	4,012,433	4,088,474
Prepaid expenses and other	772,383	925,707
Total current assets	29,501,393	25,120,152
PROPERTY AND EQUIPMENT, net	6,782,896	7,427,950
PATENTS AND PRODUCT RIGHTS, net	2,051,920	2,543,519
OTHER ASSETS	615,801	645,626
	$ 38,952,010	$ 35,737,247
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	$ 1,125,581	$ 1,065,966
Accounts payable	1,776,039	1,801,952
Accrued expenses	5,104,684	3,321,509
Total current liabilities	8,006,304	6,189,427
LONG-TERM DEBT	2,738,855	3,409,362
OTHER LIABILITIES	176,899	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, 38,909,299 and 38,100,557 shares issued and outstanding	39	38
Additional paid-in capital	159,230,306	155,638,314
Accumulated other comprehensive loss	(195,134)	(184,676)
Accumulated deficit	(131,005,259)	(129,434,764)
Total stockholders' equity	28,029,952	26,018,912
	$ 38,952,010	$ 35,737,247

The accompanying notes are an integral part of these statements.

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ORASURE TECHNOLOGIES, INC.
STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
REVENUES:				
Product	$ 10,221,656	$ 8,103,274	$ 28,002,175	$ 23,445,971
Licensing and product development	109,615	3,259	568,590	316,068
	10,331,271	8,106,533	28,570,765	23,762,039
COSTS OF PRODUCTS SOLD	4,002,032	3,349,522	11,403,023	9,444,203
Gross profit	6,329,239	4,757,011	17,167,742	14,317,836
COSTS AND EXPENSES:				
Research and development	2,201,946	1,890,266	6,221,932	6,520,753
Sales and marketing	2,512,999	1,947,388	7,485,533	6,327,894
General and administrative	1,601,819	1,320,649	5,124,809	4,886,530
	6,316,764	5,158,303	18,832,274	17,735,177
Operating income (loss)	12,475	(401,292)	(1,664,532)	(3,417,341)
INTEREST EXPENSE	(44,520)	(70,108)	(140,333)	(233,453)
INTEREST INCOME	78,360	86,827	247,306	390,811
FOREIGN CURRENCY GAIN (LOSS)	8,977	(2,271)	5,181	(694)
Income (loss) before income taxes	55,292	(386,844)	(1,552,378)	(3,260,677)
INCOME TAXES	2,674	—	18,117	—
NET INCOME (LOSS)	$ 52,618	$ (386,844)	$ (1,570,495)	$ (3,260,677)
EARNINGS (LOSS) PER SHARE:				
BASIC	$ 0.00	$ (0.01)	$ (0.04)	$ (0.09)
DILUTED	$ 0.00	$ (0.01)	$ (0.04)	$ (0.09)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING:				
BASIC	38,665,545	37,536,302	38,444,062	37,488,419
DILUTED	39,777,279	37,536,302	38,444,062	37,488,419

The accompanying notes are an integral part of these statements.

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

	Nine Months Ended September 30,	
	2003	2002
OPERATING ACTIVITIES:		
Net loss	$ (1,570,495)	$ (3,260,677)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Stock-based compensation expense	33,900	50,939
Amortization of deferred revenue	—	(107,500)
Depreciation and amortization	1,914,022	1,639,857
Loss on disposition of property and equipment	—	2,053
Write-off of inventory	438,069	949,752
Changes in assets and liabilities:		
Accounts receivable	(1,827,011)	1,252,263
Notes receivable from officer	—	75,000
Inventories	(362,028)	(1,088,139)
Prepaid expenses and other assets	378,015	461,068
Accounts payable and accrued expenses	1,929,835	(764,168)
Net cash provided by (used in) operating activities	934,307	(789,552)
INVESTING ACTIVITIES:		
Purchases of short-term investments	(13,995,647)	(3,761,117)
Proceeds from the sale of short-term investments	10,358,896	8,316,007
Purchases of property and equipment	(862,186)	(987,419)
Proceeds from the sale of property and equipment	—	2,393
Purchase of patents and product rights	(250,000)	(200,000)
Increase in other assets	(1,360)	(11,892)
Net cash provided by (used in) investing activities	(4,750,297)	3,357,972
FINANCING ACTIVITIES:		
Borrowings of long-term debt	211,590	4,078,982
Repayments of long-term debt	(822,482)	(4,239,581)
Proceeds from issuance of common stock	3,558,093	400,598
Net cash provided by financing activities	2,947,201	239,999
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	27,603	(3,647)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(841,186)	2,804,772
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	4,364,308	2,426,346
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 3,523,122	$ 5,231,118

The accompanying notes are an integral part of these statements.

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

1. The Company

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

2. Summary of Significant Accounting Policies

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

Supplemental Cash Flow Information. As of September 30, 2003, we accrued approximately $225,000 of prepaid expenses, related to our October 2003 public stock offering, as other current assets on our balance sheet.

Inventories. Inventories are stated at the lower of cost or market determined on a first-in, first-out basis and are comprised of the following:

	September 30, 2003	December 31, 2002
Raw materials	$ 2,729,786	$ 2,787,967
Work-in-process	506,541	430,977
Finished goods	776,106	869,530
	$ 4,012,433	$ 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"). SAB 101 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 nine-month periods ended September 30, 2003, one customer accounted for 20 percent of total revenues, as compared to 28 percent and 26 percent for the same periods of 2002, respectively. The same customer accounted for approximately 13 percent and 19 percent of accounts receivable as of September 30, 2003 and December 31, 2002, respectively.

During the three-month and nine-month periods ended September 30, 2003, another customer accounted for 16% and 10% of total revenues, respectively. We had no sales to this customer in the comparable periods of 2002. This customer also accounted for approximately 23% of accounts receivable at September 30, 2003. As of December 31, 2002, we did not have a receivable balance due from this customer.

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Net income (loss)	$ 52,618	$ (386,844)	$ (1,570,495)	$ (3,260,677)
Weighted average shares of common stock outstanding:				
Basic	38,665,545	37,536,302	38,444,062	37,488,419
Dilutive effect of stock options and warrants	1,111,734	—	—	—
Diluted	39,777,279	37,536,302	38,444,062	37,488,419
Earnings (loss) per share:				
Basic	$ 0.00	$ (0.01)	$ (0.04)	$ (0.09)
Diluted	$ 0.00	$ (0.01)	$ (0.04)	$ (0.09)

The computations of diluted earnings (loss) per share for the three-month and nine-month periods ended September 30, 2003 and 2002 exclude the effect of outstanding stock options and warrants to purchase 374,460, 4,645,733, 4,097,326 and 4,645,733 common shares, respectively, because the effect of including such shares is anti-dilutive.

Stock-Based Compensation. We account for stock-based compensation to employees and directors using the intrinsic value method in accordance with Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations. We account for stock-based compensation to nonemployees using the fair value method in accordance with SFAS No. 123, "Accounting for Stock-Based Compensation", and 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 income (loss) for three-month and nine-month periods ended September 30, 2003 and 2002 would have been as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2003	2002	2003	2002
Net income (loss):				
As reported	$ 52,618	$ (386,844)	$ (1,570,495)	$ (3,260,677)
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	(1,010,111)	(891,987)	(3,267,470)	(2,582,781)
Pro forma	$ (957,493)	$ (1,278,831)	$ (4,804,065)	$ (5,843,458)
Net income (loss) per share:				
As reported:				
Basic and diluted	$ 0.00	$ (0.01)	$ (0.04)	$ (0.09)
Pro forma:				
Basic and diluted	$ (0.02)	$ (0.03)	$ (0.12)	$ (0.16)

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. Long-Term Debt

In September 2002, we entered into a $10.9 million credit facility ("Credit Facility") with Comerica Bank, comprised of an $887,000 mortgage loan, a $3.0 million term loan, a $3.0 million non-revolving equipment line of credit, and a $4.0 million revolving working capital line of credit. In September 2003, we executed an amendment to this Credit Facility, pursuant to which the $3.0 million non-revolving equipment line of credit (the "Original Non-Revolving Line") was replaced with a new $4.0 million non-revolving line of credit (the "New Non-Revolving Line") for the purchase of both capital equipment and software, through December 31, 2004. Accordingly, the Original Non-Revolving Line expired. Borrowings outstanding under the Original Non-Revolving Line at the time of the amendment will not be applied against the credit limit for the New Non-Revolving Line and will remain payable in accordance with their original terms. Interest on outstanding borrowings under the New Non-Revolving Line will accrue 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 2.3%, determined at the time of each borrowing. Borrowings are repayable in either 36 or 48 consecutive, equal monthly principal installments, depending upon type of purchase financed, plus interest. This amendment also extended the maturity date of the $4.0 million revolving working capital line of credit until September 10, 2004, modified certain covenants related to liquidity and tangible net worth, and eliminated the covenant requiring us to achieve positive net income for the year ended December 31, 2003 and for each year thereafter. The term loan and mortgage loan were not affected by this amendment.

4. 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 September 30,		For the nine months ended September 30,	
	2003	2002	2003	2002
United States	$ 9,273	$7,158	$ 25,178	$ 20,819
Europe	721	538	2,256	2,018
Other regions	337	411	1,137	925
	$ 10,331	$8,107	$ 28,571	$ 23,762

5. Subsequent Events

In October 2003, we successfully completed a public offering in which we raised approximately $42.2 million, net of expenses, on the sale of 5,000,000 shares of our common stock. As of September 30, 2003, approximately $300,000 of prepaid expenses related to this offering were included in other current assets on our balance sheet.

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 (including our ability to implement a direct sales effort or alternative distribution for OraQuick®); 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 (including the outcome of our dispute with Abbott Laboratories); 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 statements, 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 September 30, 2003 compared to September 30, 2002

Total revenues increased 27% to approximately $10.3 million in the third quarter of 2003 from approximately $8.1 million in the comparable quarter in 2002, primarily as a result of increased sales of our OraQuick® rapid HIV-1 antibody test and higher than expected 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 third quarter of 2002. Revenues derived from products sold in countries outside the U.S. were approximately $1.1 million and $950,000 for each of the third quarters of 2003 and 2002, or 10% and 12% of total revenues, respectively, for such periods.

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.

	Three Months ended September 30,				
	Dollars			Percentage of Total Revenues	
Market Revenues	2003	2002	% Change	2003	2002
Insurance risk assessment	$ 2,827	$ 2,987	(5)%	27%	37%
Infectious disease testing	2,295	1,472	56	22	18
Substance abuse testing	1,801	1,805	—	18	22
Cryosurgical systems	3,298	1,840	79	32	23
Product revenues	10,221	8,104	26	99	100
Licensing and product development	110	3	3,567	1	—
Total revenues	$ 10,331	$ 8,107	27	100%	100%

Sales to the insurance risk assessment market declined by 5% to approximately $2.8 million in the third quarter of 2003, primarily as a result of lower urine assay and reagent sales, which more than offset a 26% increase in OraSure® oral fluid collection device sales during the quarter. We expect that sales of our urine assays and reagents will continue to come under competitive pressure because of sluggish sales and competition in the life insurance testing 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 urine 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 56% to approximately $2.3 million in the third quarter of 2003, primarily as a result of sales of our OraQuick® rapid HIV-1 antibody test, partially offset by lower sales of our OraSure® oral fluid collection device. OraQuick® and OraSure® sales in the third quarter of 2003 totaled approximately $1.1 million and $1.2 million, respectively, compared to $35,000 and $1.4 million, respectively, for the comparable quarter of 2002.

Abbott Laboratories, our co-exclusive distribution partner for the U.S. market, purchased 92,500 OraQuick® devices, representing approximately 33% of the total OraQuick® sales in the third quarter. Under our agreement with Abbott, which has an initial five-year term, Abbott is required to make minimum monthly purchases totaling approximately $4.0 million during a 15-month period following initial FDA approval of the product. As previously reported, Abbott's purchases through the first 10 months of this period have been below these minimum obligations, totaling only $1.5 million. We notified Abbott of this deficiency and requested that it be cured. We have also been working with Abbott, in the context of negotiating an amendment to the agreement affecting minimum purchase requirements and other terms, to correct this deficiency and to relieve Abbott of the consequences of its breach, which include termination of its distribution rights under the agreement.

As a result of Abbott's failure to cure its purchase deficiency and recently stalled efforts to reach agreement on an amendment, we declared the agreement terminated. At the same time, we invited Abbott to continue negotiations toward an amended distribution arrangement and offered to continue supplying OraQuick® devices to Abbott, on terms acceptable to us. Abbott has not accepted our invitation, and we have since advised Abbott that we are no longer prepared to continue to supply Abbott with product in response to orders we have received following termination.

Abbott has advised us that it disputes the termination of the agreement and that it wishes to proceed to have this dispute resolved through the arbitration mechanism provided in the agreement. Although we believe that the agreement has been lawfully terminated, there is no assurance that we will prevail if this matter is submitted to arbitration.

We are evaluating alternative distribution arrangements, including expanding our internal sales force to sell directly to hospitals, which was a primary market targeted by Abbott. We believe that expanding our direct sales efforts will provide us with greater control over distribution, a higher margin contribution from this product and a channel for distributing other high value-added products to these customers.

We currently intend to establish a small, but highly effective sales force focusing on the top metropolitan areas in the country, possibly supplemented with selective telemarketing and outside sales forces. We would also have the potential to develop, purchase or license additional products to be sold by this sales force in the future. However, in the event we are unsuccessful in deploying our own sales force or are unable to implement an alternative distribution arrangement in a timely manner or at all, the sales volume of our OraQuick® devices may decrease.

As previously announced, we have received a $2.0 million purchase order from The Centers for Disease Control and Prevention ("CDC") for our OraQuick® device. Pursuant to the CDC's purchase order, we expect to sell 250,000 devices to the CDC by December 31, 2003. During the third quarter, we shipped approximately $280,000 of devices against this order and expect to fill the rest of this order in the fourth quarter of 2003. In addition to supplying the tests, we will provide training to prospective OraQuick® customers at various sites throughout the U.S.

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

In September 2003, we received approval from the U.S. Food and Drug Administration ("FDA") for use of the OraQuick® device to detect HIV-1 antibodies in venipuncture whole blood samples. The device had previously received FDA approval for use with finger-stick whole blood samples, and has received a waiver under CLIA (Clinical Laboratory Improvement Amendments of 1988). During September 2003, we completed the necessary clinical trials and filed an application with the FDA for approval of the OraQuick® device for use with both oral fluid and plasma samples. We believe the venipuncture whole blood and plasma claims will assist us in fully penetrating the hospital market with our OraQuick® device.

We have also 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 directly with Bio-Rad Laboratories, the holder of the HIV-2 patents, or through a distribution arrangement with a third party. 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. However, there is no assurance that we will receive FDA approval of an HIV-2 claim.

We have approached Bio-Rad about securing a world-wide non-exclusive license for HIV-2 and have completed negotiation of a license agreement that we believe is complete and satisfactory to both parties. Bio-Rad is now in the process of securing the necessary signatures and approval from several other licensees and other relevant parties. Although there can be no assurance that we will secure all of the necessary signatures, we are cautiously optimistic that the license agreement will be executed by all required parties.

Sales to the substance abuse testing market were approximately $1.8 million, or essentially the same as the comparable period in 2002. Higher sales of our Intercept® oral fluid collection device and related oral fluid drug assays in the workplace, criminal justice and the international marketplaces, were largely offset by the absence of $276,000 in laboratory equipment sales included in our substance abuse testing market revenues for the third quarter of 2002. Sales of our Intercept® device and related drug assays for the third quarter of 2003 increased by 26%, or by approximately $242,000, over the comparable period in 2002.

In September 2003, we filed an application with the FDA for 510(k) clearance of our UP*link*® rapid point-of-care oral fluid drug detection system, including assays for the detection of drugs of abuse commonly identified by the National Institute for Drug Abuse ("NIDA") as the NIDA-5, i.e. cocaine, opiates, amphetamines/methamphetamines, PCP and marijuana. We do not expect to generate revenues from the sale of this product until 2004, when our partner, Dräger Safety, is expected to begin distributing this product primarily in the roadside testing market in Europe.

Sales of our products in the cryosurgical systems market (which includes both the physicians' office and OTC markets) increased 79% to approximately $3.3 million in the third quarter of 2003. This increase was primarily the result of $1.6 million of 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 was launched by Medtech in the third quarter of 2003 is called Freeze Off™ and is being sold under Medtech's Compound W® trademark. The five-year distribution agreement requires minimum purchases by Medtech of at least $2.0 million each year over the life of the contract in order for Medtech to maintain its exclusive distribution rights to the OTC market in the U.S. However, based on additional purchase orders received to date, we expect sales of product to Medtech in 2003 to aggregate at least $4.0 million.

Sales of our Histofreezer® product to physicians' offices in the U.S. and international markets declined 8% and 22% to approximately $1.4 million and $200,000, respectively, in the third quarter of 2003, when compared to 2002 as a result of lower distributor purchases. We anticipate that U.S. sales of Histofreezer® in the professional market will increase in the fourth quarter of 2003 as a result of an annual price increase scheduled for December 2003. This normally results in the purchase of additional product in advance of the scheduled price increase and is expected to reduce purchases in the first quarter of 2004. Sales in the international market are expected to remain at approximately the current levels 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 revenues increased to $110,000 in the third quarter of 2003 from $3,000 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 was 61% in the third quarter of 2003, compared to 59% in the comparable quarter of 2002. This increase resulted primarily from lower scrap and spoilage during the quarter.

Research and development expenses increased 16% to approximately $2.2 million in the third quarter of 2003 from approximately $1.9 million in 2002, primarily as a result of clinical trial expenses for our OraQuick® test and our UP*link*® rapid oral fluid drug detection system, higher staffing costs and consulting fees, and higher materials expense related to the transfer of product lines from Oregon to our Bethlehem, Pennsylvania facilities.

Sales and marketing expenses increased 29% to approximately $2.5 million in the third quarter of 2003 from approximately $1.9 million in 2002. This increase was primarily the result of higher advertising, travel and public relations fees related to our Intercept®, OraQuick® and Freeze Off™ products. 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. Sales and marketing expenses are also expected to increase as a result of our recruitment and deployment of an additional sales force focused on selling our OraQuick® test in the hospital market. 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 for advertising and promoting this product in the OTC market.

General and administrative expenses increased 21% to approximately $1.6 million in the third quarter of 2003 from approximately $1.3 million in 2002. This increase was primarily attributable to higher facility-related expenses incurred in 2003.

Interest expense decreased to $45,000 in the third quarter of 2003 from $70,000 in 2002 as a result of lower effective interest rates. Interest income decreased to $78,000 in the third quarter of 2003 from $87,000 in 2002, as a result of lower interest rates on investments.

During the third quarter of 2003, a provision for foreign income taxes of approximately $3,000 was recorded.

Nine months ended September 30, 2003 compared to September 30, 2002

Total revenues increased 20% to approximately $28.6 million for the nine months ended September 30, 2003 from approximately $23.8 million in the comparable nine month period in 2002, primarily as a result of increased sales of our OraQuick® rapid HIV-1 antibody test, higher than expected sales of our Freeze Off™ wart removal product, and higher 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 nine months of 2002, and lower sales of Histofreezer® in the physicians' office market in the U.S. Revenues derived from products sold in countries outside the U.S. were approximately $3.4 million and $2.9 million for the nine months ended September 30, 2003 and 2002, respectively, or 12% 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.

	Nine months ended September 30,				
	Dollars			Percentage of Total Revenues	
Market Revenues	2003	2002	% Change	2003	2002
Insurance risk assessment	$ 8,285	$ 8,899	(7)%	29%	38%
Infectious disease testing	7,766	4,546	71	27	19
Substance abuse testing	5,234	4,768	10	18	20
Cryosurgical systems	6,717	5,233	28	24	22
Product revenues	28,002	23,446	19	98	99
Licensing and product development	569	316	80	2	1
Total revenues	$ 28,571	$ 23,762	20	100%	100%

Sales to the insurance risk assessment market declined by 7% to approximately $8.3 million for the nine months ended September 30, 2003 from approximately $8.9 million in the comparable period in 2002, primarily as a result of lower urine assay and reagent sales. We expect that sales of our urine assays and reagents will continue to come

under competitive pressure because of sluggish sales and competitive conditions in the life insurance testing 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 urine 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 71% to approximately $7.8 million for the nine months ended September 30, 2003, primarily as a result of sales of our OraQuick® rapid HIV-1 antibody test. OraQuick® and OraSure® sales for the nine months ended September 30, 2003 totaled approximately $3.6 million and $4.2 million, respectively, as compared to approximately $95,000 and $4.5 million, respectively, for the comparable period in 2002.

Abbott Laboratories, our co-exclusive distribution partner for the U.S. market, purchased 337,250 OraQuick® devices, representing approximately 37% of the total OraQuick® sales, in the nine months ended September 30, 2003. Under our agreement with Abbott, which has an initial five-year term, Abbott is required to make minimum monthly purchases totaling approximately $4.0 million during a 15-month period following initial FDA approval of the product. As previously reported, Abbott's purchases through the first 10 months of this period have been below these minimum obligations, totaling only $1.5 million. We notified Abbott of this deficiency and requested that it be cured. We have also been working with Abbott, in the context of negotiating an amendment to the agreement affecting minimum purchase requirements and other terms, to correct this deficiency and to relieve Abbott of the consequences of its breach, which include termination of its distribution rights under the agreement.

As a result of Abbott's failure to cure its purchase deficiency and recently stalled efforts to reach agreement on an amendment, we declared the agreement terminated. At the same time, we invited Abbott to continue negotiations toward an amended distribution arrangement and offered to continue supplying OraQuick® devices to Abbott without an agreement, on terms acceptable to us. Abbott has not accepted our invitation, and we have since advised Abbott that we are no longer prepared to continue to supply Abbott with product in response to orders we have received following termination.

Abbott has advised us that it disputes the termination of the agreement and that it wishes to proceed to have this dispute resolved through the arbitration mechanism provided in the agreement. Although we believe that the agreement has been lawfully terminated, there is no assurance that we will prevail if this matter is submitted to arbitration.

We are evaluating alternative distribution arrangements, including expanding our internal sales force so that we can sell directly to hospitals, which was a primary market targeted by Abbott. We believe that expanding our direct sales efforts will provide us with greater control over distribution, a higher margin contribution from this product and a channel for distributing other high value-added products to these customers.

We currently intend to establish a small, but highly effective sales force focusing on the top metropolitan areas in the country, possibly supplemented with selective telemarketing and outside sales forces. We would also have the potential to develop, purchase or license additional products to be sold by this sales force in the future. However, in the event we are unsuccessful in deploying our own sales force or are unable to implement an alternative distribution arrangement in a timely manner or at all, the sales volume of our OraQuick® devices may decrease.

As previously announced, we have received a $2.0 million purchase order 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.

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

In September 2003, we received approval from the U.S. Food and Drug Administration ("FDA") for use of the OraQuick® device to detect HIV-1 antibodies in venipuncture whole blood samples. The device had previously received FDA approval for use with finger-stick whole blood samples, and has received a waiver under CLIA (Clinical Laboratory Improvement Amendments of 1988). During September 2003, we completed the necessary clinical trials and filed an application with the FDA for approval of the OraQuick® device for use with both oral fluid and plasma samples. We believe the venipuncture whole blood and plasma claims will assist us in fully penetrating the hospital market with our OraQuick® device.

We have also 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 directly with Bio-Rad Laboratories, the holder of the HIV-2 patents, or through a distribution arrangement with a third party. 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. However, there is no assurance that we will receive FDA approval of an HIV-2 claim.

We have approached Bio-Rad about securing a world-wide non-exclusive license for HIV-2 and have completed negotiation of a license agreement that we believe is complete and satisfactory to both parties. Bio-Rad is now in the process of securing the necessary signatures and approval from several other licensees and other relevant parties. Although there can be no assurance that we will secure all of the necessary signatures, we are cautiously optimistic that the license agreement will be executed by all required parties.

Sales to the substance abuse testing market increased 10% to approximately $5.2 million for the nine months ended September 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 approximately $439,000 in laboratory equipment sales included in our substance abuse testing market revenues for the nine months ended September 30, 2002. Sales of our Intercept® device and related drug assays for the nine months ended September 30, 2003, increased 36% or by approximately $770,000 over the comparable period in 2002.

In September 2003, we filed an application with the FDA for 510(k) clearance of our UP*link*® rapid point-of-care oral fluid drug detection system, including assays for the detection of drugs of abuse commonly identified by the National Institute for Drug Abuse ("NIDA") as the NIDA-5, i.e. cocaine, opiates, amphetamines/methamphetamines, PCP and marijuana. We do not expect to generate revenues from the sale of this product until 2004, when our partner, Dräger Safety, is expected to begin distributing this product primarily in the roadside testing market in Europe.

Sales of our products in the cryosurgical systems market (which includes both the physicians' office and over-the-counter ("OTC") markets) increased 28% to approximately $6.7 million for the nine months ended September 30, 2003. This increase was primarily the result of $2.9 million of 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 was launched by Medtech in the third quarter of 2003, is called Freeze Off™ and is being sold under Medtech's Compound W® trademark. The five-year distribution agreement requires minimum purchases by Medtech of at least $2.0 million each year over the life of the contract in order for Medtech to maintain its exclusive distribution rights to the OTC market in the U.S. However, based on additional purchase orders received to date, we expect sales of product to Medtech in 2003 to aggregate at least $4.0 million.

Sales of our Histofreezer® product to physicians' offices in the U.S. and international markets declined 31% and 8% to approximately $2.8 million and $1.1 million, respectively, in the first nine months of 2003, when compared to 2002, as a result of lower distributor purchases. We anticipate that U.S. sales of Histofreezer® in the professional market will increase in the fourth quarter of 2003 as a result of an annual price increase scheduled for December 2003. This normally results in the purchase of additional product in advance of the scheduled price increase and is expected to reduce purchases in the first quarter of 2004. Sales in the international market are expected to remain at approximately the current levels 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 revenues increased 80% to approximately $569,000 for the nine months ended September 30, 2003 from approximately $316,000 in the comparable period in 2002. Licensing and product development revenues for the nine months ended September 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 was 60% for the nine months ended September 30, 2003, which was unchanged from the same period in 2002.

Research and development expenses decreased 5% to approximately $6.2 million for the nine months ended September 30, 2003 from approximately $6.5 million for the comparable period in 2002, primarily as a result of lower staffing costs, partially offset by higher clinical trial expenses.

Sales and marketing expenses increased 18% to approximately $7.5 million for the nine months ended September 30, 2003 from approximately $6.3 million in the comparable period in 2002. This increase was primarily the result of higher advertising, travel, market research and public relations fees. 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. Sales and marketing expenses are also expected to increase as a result of our recruitment and deployment of an additional sales force focused on selling our OraQuick® test in the hospital market. 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 increased 5% to approximately $5.1 million for the nine months ended September 30, 2003 from approximately $4.9 million for the comparable period in 2002. This increase was primarily attributable to higher facility-related expenses, partially offset by the absence of a $500,000 severance charge related to the departure of the Company's former Chief Executive Officer in 2002.

Interest expense decreased to approximately $140,000 for the nine months ended September 30, 2003 from approximately $233,000 for the comparable period in 2002, as a result of lower effective interest rates. Interest income decreased to approximately $247,000 for the nine months ended September 30, 2003 from approximately $391,000 for the comparable period in 2002, as a result of lower interest rates on investments.

During the nine months ended September 30, 2003, a provision for foreign income taxes of approximately $18,000 was recorded.

Liquidity and Capital Resources

	September 30, 2003	December 31, 2002
	(In thousands)	
Cash and cash equivalents	$ 3,523	$ 4,364
Short-term investments	14,169	10,544
Working capital	21,495	18,931

Our cash, cash equivalents and short-term investment position increased approximately $2.8 million during the first nine months of 2003 to approximately $17.7 million at September 30, 2003, primarily as a result of the receipt of approximately $3.6 million in proceeds from the exercise of stock options and cash provided by operations of approximately $934,000, partially offset by capital equipment expenditures of approximately $862,000, a $250,000 payment under our distribution agreement with bioMerieux, Inc., and net term debt repayments of approximately $611,000. At September 30, 2003, our working capital was approximately $21.5 million. As discussed below, we received approximately $42.2 million in net proceeds from a public stock offering which closed in early October 2003.

Net cash provided by operating activities was approximately $934,000 for the nine months ended September 30, 2003, primarily as a result of the net loss of approximately $1.6 million for the nine months ended September 30, 2003, an increase in accounts receivable of approximately $1.8 million and an increase in prepaid expenses of approximately $378,000, offset by non-cash items totaling approximately $472,000 related to inventory write-offs and stock-based compensation, depreciation and amortization of approximately $1.9 million, a decrease in inventory of approximately $362,000 and an aggregate increase of approximately $1.9 million in accounts payable and accruals.

Net cash used in investing activities during the nine months ended September 30, 2003 was approximately $4.8 million, primarily as a result of an approximate $3.6 million net increase in short-term investments, the purchase of approximately $862,000 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 $2.9 million during the nine months ended September 30, 2003 as a result of approximately $3.6 million in proceeds from the exercise of stock options, partially offset by approximately $611,000 of net long-term debt repayments.

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

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

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 September 30, 2003 was $834,681.

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 September 30, 2003 was $2,142,857.

Under the New Non-Revolving Line, we can borrow up to $4.0 million to finance eligible equipment and software purchases through December 31, 2004. Interest on outstanding borrowings accrues at a rate, selected at our option, equal to Comerica's prime rate, 180-day or 360-day LIBOR plus 2.625%, or the 4-year Treasury Note Rate plus 2.30%, determined at the time of each borrowing. Borrowings are repayable in 48 (for equipment purchases) or 36 (for software purchases) consecutive, equal monthly principal installments, plus interest. As of September 30, 2003, there were no borrowings outstanding under this facility.

As of September 30, 2003, we had an outstanding balance of $533,548 under the Original Non-Revolving Line consisting of four individual loans of (i) $143,829 with a fixed annual interest rate of 5.07%, (ii) $198,146 with a floating annual interest rate equal to Comerica's prime rate of 4.00% at September 30, 2003, (iii) $95,097 with a floating annual interest rate equal to Comerica's prime rate of 4.00% at September 30, 2003, and (iv) $96,476 with a floating annual interest rate equal to Comerica's prime rate of 4.00% at September 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 10, 2004, with interest payable monthly. We had no outstanding borrowings under this facility at September 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 software non-revolving line and the working capital line are limited to commercially standard percentages of equipment and software purchases and accounts receivable, respectively. The Credit Facility contains certain covenants that set forth minimum requirements for our quick ratio, liquidity, and tangible net worth. 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.

In October 2003, we sold 5,000,000 shares of our common stock, which generated approximately $42.2 million in net cash proceeds. These securities were issued under a universal shelf registration statement and were sold in a firm commitment underwritten public offering. Proceeds from the sale of stock are expected to be used for general working capital, including commercialization of new products, research and development activities, potential acquisitions, capital expenditures, patent license fees, debt service and retirement, and general corporate purposes.

The combination of our current cash position and available borrowings under the 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 expansion of sales and marketing activities, 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 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"). SAB 101 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 $316,982 at September 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 September 30, 2003, approximately $2,556,000, or 36% of our accounts receivable, were due from two major customers. Any significant changes in the liquidity or financial position of these customers, or others, could have a material adverse impact on the collectibility of our accounts receivable and future operating results.

Inventories. Our inventories are valued at the lower of cost or market, determined on a first-in, first-out basis, and include the cost of raw materials, labor and overhead. The majority of our inventories are subject to expiration dating. We continually evaluate the carrying value of our inventories and when, in the opinion of management, factors indicate that impairment has occurred, either 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, $600,000 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 $9.1 million or 24% of our total assets at September 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 September 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 ("SFAS") No. 5, "Accounting for Contingencies". SFAS No. 5 requires us to record an estimated loss contingency when information available prior to issuance of our financial statements indicates that it is probable that an asset has been impaired or a liability has been incurred at the date of the financial statements and the amount of the loss can be reasonably estimated. Accounting for contingencies arising from contractual or legal proceedings requires that we use our best judgment when estimating an accrual related to such contingencies. As additional information becomes known, our accrual for a loss contingency could fluctuate, thereby creating variability in our results of operations from period to period. Likewise, an actual loss arising from a loss contingency which significantly exceeds the amount accrued for in our financial statements could have a material adverse impact on our operating results for the period in which such actual loss becomes known.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We do not hold any 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 $260,000 and $1,133,000 or 3% and 4% of the Company's total revenues for the three months and nine months ended September 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 September 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 September 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 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 July 29, 2003, reporting our announcement of financial results for the quarter ended June 30, 2003, and certain other matters.

Current Report on Form 8-K, dated September 9, 2003, reporting our announcement that the U.S. Food and Drug Administration approved our OraQuick® Rapid HIV-1 Antibody Test for use with venipuncture whole blood samples.

Current Report on Form 8-K, dated September 11, 2003, announcing our plans to publicly offer 5,000,000 shares of our common stock pursuant to a registration statement that became effective August 8, 2003.

Current Report on Form 8-K, dated September 17, 2003, announcing that the use of our OraQuick® Rapid HIV-1 Antibody Test at the point of care was found to provide results faster than when the test was used in a laboratory setting in the Mother Infant Rapid Intervention at Delivery study conducted by The Centers for Disease Control and Prevention.

Current Report on Form 8-K, dated September 17, 2003, announcing the renewal and amendment of our existing credit facility with Comerica Bank.

Current Report on Form 8-K, dated September 23, 2003, announcing our filing of an application with the U.S. Food and Drug Administration for 510(k) clearance of our UP*link*® rapid point-of-care oral fluid drug detection system.

Current Report on Form 8-K, dated September 29, 2003, announcing our filing of an application with the U.S. Food and Drug Administration for pre-market approval of our OraQuick® Rapid HIV-1 Antibody Test for use in detecting HIV-1 antibodies in oral fluid and plasma samples.

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: October 31, 2003

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

/s/ Mark L. Kuna

Date: October 31, 2003

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

EXHIBIT INDEX

Exhibit	
10	Second Amendment to Loan and Security Agreement, dated as of September 12, 2003, between OraSure Technologies, Inc. and Comerica Bank, is incorporated herein by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K, dated September 17, 2003.
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: October 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: October 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 September 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

October 31, 2003

Exhibit 32.2

Certification

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

October 31, 2003