ORASURE TECHNOLOGIES INC
Form 10-Q/A
August 01, 2002

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q/A
(Amendment No. 1)

(Mark One)

[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the quarterly period ended June 30, 2002.

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 1-10492

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.)

150 Webster Street, Bethlehem, Pennsylvania	18015
(Address of Principal Executive Offices)	(Zip code)

(610) 882-1820
(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X] No [_]

Number of shares of Common Stock, par value $.000001 per share, outstanding as of July 26, 2002: 37,533,013

PART I. FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

ORASURE TECHNOLOGIES, INC.
BALANCE SHEETS
(Unaudited)

	June 30, 2002	Dece
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 1,437,446	$
Short-term investments	10,873,890	
Accounts receivable, net of allowance for doubtful accounts of $328,386 and $209,492	4,869,849	
Note receivable from officer	-	
Inventories	4,989,357	
Prepaid expenses and other	878,709	
Total current assets	23,049,251	
PROPERTY AND EQUIPMENT, net	7,566,375	

PATENTS AND PRODUCT RIGHTS, net	2,060,084	
OTHER ASSETS	634,967	
	$ 33,310,677	$
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	$ 1,000,879	$
Accounts payable	1,528,842	
Accrued expenses	3,516,371	
Total current liabilities	6,046,092	
LONG-TERM DEBT	3,142,995	
OTHER LIABILITIES	179,480	
STOCKHOLDERS' EQUITY:		
Preferred stock, par value $.000001, 25,000,000 shares authorized, none issued	-	
Common stock, par value $.000001, 120,000,000 shares authorized, 37,532,137 and 37,403,269 shares issued and outstanding	38	
Additional paid-in capital	153,146,605	
Accumulated other comprehensive loss	(238,409)	
Accumulated deficit	(128,966,124)	
Total stockholders' equity	23,942,110	
	$ 33,310,677	$

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.
STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended June 30,		Six Months Ende	
	2002	2001	2002	
REVENUES:				
Product	$ 7,874,076	$ 8,080,266	$ 15,342,697	$
Licensing and product development	55,956	427,530	312,809	
	7,930,032	8,507,796	15,655,506	

COST OF PRODUCTS SOLD	3,200,451	3,013,355	6,094,681	
Gross profit	4,729,581	5,494,441	9,560,825	
COSTS AND EXPENSES:				
Research and development	2,210,224	2,423,422	4,630,487	
Sales and marketing	2,392,325	2,066,253	4,380,506	
General and administrative	1,481,580	1,601,626	3,565,881	
Restructuring-related	-	-	-	
	6,084,129	6,091,301	12,576,874	
Operating loss	(1,354,548)	(596,860)	(3,016,049)	
INTEREST EXPENSE	(79,096)	(103,159)	(163,345)	
INTEREST INCOME	150,749	207,383	303,984	
FOREIGN CURRENCY GAIN	1,759	54,435	1,577	
Loss before income taxes	(1,281,136)	(438,201)	(2,873,833)	
INCOME TAXES	-	5,976	-	
NET LOSS	$ (1,281,136)	$ (444,177)	$ (2,873,833)	$
BASIC AND DILUTED NET LOSS PER SHARE	$ (0.03)	$ (0.01)	$ (0.08)	$
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	37,493,741	36,701,511	37,464,073	

The accompanying notes are an integral part of these statements.

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

	Six Months
	2002
OPERATING ACTIVITIES:	
Net loss	$ (2,873,833)
Adjustments to reconcile net loss to net cash used in operating activities:	

Stock based compensation expense	-
Amortization of deferred revenue	(107,500)
Depreciation and amortization	1,084,451
Loss on disposition of property and equipment	2,053
Gain on sale of investment in affiliated company	-
Write-off of inventory	482,056
Changes in assets and liabilities:	
Accounts receivable	1,188,078
Inventories	(1,026,641)
Prepaid expenses and other assets	159,802
Accounts payable and accrued expenses	(892,779)
Net cash used in operating activities	(1,984,313)
INVESTING ACTIVITIES:	
Purchases of short-term investments	(3,710,389)
Proceeds from the sale of short-term investments	5,490,428
Purchases of property and equipment	(651,896)
Proceeds from the sale of property and equipment	2,393
Proceeds from sale of investment in affiliated company	-
Increase in other assets	(21,211)
Net cash provided by investing activities	1,109,325
FINANCING ACTIVITIES:	
Repayments of term debt	(500,156)
Proceeds from issuance of common stock	388,015
Net cash provided by (used in) financing activities	(112,141)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	(1,771)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(988,900)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	2,426,346
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 1,437,446

The accompanying notes are an integral part of these statements.

Notes to Financial Statements (Unaudited)

1. The Company

OraSure Technologies, Inc. (the "Company") develops, manufactures and markets oral specimen collection devices using its proprietary oral fluid technologies, proprietary diagnostic products including in vitro diagnostic tests, and other medical devices. These products are sold in the United States and certain

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

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, 2001. Results of operations for the three-month and six-month periods ended June 30, 2002 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 requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

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

	June 30, 2002	December 31, 2001
Raw materials	$ 3,504,196	$ 2,918,825
Work-in-process	764,328	644,397
Finished goods	720,833	881,550
	$ 4,989,357	$ 4,444,772

Revenue Recognition. The Company recognizes product revenues when products are shipped. The Company does not grant price protection or product return rights to its customers, except for warranty returns. Historically, returns arising from warranty issues have been infrequent and immaterial. Accordingly, the Company expenses warranty returns as incurred.

The Company follows 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. 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 and are included in the accrued expenses caption on the accompanying balance sheet. 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," the Company records shipping and handling charges billed to customers as revenue, and the related expense as cost of products sold.

Significant Customer Concentration. For the three-month and six-month periods ended June 30, 2002, one customer accounted for 26 and 25 percent of total revenues, respectively, as compared to 29 percent for each of the same periods

of 2001.

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 the Company's 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. The Company has presented basic and diluted net loss per common share pursuant to SFAS No. 128, "Earnings per Share" ("SFAS No. 128"). In accordance with SFAS No. 128, basic and diluted net loss per common share has been computed using the weighted-average number of shares of common stock outstanding during the period. Diluted loss per common share is generally computed assuming the conversion or exercise of all dilutive securities such as common stock options and warrants; however, outstanding common stock options and warrants to purchase 4,572,515 and 4,225,751 shares were excluded from the computation of diluted net loss per common share for both the three-month and six-month periods ended June 30, 2002 and 2001, respectively, because they were anti-dilutive due to the Company's losses.

Other Comprehensive Income (Loss). The Company follows SFAS No. 130, "Reporting Comprehensive Income." This statement requires the classification of items of other comprehensive income (loss) by their nature and disclosure of the accumulated balance of other comprehensive income (loss), separately from retained earnings and additional paid-in capital in the equity section of the balance sheet.

Restructuring-related Expenses. In February 2001, the Company announced plans to restructure certain of its manufacturing operations. As a result of this restructuring, the Company incurred an infrequent charge of $450,000 for restructuring costs, primarily comprised of expenses for employee severance, travel and transport resulting from relocating and consolidating manufacturing operations. All restructuring-related expenses were paid by June 30, 2001.

Recent Accounting Pronouncements. In June 2001, the Financial Accounting Standards Board ("FASB") issued SFAS No. 141, "Business Combinations" ("SFAS No. 141"), which requires that all business combinations initiated after June 30, 2001 be accounted for under the purchase method and addresses the initial recognition and measurement of goodwill and other intangible assets acquired in a business combination. Business combinations accounted for under the pooling of interests method prior to June 30, 2001 will not be changed. The adoption of SFAS No. 141 by the Company did not have any impact on the Company's financial position or results of operations.

In June 2001, the FASB issued SFAS No. 142, "Goodwill and Other Intangible Assets" ("SFAS No. 142"). SFAS No. 142 addresses the initial recognition and measurement of intangible assets acquired in a business combination and the accounting for goodwill and other intangible assets subsequent to their acquisition. SFAS No. 142 provides that intangible assets with finite useful lives be amortized, and that goodwill and intangible assets with indefinite lives not be amortized, but rather tested at least annually for impairment. The adoption of SFAS No. 142 did not have any impact on the Company's financial position or results of operations.

In June 2001, the FASB issued SFAS No. 143, "Accounting for Asset Retirement Obligations" ("SFAS No. 143"). SFAS No. 143 addresses financial accounting and reporting for obligations associated with the retirement of long-lived assets and the associated asset retirement costs. SFAS No. 143 requires that the fair value of a liability associated with an asset retirement be recognized in the period in which it is incurred, with the associated retirement costs capitalized as part of the carrying amount of the long-lived asset and subsequently depreciated over its useful life. The adoption of SFAS No. 143 did not have any impact on the Company's financial position or results of operations.

In June 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" ("SFAS No. 146"). SFAS No. 146 addresses significant issues regarding the recognition, measurement, and reporting of costs associated with exit and disposal activities, including restructuring activities. SFAS No. 146 also addresses recognition of certain costs related to terminating a contract that is not a capital lease, costs to consolidate facilities or relocate employees, and termination benefits provided to employees that are involuntarily terminated under the terms of a one-time benefit arrangement that is not an ongoing benefit arrangement or an individual deferred-compensation contract. SFAS No. 146 is effective for exit or disposal activities that are initiated after December 31, 2002. Given that SFAS No. 146 was issued in June 2002 and is not yet effective, the impact on the Company's financial position or results of operations from adopting SFAS No. 146 has not been determined.

3. Related Party Transactions

Officer Note and Employment Agreement. In March 2000, the Company issued a note receivable to an executive officer of the Company ("Officer Note") for $75,000, for relocation purposes. The Officer Note did not bear interest if it was repaid on or before the earlier of the tenth day following the close of sale on the officer's previous residence or the due date of the Officer Note, as extended.

On January 31, 2002, the Company terminated an employment agreement with this executive officer and the Company recorded $480,063 in severance-related expenses. These expenses include continued salary and benefit premium payments to this officer, related employment taxes, and the value of certain computer equipment transferred to this individual. As part of his severance agreement, this executive officer agreed to repay the Officer Note in bi-weekly principal installments of approximately $7,000, commencing in April 2002. For financial statement presentation purposes, at June 30, 2002 the remaining balance of accrued severance expenses payable to this former officer has been offset by the $39,892 remaining balance receivable under the terms of this Officer Note.

Facility Lease.

Effective March 1, 2002, the Company signed a 10-year operating lease with Tech III Partners, LLC, an entity owned and controlled by two of the Company's executive officers. Under the terms of this lease, the Company will lease an approximate 48,000 square foot facility currently being constructed on land adjacent to the Company's headquarters, at a base rent of $480,000 per year, increasing to $528,000 per year, during the initial 10-year term. The lease also provides for certain renewal and purchase options.

4. Geographic Area Information

Under the disclosure requirements of SFAS No. 131, "Segment Disclosures and Related Information," the Company operates within one segment: medical devices and products. The Company's products are sold principally in the United States and Europe. Segmentation of operating income and identifiable assets is not applicable since all of the Company's revenues outside the United States are export sales.

The following table represents total revenues by geographic area (amounts in thousands):

	For the three month ended June 30,		For the six months ended June 30,	
	2002	2001	2002	2001
United States	$6,864	$7,333	$13,661	$13,295
Europe	816	822	1,481	1,772
Other regions	250	353	514	845
	$7,930	$8,508	$15,656	$15,912

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 Private Securities Litigation Reform Act of 1995. 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 timing of obtaining necessary regulatory approvals; ability to develop product distribution channels; uncertainty relating to patent protection and potential patent infringement claims; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; loss or impairment of sources of capital; 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 and 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 and civil unrest; 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 the Company's filings with the Securities and Exchange Commission, including its registration statements, its Annual Report on Form 10-K for the year ended December 31, 2001, and its Quarterly Reports on Form 10-Q. Although forward-looking statements help to provide information about future prospects, they may not be reliable. The forward-looking statements are made as of the date of this Report and the Company undertakes no duty to update these statements.

Results of Operations

Three months ended June 30, 2002 compared to June 30, 2001

Total revenues decreased 7% to approximately $7.9 million in the second quarter of 2002 from approximately $8.5 million in the comparable quarter in 2001, primarily as a result of lower licensing and product development revenue, lower analytical equipment sales in the substance abuse testing market, and decreased sales of the Histofreezer(R) portable cryosurgical system in the physicians' office therapies market, partially offset by increased sales of OraSure(R) oral fluid collection devices and test kits in the infectious disease testing market. Product revenues for the second quarter of 2002 decreased approximately 3% to $7.9 million compared to $8.1 million for the second quarter of 2001.

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 June 30,				
	Dollars		%	Percentage of Total Revenues	
Market Revenues	2002	2001	Change	2002	2001
Insurance risk assessment	$ 3,120	$ 3,255	-4%	39%	39%
Infectious disease testing	1,564	1,277	22%	20%	15%
Substance abuse testing	1,776	1,990	-11%	22%	23%
Physicians' office therapies	1,414	1,559	-9%	18%	18%
Product revenues	7,874	8,081	-3%	99%	95%
Licensing and product development	56	427	-87%	1%	5%
Total revenues	$ 7,930	$ 8,508	-7%	100%	100%

Sales to the insurance risk assessment market declined by 4% to approximately $3.1 million in the second quarter of 2002 as a result of continuing efficiency in processing urine tests at LabOne, Inc., the Company's largest customer. This efficiency is expected to have a continuing effect on the Company, resulting in an annualized revenue reduction of up to $1.0 million during 2002, based on the Company's 2001 urine test sales volumes.

Sales to the infectious disease testing market increased 22% to approximately $1.6 million in the second quarter of 2002, primarily as a result of an approximate 25% increase in the sale of OraSure(R) oral fluid HIV-1 collection devices and test kits. Offsetting this increase were reduced sales of the Company's OraQuick(R) rapid HIV antibody test.

Sales to the infectious disease testing market are expected to increase as a result of the Company's recently announced agreement with Abbott Laboratories ("Abbott") for the distribution of the Company's OraQuick(R) rapid HIV-1 antibody test. Under the terms of the agreement, Abbott was appointed as

co-exclusive distributor of the OraQuick(R) HIV-1 device in the United States and is required to meet certain minimum purchase commitments. Pursuant to these commitments, the Company expects to receive product revenues of approximately $4.0 million through the end of 2003. These expected revenues and the timing of their receipt are subject to the Company's receipt of final U.S. Food and Drug Administration ("FDA") approval of the OraQuick(R) test during the third quarter of 2002.

Sales to the substance abuse testing market declined 11% to approximately $1.8 million as a result of a reduction of approximately $400,000 in analytical equipment sales and lower oral fluid collection device sales, partially offset by increased sales of Intercept(R) oral fluid drug assays for workplace testing and sales of the Company's toxicology testing products.

During the second quarter of 2002, the Company devoted significant efforts to assisting its three newest Intercept(R) laboratory distributors, Quest Diagnostics, Clinical Reference Laboratory and NWT, Inc., with the installation of their oral fluid testing equipment and the training of their sales and technical personnel. These distributors are now able to process oral fluid samples and have begun selling the Intercept(R) drug testing system into the workplace testing market. Subject to the continued successful startup of sales efforts by these distributors, the Company expects Intercept(R) revenues to increase in the second half of 2002 and during 2003.

Sales of the Company's Histofreezer(R) portable cryosurgical system in the physicians' office therapies market decreased 9% to approximately $1.4 million in the second quarter of 2002. This decrease was primarily the result of distributors increasing their inventory levels in the first quarter of 2002 as a result of an announced price increase in

the U.S. market, which became effective on April 1, 2002. It is expected that the quarterly sales level in the U.S. will return to a more normal pattern beginning in the third quarter of 2002.

Licensing and product development revenue decreased 87% to $56,000 in the second quarter of 2002 from $427,000 in 2001. During the first quarter of 2001, the Company received certain development milestone payments from Meridian BioSciences and Drager Safety and certain funded research and development payments from the National Institutes of Health pursuant to a Phase II Small Business Innovation Research ("SBIR") grant. There were no such payments during the second quarter of 2002.

The Company's gross margin decreased to 60% in the second quarter of 2002 from 65% in 2001. This decrease was primarily attributable to the lower amount of licensing and product development revenues and higher scrap rates in the second quarter of 2002.

Research and development expenses decreased 9% to approximately $2.2 million in the second quarter of 2002 from approximately $2.4 million in 2001, primarily as a result of lower consulting fees.

Sales and marketing expenses increased 16% to approximately $2.4 million in the second quarter of 2002 from approximately $2.1 million in 2001. This increase was primarily the result of higher consulting fees for the development of strategic marketing plans partially offset by lower travel costs.

General and administrative expenses decreased 7% to approximately $1.5 million in the second quarter of 2002 from approximately $1.6 million in 2001. This

decrease was primarily attributable to lower investor relations expenses and executive recruiting fees.

Interest expense decreased to approximately $79,000 in the second quarter of 2002 from approximately $103,000 in 2001 as a result of lower outstanding loan balances. Interest income decreased to approximately $151,000 in the first quarter of 2002 from approximately $207,000 in 2001, as a result of lower cash and cash equivalents available for investment and lower interest rates on the Company's investments.

The Company recorded a foreign currency gain of approximately $2,000 in the second quarter of 2002 compared to a foreign currency gain of approximately $54,000 in the second quarter of 2001.

During the second quarter of 2001, a provision for foreign income taxes of approximately $6,000 was recorded.

Results of Operations

Six months ended June 30, 2002 compared to June 30, 2001

Total revenues decreased 2% to approximately $15.7 million for the six months ended June 30, 2002 from approximately $15.9 million in the comparable six month period in 2001, primarily as a result of lower licensing and product development revenue and lower assay sales in the insurance risk assessment market, partially offset by increased sales of OraSure(R) oral fluid collection devices and test kits in the infectious disease testing market and increased sales of the Histofreezer(R) portable cryosurgical product in the physicians' office therapies market. Product revenues for the first six months of 2002 increased approximately 2% to $15.3 million compared to $15.0 million for the first six months of 2001.

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	2002	2001	Change	2002	2001
Insurance risk assessment	$ 5,913	$ 6,391	-7%	38%	40%
Infectious disease testing	3,034	2,652	14%	19%	17%
Substance abuse testing	3,003	3,150	-5%	19%	20%
Physicians' office therapies	3,393	2,779	22%	22%	17%
Product revenues	15,343	14,972	2%	98%	94%
Licensing and product development	313	940	-67%	2%	6%
Total revenues	$ 15,656	$ 15,912	-2%	100%	100%

Sales to the insurance risk assessment market declined by 7% to approximately $5.9 million for the six months ended June 30, 2002 from approximately $6.4 million in the comparable period in 2001, as a result of continuing efficiency in processing urine tests at LabOne, Inc., the Company's largest customer.

Sales to the infectious disease testing market increased 14% to approximately $3.0 million for the six months ended June 30, 2002 from approximately $2.7 million in the comparable period in 2001, primarily as a result of an approximate 28% increase in the sale of OraSure(R) oral fluid HIV-1 collection devices and test kits. Offsetting this increase were reduced sales of the Company's OraQuick(R) rapid HIV test, which accounted for approximately $300,000 in revenues for the first six months of 2001.

Sales to the substance abuse testing market declined 5% to approximately $3.0 million for the six months ended June 30, 2002 from approximately $3.2 million in the comparable period in 2001, as a result of a reduction of approximately $400,000 in analytical equipment sales and lower oral fluid collection device sales offset by increases in sales of Intercept(R) oral fluid drug assays for workplace testing and sales of the Company's toxicology testing products.

Sales of the Company's Histofreezer(R) products in the physicians' office therapies market increased 22% to approximately $3.4 million for the six months ended June 30, 2002 from approximately $2.8 million in the comparable period in 2001. This increase was primarily the result of distributors increasing their inventory levels in the first quarter of 2002 as a result of an announced price increase in the U.S. market, which became effective on April 1, 2002.

Licensing and product development revenue decreased 67% to approximately $300,000 for the six months ended June 30, 2002 from approximately $0.9 million in the comparable period in 2001. During the six months ended June 30, 2001, the Company received certain development milestone payments from Meridian BioSciences and Drager Safety and certain funded research and development payments from the National Institutes of Health pursuant to a Phase II SBIR grant. There were no such payments during the six months ended June 30, 2002.

The Company's gross margin decreased to approximately 61% for the six months ended June 30, 2002 from 64% for the comparable period in 2001. The decrease was primarily attributable to the lower amount of licensing and product development revenues and higher scrap rates in the first six months of 2002.

Research and development expenses remained flat at approximately $4.6 million for the six months ended June 30, 2002. Increased costs associated with clinical trials and the Company's efforts to obtain FDA approval of the OraQuick(R) HIV-1 rapid antibody test were offset by decreased expenditures for consulting and travel.

Sales and marketing expenses increased 12% to approximately $4.4 million for the six months ended June 30, 2002 from approximately $3.9 million in the comparable period in 2001. This increase was primarily the result of consulting fees for the development of strategic marketing plans, partially offset by lower travel costs.

General and administrative expenses increased 16% to approximately $3.6 million for the six months ended June 30, 2002 from approximately $3.1 million for the comparable period in 2001. This increase was primarily attributable to an approximate $0.5 million severance charge related to the departure of the Company's former Chief Executive Officer.

Restructuring-related expenses were $450,000 in the six months ended June 30, 2001 as a result of a manufacturing restructuring. There was no such charge in the first six months of 2002.

Interest expense decreased to approximately $163,000 for the six months ended June 30, 2002 from approximately $209,000 for the comparable period in 2001, as a result of lower outstanding loan balances. Interest income decreased to approximately $304,000 for the six months ended June 30, 2002 from approximately $501,000 for the comparable period in 2001, as a result of lower cash and cash equivalents available for investment and lower interest rates on the Company's investments.

The Company recorded a foreign currency gain of approximately $2,000 for the six months ended June 30, 2002 compared to a foreign currency gain of approximately $118,000 for the comparable period in 2001.

During the six months ended June 30, 2001, a provision for foreign income taxes of approximately $22,000 was recorded.

Liquidity and Capital Resources

	June 30, 2002	December 31, 2001
	(In thousands)	
Cash and cash equivalents	$ 1,437	$ 2,426
Short-term investments	10,874	12,765
Working capital	17,003	19,764

The Company's cash, cash equivalents and short-term investments decreased approximately $2.9 million during the first six months of 2002 to approximately $12.3 million at June 30, 2002, primarily as a result of the Company's net loss for the first six months of 2002, a reduction of accounts payable and accrued expenses, the repayment of long-term debt, certain capital expenditures, and an increase in inventory levels. Offsetting these uses of cash were an increase in accounts receivable collections and proceeds from stock option exercises. At June 30, 2002, the Company's working capital was approximately $17.0 million.

The combination of the Company's current cash position and borrowings under the Company's existing and planned credit facilities is expected to be sufficient to fund the Company's foreseeable operating and capital needs. However, the Company's cash requirements may vary materially from those now planned due to many factors, including, but not limited to, the progress of the Company's 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 in obtaining regulatory approvals, the costs involved in obtaining and enforcing patents, proprietary rights and any necessary licenses, the ability of the Company to establish development and commercialization capacities or relationships, the costs of manufacturing, the success of the Company's sales and marketing efforts, market acceptance of new products and other factors.

Net cash used in operating activities was approximately $2.0 million for the six months ended June 30, 2002, primarily as a result of the net loss for the period, increased inventory levels and the reduction of accounts payable and accrued expenses, offset by increased accounts receivable collections.

Net cash provided by investing activities for the six months ended June 30, 2002 was approximately $1.1 million, primarily as a result of $1.8 million in net proceeds received from the sale of short-term investments offset by the purchase of approximately $0.7 million of capital equipment.

Net cash used in financing activities was approximately $100,000 for the six months ended June 30, 2002 as a result of approximately $0.5 million of term debt repayments offset by approximately $400,000 in proceeds from the exercise of stock options.

At June 30, 2002, the Company had a $1.0 million working capital line of credit in place that accrues interest at LIBOR plus 235 basis points and a $3.0 million equipment line of credit in place that accrues interest at a rate fixed at prime at the time of draw down. There were no borrowings under these lines of credit at June 30, 2002. These lending facilities expire on August 31, 2002 and are expected to be replaced with other credit or bank facilities, although there can be no assurance that the Company will be successful in this effort.

Critical Accounting Policies and Estimates

Management's Discussion and Analysis of Financial Condition and Results of Operations discusses the Company's financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to 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, management evaluates its judgments and estimates, including those related to bad debts, inventories, investments, intangible assets, income taxes, revenue recognition, contingencies, and litigation. Management bases its 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.

Management considers the following policies to be most critical in understanding the more complex judgments that are involved in preparing the Company's financial statements and the uncertainties that could impact its results of operations, financial condition, and cash flows.

Revenue Recognition. The Company follows 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. The Company licenses certain products or technology to outside third parties, in return for which the Company receives up-front licensing fees, some of which can be significant. In accordance with SAB 101, the Company is required to defer immediate recognition of these fees as revenue, and instead ratably recognize this revenue over the related license period.

The Company also enters into research and development contracts with corporate, government or private entities. These contracts generally provide for payments to the Company 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.

The Company recognizes product revenues when products are shipped. The Company does not grant price protection or product return rights to its customers, except for warranty returns. Where a product fails to comply with its limited warranty, the Company 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, the Company expenses warranty returns as incurred. While such returns have been immaterial in the past, management cannot guarantee that the Company will continue to experience the same low rate of warranty claims as it has in the past. Any significant increase in product warranty claims could have a material adverse impact on the Company's operating results for the period in which such 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, management performs credit evaluations of the Company's customers and adjusts credit limits based upon the customer's payment history and creditworthiness, as determined by a review of their current credit information. The Company continuously monitors collections and payments from its customers. Based upon the Company's historical experience and any specific customer collection issues that are identified, management uses its judgment to establish and evaluate the adequacy of the Company's allowance for estimated credit losses. While such credit losses have been within the Company's expectations and the allowance provided, the Company cannot guarantee that it will continue to experience the same credit loss rates as it has in the past. Furthermore, some of the Company's accounts receivable have resulted from sales to distributors located in foreign countries. Any significant changes in the liquidity or financial position of its customers, or the economies of certain foreign nations, could have a material adverse impact on the collectibility of the Company's accounts receivable and its future operating results.

Inventories. The Company's 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 the Company's inventories are subject to expiration dating. The Company continually evaluates the carrying value of its 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. Management bases these decisions on the level of inventories on hand in relation to the Company's estimated forecast of product demand, production requirements over the next twelve months and the expiration dates of raw materials and finished goods. Although the Company makes every effort to ensure the accuracy of its forecasts of future product demand, any significant unanticipated changes in demand could have a significant impact on the carrying value of the Company's inventories and its reported operating results.

Contingencies. In the ordinary course of business, the Company has entered into various contractual relationships with strategic corporate partners, customers, distributors, research laboratories and universities, licensors, licensees, suppliers, vendors and other parties. As such, the Company could be subject to litigation, claims or assessments arising from any or all of these relationships. The Company accounts for contingencies such as these in accordance with Statement of Financial Accounting Standards ("SFAS") No. 5, "Accounting for Contingencies". SFAS No. 5 requires the Company to record an estimated loss contingency when information available prior to issuance of the

Company's 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 Company management to use its best judgment when estimating an accrual related to such contingencies. As additional information becomes known, the Company's accrual for a loss contingency could fluctuate, thereby creating variability in the Company's results of operations from period to period. Likewise, an actual loss arising from a loss contingency which significantly exceeds the amount accrued for in the Company's financial statements could have a material adverse impact on the Company's operating results for the period in which such actual loss becomes known.

Income Taxes. The Company has a history of losses, which has generated a sizeable federal tax net operating loss ("NOL") carryforward of approximately $69.1 million as of December 31, 2001. Generally accepted accounting principles require the Company to record a valuation allowance against the deferred tax asset associated with this NOL carryforward if it is more likely than not that the Company will not be able to utilize the NOL carryforward to offset future taxes. Due to the size of the NOL carryforward in relation to the Company's history of unprofitable operations, the Company has not recognized any of this net deferred tax asset.

It is possible that the Company could be profitable in the future at levels which would cause management to conclude that it is more likely than not that the Company will be able to realize all or a portion of the NOL carryforward. Upon reaching such a conclusion, the Company 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 the Company's combined federal and state effective rates, which management believes would approximate 40%. Subsequent revisions to the estimated net realizable value of the deferred tax asset could cause the Company's provision for income taxes to vary significantly from period to period.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

The Company does not hold any amounts of derivative financial instruments or derivative commodity instruments, and accordingly, has no material derivative risk to report under this Item.

The Company's 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. The Company's debt security portfolio represents funds held temporarily pending use in its business and operations. The Company seeks 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, the Company could decide to hold the security to maturity or sell the security. The Company's holdings are also exposed to the risk of change in the credit quality of issuers. The Company typically invests in the shorter end of the maturity spectrum.

The Company does not currently have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. The Company has operations in The Netherlands that 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. Revenues generated in The Netherlands represented approximately $530,000 and $908,000 or 6.7% and 5.8% of the Company's total revenues for the three months and six months ended June 30, 2002, respectively. Management does not expect the risk of foreign currency fluctuations to be material.

PART II. OTHER INFORMATION

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

At the 2002 Annual Meeting of Stockholders of the Company (the "Annual Meeting") held on May 20, 2002, the following individuals were elected by the votes indicated as Class II directors of the Company for terms expiring at the 2005 Annual Meeting of Stockholders:

Nominee	Votes For	Votes Withheld
William W. Crouse	34,271,886	980,750
Roger L. Pringle	34,303,127	949,509

Following the Annual Meeting, Michael G. Bolton retired from the Board and his service as a Director of the Company ended at that time. The other directors whose terms of office continued after the Annual Meeting are: Michael J. Gausling, Frank G. Hausmann, Gregory B. Lawless, and Carter H. Eckert. At a meeting of the Board following the Annual Meeting, Richard J. Lane and Douglas G. Watson were elected to fill vacancies on the Board.

At the Annual Meeting, stockholders also approved an amendment to the OraSure Technologies, Inc. 2000 Stock Award Plan (the "Plan"), which increased the number of shares authorized for issuance under the Plan by 1,800,000 shares, from 2,500,000 shares to 4,300,000 shares, plus other shares that become available under the terms of the Plan. Voting results on the amendment were as follows: 32,433,741 shares were voted for the amendment, 2,695,181 shares were voted against this amendment, and 123,714 shares abstained. There were no broker non-votes.

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, 2002, reporting the Company's announcement of financial results for the quarter ended March 31, 2002, and certain other matters.

Current Report on Form 8-K, dated May 13, 2002, reporting the Company's announcement of its receipt of notification from the U.S. Food and Drug Administration that the Company's OraQuick(R) Rapid HIV-1 Antibody Test is approvable, subject to the Company meeting certain conditions.

Current Report on Form 8-K, dated May 21, 2002, reporting the Company's announcement of its dismissal of Arthur Andersen LLP as its independent public

accountants and the appointment of KPMG LLP as the Company's independent public accountants for the year ending December 31, 2002.

Current Report on Form 8-K, dated June 17, 2002, reporting the Company's announcement of its agreements with Abbott Laboratories for the co-exclusive distribution of the Company's OraQuick(R) rapid test for the detection of antibodies of the Human Immunodeficiency Virus Type I, and for a non-exclusive sublicense of certain lateral-flow patents for which Abbott Laboratories is the exclusive licensor.

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: July 31, 2002
Ronald H. Spair
Executive Vice President and
Chief Financial Officer
(Principal Financial Officer)

/s/ Mark L. Kuna

Date: July 31, 2002
Mark L. Kuna
Controller
(Principal Accounting Officer)

EXHIBIT INDEX

Exhibit	
10.1	OraSure Technologies, Inc. 2000 Stock Award Plan, amended effective as of May 20, 2002.
10.2	Description of OraSure Technologies, Inc. 2002 Employee Cash Bonus Plan
99.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
99.2	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.