

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarter ended March 31, 2001.

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
(Address of Principal Executive Offices)

18015
(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 May 9, 2001: 36,625,703

PART I. FINANCIAL INFORMATION

Table with 2 columns: Item Description and Page No. Includes items like Financial Statements (Unaudited), Management's Discussion and Analysis, and Quantitative and Qualitative Disclosures about Market Risk.

PART II. OTHER INFORMATION

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Item 1. FINANCIAL STATEMENTS

ORASURE TECHNOLOGIES, INC.
BALANCE SHEETS
(UNAUDITED)

| | MARCH 31, 2001 ----- | DECEMBER 31, 2000 ----- |
|--|-------------------------|----------------------------|
| ASSETS | | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | \$ 6,030,738 | \$ 5,095,639 |
| Short-term investments | 10,638,537 | 14,956,779 |
| Accounts receivable, net of allowance for doubtful accounts of \$107,138 and \$114,685 | 5,942,355 | 5,276,772 |
| Notes receivable from officer | 181,318 | 175,649 |
| Inventories | 1,847,373 | 1,495,604 |
| Prepaid expenses and other | 1,105,796 | 1,189,210 |
| | ----- | ----- |
| Total current assets | 25,746,117 | 28,189,653 |
| | ----- | ----- |
| PROPERTY AND EQUIPMENT, net | 7,011,092 | 6,738,034 |
| PATENTS AND PRODUCT RIGHTS, net | 2,312,423 | 2,402,386 |
| OTHER ASSETS | 387,700 | 406,099 |
| | ----- | ----- |
| | \$ 35,457,332 | \$ 37,736,172 |
| | ===== | ===== |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| CURRENT LIABILITIES: | | |
| Current portion of long-term debt | \$ 1,146,921 | \$ 1,125,138 |
| Accounts payable | 1,575,740 | 1,522,295 |
| Accrued expenses | 2,870,722 | 4,047,231 |
| | ----- | ----- |
| Total current liabilities | 5,593,383 | 6,694,664 |
| | ----- | ----- |
| LONG-TERM DEBT | 4,347,713 | 4,644,098 |
| | ----- | ----- |
| OTHER LIABILITIES | 209,631 | 225,334 |
| | ----- | ----- |
| STOCKHOLDERS' EQUITY: | | |
| Preferred stock, par value \$.000001, 25,000,000 shares authorized, none issued | - | - |
| Common stock, par value \$.000001, 120,000,000 shares authorized, 36,510,733 and 36,434,004 shares issued and outstanding | 36 | 36 |
| Additional paid-in capital | 149,057,565 | 148,767,789 |
| Accumulated other comprehensive loss | (389,735) | (231,247) |
| Accumulated deficit | (123,361,261) | (122,364,502) |
| | ----- | ----- |
| Total stockholders' equity | 25,306,605 | 26,172,076 |
| | ----- | ----- |
| | \$ 35,457,332 | \$ 37,736,172 |
| | ===== | ===== |

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.
STATEMENTS OF OPERATIONS (UNAUDITED)

| | THREE MONTHS ENDED MARCH 31, | |
|--|------------------------------|--------------|
| | 2001 | 2000 |
| | ----- | ----- |
| REVENUES: | | |
| Product | \$ 6,890,727 | \$ 6,487,499 |
| Licensing and product development | 513,297 | 131,874 |
| | ----- | ----- |
| | 7,404,024 | 6,619,373 |
| | ----- | ----- |
| COSTS AND EXPENSES: | | |
| Cost of products sold | 2,693,644 | 2,508,977 |
| Research and development | 2,166,659 | 1,717,305 |
| Sales and marketing | 1,860,362 | 1,396,823 |
| General and administrative | 1,465,511 | 1,889,187 |
| Restructuring-related | 450,000 | - |
| | ----- | ----- |
| | 8,636,176 | 7,512,292 |
| | ----- | ----- |
| Operating loss | (1,232,152) | (892,919) |
| INTEREST EXPENSE | (105,564) | (128,165) |
| INTEREST INCOME | 293,629 | 227,862 |
| FOREIGN CURRENCY GAIN | 63,295 | 15,424 |
| | ----- | ----- |
| Loss before income taxes | (980,792) | (777,798) |
| INCOME TAXES | 15,967 | 55,950 |
| | ----- | ----- |
| NET LOSS | \$ (996,759) | \$ (833,748) |
| | ===== | ===== |
| BASIC AND DILUTED NET LOSS PER SHARE | \$ (0.03) | \$ (0.03) |
| | ===== | ===== |
| WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING | 36,456,576 | 33,441,765 |
| | ===== | ===== |

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.
STATEMENT OF STOCKHOLDERS' EQUITY (Unaudited)

| | COMMON STOCK | | ADDITIONAL | ACCUMULATED OTHER COMPREHENSIVE | INCOME | ACCUMULATED | TOTAL |
|---|--------------|--------|-----------------|---------------------------------------|-----------------|-------------|--------------|
| | SHARES | AMOUNT | PAID-IN CAPITAL | (LOSS) | DEFICIT | | ----- |
| BALANCE AT DECEMBER 31, 2000 | 36,434,004 | \$36 | \$148,767,789 | \$(231,247) | \$(122,364,502) | | \$26,172,076 |
| Common stock issued upon exercise of options | 76,729 | - | 219,196 | - | - | | 219,196 |
| Compensation expense for stock option grants | - | - | 70,580 | - | - | | 70,580 |
| Comprehensive loss: | | | | | | | ----- |
| Net loss | - | - | - | - | (996,759) | | (996,759) |
| Currency translation adjustment | - | - | - | (108,213) | - | | (108,213) |
| Unrealized loss on marketable securities | - | - | - | (50,275) | - | | (50,275) |
| Total comprehensive loss | - | - | - | - | - | | (1,155,247) |
| | ----- | --- | ----- | ----- | ----- | | ----- |
| BALANCE AT MARCH 31, 2001 | 36,510,733 | \$36 | \$149,057,565 | \$(389,735) | \$(123,361,261) | | \$25,306,605 |
| | ===== | === | ===== | ===== | ===== | | ===== |

The accompanying notes are an integral part of these statements.

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

| | THREE MONTHS ENDED MARCH 31, | |
|---|------------------------------|--------------|
| | 2001 | 2000 |
| | ----- | ----- |
| OPERATING ACTIVITIES: | | |
| Net loss | \$ (996,759) | \$ (833,748) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Stock based compensation expense | 70,580 | 28,373 |
| Amortization of deferred revenue | (35,833) | (35,833) |
| Depreciation and amortization | 502,601 | 422,850 |
| Loss on disposition of assets | 7,283 | 40 |
| Changes in assets and liabilities: | | |
| Accounts receivable | (665,583) | (657,733) |
| Inventories | (351,769) | (10,945) |
| Prepaid expenses and other assets | 99,294 | (19,155) |
| Accounts payable and accrued expenses | (1,102,934) | (499,129) |
| | ----- | ----- |
| Net cash used in operating activities | (2,473,120) | (1,605,280) |
| | ----- | ----- |
| INVESTING ACTIVITIES: | | |
| Purchases of short-term investments | (11,218,333) | (6,247,322) |
| Proceeds from the sale of short-term investments | 15,483,150 | 6,896,239 |
| Purchases of property and equipment | (720,943) | (750,194) |
| Proceeds from the sale of property and equipment | 27,964 | - |
| Purchase of patents and product rights | - | (7,649) |
| Investment in affiliated company | - | (10,095) |
| | ----- | ----- |
| Net cash provided by (used in) investing activities | 3,571,838 | (119,021) |
| | ----- | ----- |
| FINANCING ACTIVITIES: | | |
| Proceeds from issuance of common stock | 219,196 | 8,306,837 |
| Repayments of term debt | (274,602) | (256,638) |
| | ----- | ----- |
| Net cash provided by (used in) financing activities | (55,406) | 8,050,199 |
| | ----- | ----- |
| EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH | (108,213) | (17,094) |
| | ----- | ----- |
| NET INCREASE IN CASH AND CASH EQUIVALENTS | 935,099 | 6,308,804 |
| CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD | 5,095,639 | 2,049,644 |
| | ----- | ----- |
| CASH AND CASH EQUIVALENTS, END OF PERIOD | \$ 6,030,738 | \$ 8,358,448 |
| | ===== | ===== |

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, oral fluid assays, proprietary diagnostic products including in vitro diagnostic tests, and other medical devices. These products are sold to public and private-sector clients, clinical laboratories, physician offices, hospitals, and for workplace testing in the United States and certain foreign countries.

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, 2000. Results of operations for the period ended March 31, 2001 are not necessarily indicative of the results of operations expected for the full year. Certain reclassifications have been made to the prior year financial statements to conform to the current year presentation.

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:

| | MARCH 31, 2001 | DECEMBER 31, 2000 |
|-----------------|-------------------|----------------------|
| | ----- | ----- |
| Raw materials | \$ 584,961 | \$ 473,575 |
| Work-in-process | 430,862 | 348,819 |
| Finished goods | 831,550 | 673,210 |
| | ----- | ----- |
| | \$1,847,373 | \$1,495,604 |
| | ===== | ===== |

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. Up-front licensing fees are deferred and recognized ratably over the related license period. Product development revenues are recognized over the period the related product development efforts are performed. Amounts received prior to the performance of product development efforts are recorded as deferred revenues.

In December 1999, the U.S. Securities and Exchange Commission issued 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 license and development fees. The Company has applied the provisions of SAB 101 in the accompanying financial statements.

SIGNIFICANT CUSTOMER CONCENTRATION. In the first quarter of 2001, one customer accounted for 24 percent of total revenues as compared to 23 percent for the same quarter of 2000. The Company believes its relationship with this customer is strong and that the customer will purchase comparable or increasing volumes of the Company's products for the foreseeable future. There can be no assurance, however, that sales to this customer will not decrease or that this customer will not choose to replace the Company's products with those of competitors. The loss of this customer or a significant decrease in the volume of products purchased by it would have a material adverse effect on the Company.

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 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 128"), and the Securities and Exchange Commission Staff Accounting Bulletin No. 98. In accordance with SFAS 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 4,596,878 and 5,606,622 shares were excluded from the computation of diluted net loss per common share for the three month periods ended March 31, 2001 and 2000, 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 realign certain of its manufacturing operations. Accordingly, during the three months ended March 31, 2001, the Company incurred \$450,000 in non-recurring restructuring costs, primarily comprised of expenses for employee severance, travel and transport resulting from relocating and consolidating manufacturing operations. As of March 31, 2001, approximately \$135,000 of restructuring costs, which will be paid in the second quarter of 2001, were included in accrued expenses.

3. SEGMENT AND 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. Operating income and identifiable assets are not included herein 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 MONTHS ENDED MARCH 31, | |
|---------------|---|---------|
| | 2001 | 2000 |
| United States | \$5,962 | \$5,936 |
| Europe | 950 | 423 |
| Other regions | 492 | 260 |
| | ----- | ----- |
| | \$7,404 | \$6,619 |
| | ===== | ===== |

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. 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; equipment failures and ability to obtain needed raw materials and components; and general business and economic conditions. These and other factors that could cause the forward-looking statements to be materially different are described in greater detail in the Sections entitled, "Forward-Looking Statements" and "Risk Factors," in Item 1 and elsewhere in the Company's Annual Report on Form 10-K for the year ended December 31, 2000. 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

Comparative results of operations (in thousands, except %) are summarized as follows:

| | Three Months Ended March 31, | | | | |
|---------------------------------|------------------------------|----------|-----------------------|------------------------------------|------|
| | Dollars | | Percent Change (%) | Percentage of Total Revenue (%) | |
| | 2001 | 2000 | | 2001 | 2000 |
| Revenue | | | | | |
| Product | \$6,891 | \$6,487 | 6 | 93 | 98 |
| License and product development | 513 | 132 | 289 | 7 | 2 |
| | 7,404 | 6,619 | 12 | 100 | 100 |
| Cost and expenses | | | | | |
| Cost of products sold | 2,694 | 2,509 | 7 | 36 | 38 |
| Research and development | 2,167 | 1,717 | 26 | 29 | 26 |
| Sales and marketing | 1,860 | 1,397 | 33 | 25 | 21 |
| General and administrative | 1,465 | 1,889 | (22) | 20 | 29 |
| Restructuring-related | 450 | - | N/A | 6 | - |
| | 8,636 | 7,512 | 15 | 117 | 113 |
| Operating loss | (1,232) | (893) | (38) | (17) | (13) |
| Interest expense | (106) | (128) | 17 | (1) | (2) |
| Interest income | 294 | 228 | 29 | 4 | 3 |
| Foreign currency gain | 63 | 15 | 320 | 1 | 0 |
| Loss before income taxes | (981) | (778) | (26) | (13) | (12) |
| Income taxes | 16 | 56 | 71 | - | 1 |
| Net Loss | \$ (997) | \$ (834) | (20) | (13) | (13) |

Total revenue increased 12% to approximately \$7.4 million in the first quarter of 2001 from approximately \$6.6 million in the comparable quarter in 2000, primarily as a result of strong international demand. Excluding revenue in the prior period for the discontinued Serum Western Blot product line, total revenue would have increased 18%.

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

| | Three Months Ended March 31, | | | | |
|-------------------------------------|------------------------------|---------|-----------------------|------------------------------------|------|
| | Dollars | | Percent Change (%) | Percentage of Total Revenue (%) | |
| | 2001 | 2000 | | 2001 | 2000 |
| Product revenue | | | | | |
| Oral specimen collection devices | \$ 3,253 | \$2,528 | 29 | 44 | 38 |
| OraQuick | 234 | - | N/A | 3 | 0 |
| Histofreezer cryosurgical systems | 1,220 | 1,364 | (11) | 16 | 21 |
| Immunoassay tests | 1,670 | 1,762 | (5) | 23 | 27 |
| Western Blot HIV confirmatory tests | 224 | 416 | (46) | 3 | 6 |
| Other product revenue | 290 | 417 | (30) | 4 | 6 |
| | ----- | ----- | | --- | --- |
| | 6,891 | 6,487 | 6 | 93 | 98 |
| License and product development | 513 | 132 | 289 | 7 | 2 |
| | ----- | ----- | | --- | --- |
| Total revenues | \$7,404 | \$6,619 | 12 | 100 | 100 |
| | ===== | ===== | | === | === |

Product revenue increased 6% to approximately \$6.9 million for the first quarter of 2001 from approximately \$6.5 million in the first quarter of 2000. Sales of oral specimen collection devices increased 29% to approximately \$3.3 million as a result of increased sales to the public health market. Histofreezer revenues decreased 11% to approximately \$1.2 million largely as a result of sales staffing turnover and inventory consolidation at the distributor level in the U.S. market. OraQuick, which began shipping in December 2000, generated approximately \$234,000 of revenue for the first quarter as a result of market introduction into sub-Saharan Africa. Intercept generated approximately \$470,000 in revenue as a result of strong demand both domestically and internationally. Immunoassay test sales decreased 5% to approximately \$1.7 million in the first quarter of 2001. During the first quarter of 2000, immunoassay test sales increased in the life insurance testing market as a result of regulatory changes in life insurance policy reserve levels. Sales of the Western Blot products declined 46% to approximately \$224,000 for the first quarter as a result of the discontinuation of the Serum Western Blot product in January 2001. Other revenues, which consisted primarily of sales of the Q.E.D. saliva alcohol test, declined 30% to approximately \$290,000 as a result of a non-recurring international Q.E.D. sale to a single client in the first quarter of 2000. As a percentage of product revenues, international product sales increased to approximately 18% in the first quarter of 2001 from 11% in 2000 as a result of increased international sales of the Histofreezer product and oral fluid collection devices.

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

| | Three Months Ended March 31, | | | | |
|---------------------------------|------------------------------|---------|--------------------|---------------------------------|------|
| | Dollars | | | Percentage of Total Revenue (%) | |
| | 2001 | 2000 | Percent Change (%) | 2001 | 2000 |
| Market sales | | | | | |
| Insurance testing | \$2,933 | \$3,312 | (11) | 40 | 50 |
| Public health | 1,447 | 851 | 70 | 20 | 13 |
| Physician offices | 1,220 | 1,364 | (11) | 16 | 21 |
| Substance abuse testing | 1,184 | 822 | 44 | 16 | 12 |
| Other markets | 107 | 138 | (22) | 1 | 2 |
| | 6,891 | 6,487 | 6 | 93 | 98 |
| License and product development | 513 | 132 | 289 | 7 | 2 |
| Total revenues | \$7,404 | \$6,619 | 12 | 100 | 100 |

Sales to the insurance testing market declined by 11% to approximately \$2.9 million in the first quarter of 2001 as a result of the decreased activity in the life insurance testing market referred to above and the discontinuation of the Serum Western Blot product. Sales to the public health market increased 70% to approximately \$1.5 million in the first quarter as a result of increased penetration by the Company's higher priced public health HIV test kit and the initial OraQuick shipments to sub-Saharan Africa. Sales to physician offices, which consisted solely of the Histofreezer cryosurgical system, decreased 11% to approximately \$1.2 million in the first quarter of 2001 as a result of sales staff turnover and inventory consolidation at the distributor level in the U.S. market. Sales to the substance abuse testing market increased 44% to approximately \$1.2 million in the first quarter of 2001 as a result of the market introduction of Intercept and increased forensic toxicology sales.

License and product development revenue increased 289% to approximately \$513,000 in the first quarter of 2001 from approximately \$132,000 in 2000. This increase was attributable principally to additional income from the Company's research agreement with Drager to develop drugs-of-abuse analytes for the UPLink testing system.

The Company's gross margin increased to 64% in the first quarter of 2001 from 62% in 2000. The increase is the result of improved product mix, negotiated contract savings, and higher license and product development revenues, partially offset by the incremental costs associated with the ramp up of OraQuick manufacturing. Gross margins are anticipated to continue to improve in the second quarter of 2001 as a result of the Company's manufacturing restructuring.

In February 2001, the Company announced plans to restructure its manufacturing operations. The Company has since eliminated OraQuick manufacturing in Beaverton, Oregon and has commenced OraQuick assembly in Thailand. The restructuring provides greatly expanded capacity for OraQuick production, and is expected to have no financial impact in 2001.

Research and development expenses increased 26% to approximately \$2.2 million in the first quarter of 2001 from approximately \$1.7 million in 2000, as a result of continued development of the UPLink reader, test cassette and collector, DNA feasibility studies, the clinical trial expenses for the OraQuick HIV-1/2 rapid test, and additional Intercept products. Research and development expenses are expected to increase during 2001 as clinical trials for OraQuick and UPLink research activities continue.

Sales and marketing expenses increased 33% to approximately \$1.9 million in the first quarter of 2001 from approximately \$1.4 million in 2000. This increase was primarily the result of costs to develop and establish foreign markets for OraQuick, costs associated with the continued marketing of the Intercept drugs-of-abuse service, and expanded sales activities for the Company's other product lines.

General and administrative expenses decreased 22% to approximately \$1.5 million in the first quarter of 2001 from approximately \$1.9 million in 2000. This decrease reflects cost savings from the consolidation of duplicative overhead structures as a result of the merger of STC Technologies, Inc. and Epitepe, Inc. into the Company. General and administrative expenses, as a percentage of first quarter revenues, declined to 20% from 29% a year ago.

Restructuring-related expenses were approximately \$450,000 in the first quarter of 2001 as a result of the manufacturing restructuring. These non-recurring costs primarily included expenses for employee severance, travel and transport resulting from relocating and consolidating manufacturing operations.

Operating loss increased to approximately \$1.2 million in the first quarter ended March 31, 2001 from approximately \$893,000 in 2000 as a result of expenses associated with the manufacturing restructuring, increased research and development costs, and increased sales and marketing costs. Excluding the non-recurring manufacturing restructuring expenses, the operating loss would have been approximately \$782,000 in the first quarter of 2001.

Interest expense decreased by 17% to approximately \$106,000 in the first quarter of 2001 from approximately \$128,000 in 2000 as a result of principal loan repayments.

Interest income increased to approximately \$294,000 in the first quarter of 2001 from approximately \$228,000 in 2000 as a result of higher cash and cash equivalents available for investment.

Foreign currency gain was approximately \$63,000 in the first quarter of 2001 compared to a gain of approximately \$15,000 in 2000.

During the first quarter of 2001, a provision for foreign income taxes of approximately \$16,000 was recorded.

Net loss was approximately \$997,000 in the first quarter of 2001 compared to approximately \$834,000 in 2000. Excluding the non-recurring manufacturing restructuring expenses, the net loss would have been approximately \$547,000 in the first quarter of 2001.

LIQUIDITY AND CAPITAL RESOURCES

| | March 31, 2001 | December 31, 2000 |
|---------------------------|-------------------|----------------------|
| | ----- | ----- |
| | (In thousands) | |
| Cash and cash equivalents | \$ 6,031 | \$ 5,096 |
| Short-term investments | 10,639 | 14,957 |
| Working capital | 20,153 | 21,495 |

The Company's cash, cash equivalents and short-term investments position decreased \$3.4 million during the first quarter of 2001 to approximately \$16.7 million at March 31, 2001, primarily as a result of the first quarter loss, increased accounts receivable and inventory levels, and an upgrade of the Bethlehem manufacturing facility. At March 31, 2001, the Company's working capital was approximately \$20.2 million.

The combination of the Company's current cash position, available borrowings under the Company's credit facilities, and the Company's cash flow from operations 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, changes in existing and potential relationships with strategic 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, market acceptance of new products and other factors.

Net cash used in operating activities was approximately \$2.5 million for the first quarter of 2001, as a direct result of the first quarter net loss, increased accounts receivable and inventory levels caused by continued sales growth, and the payment of certain year-end accruals.

Net cash provided by investing activities during the first quarter of 2001 was approximately \$3.6 million as a result of the sale of securities to fund short-term cash needs. In addition, the Company also made \$721,000 of capital expenditures, primarily reflecting the Company's investment into the Bethlehem facility in anticipation of the installation of fully automated lateral flow manufacturing equipment.

Net cash used in financing activities was approximately \$55,000 during the first quarter of 2001 as a result of term debt repayments, partially offset by the proceeds from the issuance of approximately \$219,000 of common stock, as a result of option exercises.

At March 31, 2001, 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 \$1.0 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 March 31, 2001. These lending facilities expire June 30, 2001 and are expected to be renewed.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

The Company does not hold any derivative financial instruments or derivative commodity instruments, and does not hold material amounts of other financial instruments. Accordingly, the Company has no material market 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 continues to hold the security to maturity. The Company's holdings are also exposed to the risks of changes 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 which are subject to foreign currency fluctuations. As currency rates change, translation of income statements of these operations from local currencies to U.S. dollars affects year-to-year comparability of operating results. The Company's operations in The Netherlands represented approximately \$0.5 million or 6.1% of the Company's revenues for the three months ended March 31, 2001. Management does not expect the risk of foreign currency fluctuations to be material.

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 March 30, 2001, reporting under Item 5 certain additional information relating to the change from PricewaterhouseCoopers LLP to Arthur Andersen LLP as the Company's independent public accountants.

Current Report on Form 8-K dated April 2, 2001, filing under Item 5 a set of "Frequently Asked Questions" concerning the Company and answers to those questions.

SIGNATURES

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

ORASURE TECHNOLOGIES, INC.

Date: May 15, 2001

/s/ Richard D. Hooper
Richard D. Hooper
Vice President of Finance and
Chief Financial Officer
(Principal Financial Officer)

Date: May 15, 2001

/s/ Mark L. Kuna
Mark L. Kuna
Controller
(Principal Accounting Officer)

EXHIBIT INDEX

EXHIBIT

- 10 Description of Nonemployee Director Compensation Policy*
- 99 Description of OraSure Technologies Capital Stock

* Management contract or compensatory plan or arrangement

DESCRIPTION OF NONEMPLOYEE COMPENSATION POLICY

In December 2000, the Company adopted a compensation policy for nonemployee Directors (the "Policy"). Pursuant to the Policy, nonemployee Directors receive an annual fee for service on the Board of \$12,000 payable quarterly in advance. No additional fee is paid for service on a committee of the Board. Nonemployee Directors also receive an initial grant of 40,000 stock options upon joining the Board (the "Initial Grant") and an annual grant of 20,000 stock options each year thereafter (the "Annual Grant") on the annual option grant date for officers and employees of the Company. In April 2001, the Policy was amended to provide for an additional grant of 40,000 stock options for any Director who becomes Chairman of the Board (the "Chairman Grant") and to increase the Annual Grant for any nonemployee Director who serves as Chairman of the Board to 30,000 stock options.

The options granted to nonemployee Directors are nonqualified stock options, and have an exercise price equal to the mean between the high and low sales prices of the Company's Common Stock as quoted on The Nasdaq Stock Market on the grant date. Each Initial Grant and Chairman Grant generally vests on a monthly basis over the 24 months immediately following the grant date, and each Annual Grant generally vests on a monthly basis over the 12 months immediately following the grant date. All vesting of the options will cease 90 days after the nonemployee Director ceases to serve on the Board. Options become exercisable in full immediately upon the occurrence of a change in control of the Company. A change in control of the Company would occur on the happening of such events as the beneficial ownership by a person or group of 30 percent or more of the outstanding Common Stock of the Company, certain changes in Board membership affecting a majority of positions, certain mergers or consolidations, a sale or other transfer of all or substantially all the Company's assets, or approval by the stockholders of a plan of liquidation or dissolution of the Company, as well as any change in control required to be reported by the proxy disclosure rules of the Securities and Exchange Commission. Payment of the exercise price may be made in cash or by delivery of previously acquired shares of Common Stock having a fair market value equal to the aggregate exercise price.

DESCRIPTION OF ORASURE TECHNOLOGIES CAPITAL STOCK

General

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The authorized capital stock of OraSure Technologies, Inc., a corporation organized under the laws of the state of Delaware, consists of 120,000,000 shares of common stock, par value \$.000001 per share, and 25,000,000 shares of preferred stock, par value \$.000001 per share, 120,000 shares of which have been designated Series A Preferred Stock and reserved for issuance upon the exercise of the rights distributed to the holders of OraSure Technologies common stock pursuant to the rights agreement described below under "Description of Rights." All of the outstanding shares of the capital stock of OraSure Technologies are duly authorized, validly issued, fully paid and nonassessable, and no class is entitled to preemptive rights.

OraSure Technologies Common Stock

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Subject to the rights of holders of any outstanding OraSure Technologies preferred stock, the holders of outstanding shares of OraSure Technologies common stock are entitled to share ratably in dividends declared out of assets legally available therefor at such time and in such amounts as the OraSure Technologies Board of Directors may from time to time lawfully determine.

Each holder of OraSure Technologies common stock is entitled to one vote for each share held and, except as otherwise provided by law or by the OraSure Technologies Board of Directors with respect to any series of OraSure Technologies preferred stock, the holders of OraSure Technologies common stock will exclusively possess all voting power. Holders of OraSure Technologies common stock are not entitled to accumulate votes for the election of directors. The OraSure Technologies common stock is not entitled to conversion or preemptive rights and is not subject to redemption or assessment. Subject to the rights of holders of any outstanding OraSure Technologies preferred stock, upon liquidation, dissolution or winding up of OraSure Technologies, any assets legally available for distribution to stockholders as such are to be distributed ratably among the holders of the OraSure Technologies common stock at that time outstanding.

OraSure Technologies Preferred Stock

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The OraSure Technologies Board of Directors has the authority to issue OraSure Technologies preferred stock in one or more series with such distinctive serial designations, at such price or prices and for such other consideration as may be fixed by the OraSure Technologies Board of Directors. OraSure Technologies preferred stock of all series shall be in all respects entitled to the same preferences, rights and privileges and subject to the same qualifications, limitations and restrictions; provided, however, that different series of OraSure Technologies preferred stock may vary with respect to, among other things, dividend rates, conversion rights, voting rights, redemption rights, liquidation preferences and the number of shares constituting each such series as shall be determined and fixed by resolution or resolutions of the OraSure Technologies Board of Directors providing for the issuance of such series, without any further vote or action by the stockholders of OraSure Technologies. All the shares of any one series will be alike in all respects. OraSure Technologies' charter provides that no share of any series of preferred stock may be entitled to more than one vote. The ability of the OraSure Technologies Board of Directors to issue OraSure Technologies preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from acquiring, a majority of the outstanding voting stock of OraSure Technologies.

Description of Rights

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On May 6, 2000, the OraSure Technologies Board of Directors adopted a Rights Plan. Pursuant to the Rights Plan, OraSure Technologies has distributed a dividend of one right to purchase shares of capital stock of OraSure Technologies under certain circumstances specified in the Rights Plan, for each outstanding share of common stock. We refer to these purchase rights as the "Rights." The Rights trade with the common stock and will detach and become exercisable only if, in a transaction not approved by the OraSure Technologies Board of Directors, ten

business days elapse after either a person (together with that person's affiliates or associates) acquires 15% or more of the outstanding shares of OraSure Technologies common stock, or announces a tender offer the completion of which would result in ownership by a person (together with such person's affiliates or associates) of 15% or more of those shares.

If the Rights detach and become exercisable as a result of the commencement of a tender offer, unless subsequently redeemed, each Right then would entitle its holder to purchase one one-thousandth of a share of the Series A Preferred Stock

for an exercise price specified in the Rights Plan (which is intended to equal the estimated value of OraSure Technologies common stock at the end of the ten-year life of the Rights). If OraSure Technologies were to be involved in a merger or other business combination transaction after the Rights become exercisable, each Right would entitle its holder to purchase, for the Right's exercise price, a number of the acquiring or surviving company's shares of common stock having a market value equal to twice the exercise price. If, in a transaction not approved by the OraSure Technologies Board of Directors, a person (together with such person's affiliates or associates) acquires 15% or more of the outstanding shares of OraSure Technologies common stock, each Right would entitle its holder (other than the acquiring person and its affiliates and associates, all of whose Rights become automatically void) to purchase, for the Right's exercise price, a number of shares of OraSure Technologies common stock having a market value equal to twice the exercise price. At any time after a person (together with such person's affiliates or associates) acquires at least 15%, but not more than 50%, of the outstanding shares of OraSure Technologies common stock, the OraSure Technologies Board of Directors can elect to exchange one share of common stock for each Right (other than Rights held by such acquiring person and its affiliates and associates). OraSure Technologies would be entitled to redeem the Rights at \$.01 per Right at any time until ten business days following a public announcement that a person (together with such person's affiliates or associates) has acquired beneficial ownership of 15% or more of the outstanding shares of common stock. Following such an announcement, or, subject to certain exceptions specified in the Rights Plan, the acquisition of beneficial ownership of 15% or more of the outstanding shares of common stock by the acquirer (together with such person's affiliates or associates), the Rights acquired by such person or persons would be null and void. Prior to the date upon which the Rights detach, the terms of the Rights Plan could be amended by the OraSure Technologies Board of Directors without the consent of the holders of the Rights. The Rights expire on May 6, 2010, unless earlier redeemed by OraSure Technologies.

The Rights Plan may deter takeover bids for OraSure Technologies. To the extent an acquirer would be discouraged by the Rights Plan from acquiring an equity position in OraSure Technologies, stockholders may be deprived from receiving a premium for their shares. The issuance of additional shares of common stock prior to the time the Rights become exercisable would result in an increase in the number of Rights outstanding.

We anticipate that the Series A Preferred Stock, if issued, would rank junior to all other series of preferred stock as to the payment of dividends and the distribution of assets in liquidation, unless the terms of any such other series provide otherwise. Each share of Series A Preferred Stock would have a quarterly dividend rate per share equal to 1,000 times the per share amount of any dividend (other than a dividend payable in shares of common stock or a subdivision of the common stock) declared from time to time on the common stock, subject to certain adjustments. The holders of Series A Preferred Stock would be entitled to receive a preferred liquidation payment per share of \$1,000 (plus accrued and unpaid dividends) or, if greater, an amount equal to 1,000 times the payment to be made per share of common stock. Generally, the holder of each share of Series A Preferred Stock would vote together with the common stock (and any other series of preferred stock entitled to vote on such matter) on any matter as to which the common stock is entitled to vote, including the election of directors. The holder of each share of Series A Preferred Stock would be entitled to 1,000 votes, or one vote for each one one-thousandth of a share. In the event of any merger, consolidation, combination or other transaction in which shares of common stock are exchanged for or changed into other stock or securities, cash and/or property, the holder of each share of Series A Preferred Stock would be entitled to receive 1,000 times the aggregate amount of stock, securities, cash and/or property into which or for which each share of common stock is changed or exchanged.

The foregoing dividend, voting and liquidation rights of the Series A Preferred Stock would be protected against dilution in the event that additional shares of common stock are issued pursuant to a stock split or stock dividend. Because of the nature of the Series A Preferred Stock's dividend, voting, liquidation and other rights, the value of the one one-thousandth of a share of Series A Preferred Stock purchasable with each Right is intended to approximate the value of one share of common stock.

Statutory Business Combination Provision

OraSure Technologies will be subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the time that the person became an interested stockholder, unless (i) prior to such time the Board of Directors of the corporation approved either the business combination or the transaction in which the person became an interested stockholder, (ii) upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owns at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding shares owned by directors who are also officers of the corporation and by certain employee stock plans, or (iii) at or after such time the business combination is approved by the Board of Directors of the corporation and by the affirmative vote of at least 66 2/3% of the outstanding voting stock of the corporation that is not owned by the interested stockholder. A "business combination" generally includes mergers, asset sales and similar transactions between the corporation and the interested stockholder, and other transactions resulting in a financial benefit to the stockholder. An "interested stockholder" is a person who owns 15% or more of the corporation's voting stock or who is an affiliate or associate of the corporation and, together with his or her affiliates and associates, has owned 15% or more of the corporation's voting stock within the three year period immediately prior to the date on which it is sought to be determined whether such person is an interested stockholder.

Other Matters

The certificate of incorporation of OraSure Technologies provides that the number of directors shall be as determined by the Board of Directors from time to time, but shall be at least three and not more than twelve. It also provides that directors may be removed only for cause, and then only by the affirmative vote of the holders of at least a majority of all outstanding voting stock entitled to vote in an election of directors. This provision, in conjunction with the provision in the certificate of incorporation authorizing the Board of Directors to fill vacant directorships, will prevent stockholders from removing incumbent directors without cause and filling the resulting vacancies with their own nominees.

The certificate of incorporation further provides that the OraSure Technologies' Board of Directors will be divided into three classes, with each class containing as nearly as possible one-third of the total number of directors and the members of each class serving for staggered three-year terms. At each annual meeting of OraSure Technologies' stockholders, the number of directors equal to the number of the class whose term expires at the time of such meeting will be elected to hold office until the third succeeding annual meeting of stockholders. This provision could make it more difficult for stockholders to take control of the Board of Directors.

The certificate of incorporation provides that stockholders may act only at an annual or special meeting of stockholders and may not act by written consent unless such consent is unanimous. The certificate of incorporation provides that special meetings of the stockholders can be called only by the Chairman of the Board, the Chief Executive Officer, the President, or the Board of Directors pursuant to a resolution approved by a majority of the whole Board of Directors. This provision will prevent stockholders from removing board members by calling a special meeting of stockholders without the consent of the Chairman of the Board, the Chief Executive Officer, the President or the Board of Directors.

The certificate of incorporation authorizes the Board of Directors to take into account (in addition to any other considerations which the Board of Directors may lawfully take into account) in determining whether to take or to refrain from taking corporate action on any possible acquisition proposals, including proposing any related matter to the stockholders of OraSure Technologies, the long-term as well as short-term interests of OraSure Technologies and its stockholders, including the possibility that these may be best served by the continued independence of OraSure Technologies, customers, employees and other constituencies of OraSure Technologies and any subsidiaries, as well as the effect upon communities in which OraSure Technologies and any subsidiaries do business. In considering the foregoing and other pertinent factors, the Board of Directors is not required, in considering the best interests of OraSure Technologies, to regard any particular corporate interest or the interest of any particular group affected by such action as a controlling interest.

The bylaws of OraSure Technologies contain provisions (i) requiring that advance notice be delivered to OraSure Technologies of any business to be brought by a stockholder before any meeting of stockholders and (ii) establishing procedures to be followed by stockholders in nominating persons for election to the Board of Directors. Generally, such advance notice provisions provide that written notice must be given to the Secretary of OraSure Technologies by a stockholder, with respect to director nominations or stockholder proposals, not less than 50 nor more than 75 days prior to the meeting (except that if less than 65 days notice or prior public disclosure of the date of the meeting is given or made to stockholders, then notice by the stockholder, to be timely, must be received within 15 days of the date on which notice of the date of the meeting was mailed or such public disclosure was made, whichever first occurs). Such notice must set forth specific information regarding such stockholder and such business or director nominee, as described in the bylaws.

Certain provisions of the certificate of incorporation and bylaws of OraSure Technologies, including those described above, may only be amended by stockholders upon the affirmative vote of the holders of at least 66.6% of the outstanding voting capital stock entitled to vote on such amendment.