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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2004.

OR

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

For the transition period from _____ to _____.

Commission File Number 001-16537

ORASURE TECHNOLOGIES, INC.

(Exact Name of Registrant as Specified in Its Charter)

DELAWARE	**36-4370966**
(State or Other Jurisdiction of Incorporation or Organization)	**(IRS Employer Identification No.)**
220 East First Street, Bethlehem, Pennsylvania	**18015**
(Address of Principal Executive Offices)	**(Zip code)**

(610) 882-1820

(Registrant's Telephone Number, Including Area Code)

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

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

Number of shares of Common Stock, par value $.000001 per share, outstanding as of May 3, 2004: 44,457,840

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Item 1. FINANCIAL STATEMENTS

ORASURE TECHNOLOGIES, INC.
BALANCE SHEETS
(Unaudited)

	March 31, 2004	December 31, 2003
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 11,050,790	$ 30,695,177
Short-term investments	52,702,979	33,328,610
Accounts receivable, net of allowance for doubtful accounts of $361,397 and $359,158	7,430,410	8,233,869
Inventories	4,327,193	4,003,519
Prepaid expenses and other	1,069,099	922,820
Total current assets	76,580,471	77,183,995
PROPERTY AND EQUIPMENT, net	6,412,065	6,471,209
PATENTS AND PRODUCT RIGHTS, net	1,721,906	1,886,171
OTHER ASSETS	599,555	609,932
	$ 85,313,997	$ 86,151,307
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	$ 1,129,309	$ 1,126,423
Accounts payable	2,575,653	3,511,148
Accrued expenses	5,549,054	5,375,851
Total current liabilities	9,254,016	10,013,422
LONG-TERM DEBT	2,171,806	2,456,454
OTHER LIABILITIES	258,641	172,142
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Preferred stock, par value $.000001, 25,000,000 shares authorized, none issued	—	—
Common stock, par value $.000001, 120,000,000 shares authorized, 44,326,756 and 44,260,931 shares issued and outstanding	44	44
Additional paid-in capital	205,554,806	204,867,765
Deferred compensation	(1,009,143)	(614,515)
Accumulated other comprehensive loss	(183,658)	(173,704)
Accumulated deficit	(130,732,515)	(130,570,301)
Total stockholders' equity	73,629,534	73,509,289
	$ 85,313,997	$ 86,151,307

The accompanying notes are an integral part of these statements.

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ORASURE TECHNOLOGIES, INC.
STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31,	
	2004	2003
REVENUES:		
Product	$ 12,288,868	$ 8,342,964
Licensing and product development	119,740	267,672
	12,408,608	8,610,636
COST OF PRODUCTS SOLD	5,190,530	3,580,116
Gross profit	7,218,078	5,030,520
OPERATING EXPENSES:		
Research and development	1,767,157	2,054,711
Sales and marketing	3,650,716	2,235,137
General and administrative	2,125,972	1,865,621
	7,543,845	6,155,469
Operating loss	(325,767)	(1,124,949)
INTEREST EXPENSE	(31,413)	(48,605)
INTEREST INCOME	205,759	85,573
FOREIGN CURRENCY LOSS	(6,293)	—
Loss before income taxes	(157,714)	(1,087,981)
INCOME TAXES	4,500	4,879
NET LOSS	$ (162,214)	$ (1,092,860)
BASIC AND DILUTED NET LOSS PER SHARE	$ (0.00)	$ (0.03)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	44,270,845	38,248,521

The accompanying notes are an integral part of these statements.

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

	Three Months Ended March 31,	
	2004	2003
OPERATING ACTIVITIES:		
Net loss	$ (162,214)	$ (1,092,860)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Stock-based compensation expense	63,772	33,900
Depreciation and amortization	597,487	626,847
Provision for excess and obsolete inventories	140,014	111,284
Changes in assets and liabilities:		
Accounts receivable	803,459	(300,812)
Inventories	(463,688)	(71,908)
Prepaid expenses and other assets	(146,279)	10,181
Accounts payable, accrued expenses, and other liabilities	(693,574)	855,274
Net cash provided by operating activities	138,977	171,906
INVESTING ACTIVITIES:		
Purchases of short-term investments	(27,106,355)	(6,790,725)
Proceeds from the sale of short-term investments	7,733,157	4,803,559
Purchases of property and equipment	(345,904)	(411,798)
Purchases of patent and product rights	—	(250,000)
Increase in other assets	(16)	(1,287)
Net cash used in investing activities	(19,719,118)	(2,650,251)
FINANCING ACTIVITIES:		
Borrowings of term debt	—	108,683
Repayments of term debt	(281,762)	(270,545)
Proceeds from issuance of common stock	228,641	1,001,064
Net cash provided by (used in) financing activities	(53,121)	839,202
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	(11,125)	6,915
NET DECREASE IN CASH AND CASH EQUIVALENTS	(19,644,387)	(1,632,228)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	30,695,177	4,364,308
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 11,050,790	$ 2,732,080

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.
Notes to Financial Statements
(Unaudited)

1. The Company

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

2. Summary of Significant Accounting Policies

Basis of Presentation. The accompanying financial statements are unaudited and, in the opinion of management, include all adjustments (consisting only of normal and recurring adjustments) necessary for a fair presentation of the results for these interim periods. These financial statements should be read in conjunction with the financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2003. Results of operations for the three-month period ended March 31, 2004 are not necessarily indicative of the results of operations expected for the full year.

Use of Estimates. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents. We consider all highly liquid investments with a purchased maturity of ninety days or less to be cash equivalents. As of March 31, 2004 and December 31, 2003, cash equivalents consisted of certificates of deposit, commercial paper, U.S. government and agency obligations, state and local government agency obligations and corporate bonds.

Short-term Investments. We consider all short-term investments to be available-for-sale securities, in accordance with Statement of Financial Accounting Standards ("SFAS") No. 115, "Accounting for Certain Investments in Debt and Equity Securities." These securities are comprised of certificates of deposits, commercial paper, U.S. government and agency obligations, state and local government agency obligations, corporate bonds, and asset-backed obligations with purchased maturities greater than ninety days. Available-for-sale securities are carried at fair value, based upon quoted market prices, with unrealized gains and losses reported in stockholders' equity as a component of accumulated other comprehensive loss.

The following is a summary of our available-for-sale securities at March 31, 2004 and December 31, 2003:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
March 31, 2004				
Certificates of deposit	$ 14,881,782	$ 613	$ (5,159)	$ 14,877,236
Commercial paper	5,085,112	248	—	5,085,360
Government and agency bonds	21,015,438	12,343	(1,366)	21,026,415
State and local government agency obligations	586,783	1,385	(283)	587,885
Corporate bonds	7,395,981	6,997	(2,779)	7,400,199
Asset-backed obligations	3,724,535	1,792	(443)	3,725,884
Total available-for-sale securities	$ 52,689,631	$ 23,378	$ (10,030)	$ 52,702,979
December 31, 2003				
Certificates of deposit	$ 14,047,127	$ 1,167	$ (5,586)	$ 14,042,708
Commercial paper	1,296,941	121	—	1,297,062
Government and agency bonds	14,483,893	7,667	—	14,491,560
State and local government agency obligations	629,999	1,118	(3)	631,114
Corporate bonds	2,867,261	1,641	(2,736)	2,866,166
Total available-for-sale securities	$ 33,325,221	$ 11,714	$ (8,325)	$ 33,328,610
At March 31, 2004, maturities of investments were as follows:				
Less than one year	$ 40,263,879	$ 13,137	$ (1,524)	$ 40,275,492
1 – 2 years	12,425,752	10,241	(8,506)	12,427,487
Total available-for-sale securities	$ 52,689,631	$ 23,378	$ (10,030)	$ 52,702,979

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, 2004	December 31, 2003
Raw materials	$3,109,945	$2,862,169
Work-in-process	589,603	486,284
Finished goods	627,645	655,066
	$4,327,193	$4,003,519

Revenue Recognition. We recognize product revenues when there is persuasive evidence that an arrangement exists, the price is fixed or determinable, title has passed and collection is reasonably assured. Product revenues are net of allowances for any discounts or rebates. We do not grant price protection or product return rights to our customers, except for warranty returns. Historically, returns arising from warranty issues have been infrequent and immaterial. Accordingly, we expense warranty returns as incurred.

Up-front licensing fees are deferred and recognized ratably over the related license period. Product development revenues are recognized over the period in which the related product development efforts are performed. Amounts received prior to the performance of product development efforts are recorded as deferred revenues. Grant revenue is recognized as the related work is performed and costs are incurred. We record shipping and handling charges billed to our customers as product revenue and the related expense as cost of products sold.

Significant Customer Concentration. In the first quarter of 2004, one customer accounted for 16 percent of total revenues as compared to 20 percent for the same quarter of 2003. The same customer accounted for approximately 11 percent and 8 percent of accounts receivable as of March 31, 2004 and December 31, 2003, respectively.

In the first quarter of 2004, another customer accounted for 25 percent of total revenues. We had approximately $1,400 in sales to this customer in the same period of 2003. This customer accounted for approximately 30 percent and 23 percent of accounts receivable as of March 31, 2004 and December 31, 2003, respectively.

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

Foreign Currency Translation. Pursuant to SFAS No. 52, “Foreign Currency Translation,” the assets and liabilities of our foreign operations are translated from euros into U.S. dollars at current exchange rates as of the balance sheet date, and revenues and expenses are translated at average exchange rates for the period. Resulting translation adjustments are reflected as a separate component of stockholders’ equity.

Net Loss Per Common Share. We have presented basic and diluted net loss per common share pursuant to SFAS No. 128, “Earnings per Share.” In accordance with SFAS No. 128, basic and diluted net loss per common share has been computed using the weighted-average number of shares of common stock outstanding during the period. Diluted loss per common share is generally computed assuming the conversion or exercise of all dilutive securities such as common stock options, warrants and unvested restricted stock. As a result of our losses in each of the quarters ended March 31, 2004 and 2003, outstanding common stock options, warrants and unvested restricted stock representing 5,213,765 and 4,691,969 shares, were excluded from the computation of diluted net loss per common share for each of these periods, respectively, as their inclusion would have been anti-dilutive.

Stock-Based Compensation. We account for stock-based compensation to employees and directors using the intrinsic value method in accordance with Accounting Principles Board Opinion No. 25, “Accounting for Stock Issued to Employees,” and related interpretations. We account for stock-based compensation to nonemployees using the fair value method in accordance with SFAS No. 123, “Accounting for Stock-Based Compensation,” and EITF Issue No. 96-18, “Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services.”

We have elected to adopt the disclosure provisions of SFAS No. 123, as amended by SFAS No. 148, "Accounting for Stock-Based Compensation – Transition and Disclosure." Under SFAS No. 123, compensation expense related to stock awards granted to employees and directors is computed based on the fair value of the award at the date of grant using an option valuation methodology, typically the Black-Scholes option pricing model. Pursuant to the disclosure requirements of SFAS No. 123, had compensation expense for our common stock awards been determined based upon the fair value of the awards at the date of grant, our net loss for the three-month periods ended March 31, 2004 and 2003 would have increased as follows:

	Three months ended March 31,	
	2004	2003
Net loss:		
As reported	$ (162,214)	$(1,092,860)
Add: stock-based employee compensation expense included in net loss	—	33,900
Deduct: total stock-based employee compensation expense determined under the fair value-based method for all awards	(1,184,616)	(1,119,921)
Pro forma	$(1,346,830)	$(2,178,881)
Basic and diluted net loss per share:		
As reported	$ (0.00)	$ (0.03)
Pro forma	$ (0.03)	$ (0.06)

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

3. Accrued Expenses:

	March 31, 2004	December 31, 2003
Payroll and related benefits	$ 1,071,217	$ 1,449,151
Royalties	1,637,958	1,428,816
Deferred revenue	811,445	705,817
Advertising	407,795	474,817
Laboratory testing fees	373,761	305,647
Professional fees	471,258	222,710
Other	775,620	788,893
	$ 5,549,054	$ 5,375,851

At March 31, 2004 and December 31, 2003, accrued royalties are primarily attributed to launching two new products during 2003.

4. Stockholders' Equity

During the period ended March 31, 2004, we granted 60,000 restricted shares of our common stock to certain key officers. These shares are nontransferable and are subject to two-year vesting requirements. Upon granting of these restricted shares, deferred compensation expense equivalent to the market value at the date of grant is charged to stockholders' equity and subsequently amortized over the two-year period during which the restrictions lapse. In connection with this restricted share grant, we recorded $458,400 of deferred compensation during the period ended March 31, 2004. Amortization of deferred compensation related to these and previous grants was $63,772 during the three months ended March 31, 2004. No such expense was recorded in the period ended March 31, 2003.

5. Geographic Area Information

Under the disclosure requirements of SFAS No. 131, “Segment Disclosures and Related Information,” we operate within one segment. Our products are sold principally in the United States and Europe. Segmentation of operating income and identifiable assets is not applicable since all of our revenues outside the United States are export sales.

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

	Three months ended March 31,	
	2004	2003
United States	$10,926	$7,520
Europe	1,076	624
Other regions	407	467
	$12,409	$8,611

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

Statements below regarding future events or performance are "forward-looking statements" within the meaning of the Federal securities laws. These include statements about expected revenues, earnings, expenses, cash flow or other financial performance, products, markets, and regulatory filings and approvals. Forward-looking statements are not guarantees of future performance or results. Factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include: ability to market products; impact of competitors, competing products and technology changes; ability to develop, commercialize and market new products; market acceptance of oral fluid testing products and up-converting phosphor technology products; ability to fund research and development and other projects and operations; ability to obtain and maintain new or existing product distribution channels (including our ability to implement a direct sales effort or alternative distribution method for OraQuick® in the hospital market); reliance on sole supply sources for critical product components; availability of related products produced by third parties; ability to obtain and timing of obtaining necessary regulatory approvals; ability to comply with applicable regulatory requirements; history of losses and ability to achieve sustained profitability; volatility of our stock price; uncertainty relating to patent protection and potential patent infringement claims; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally; loss or impairment of sources of capital; ability to meet financial covenants in agreements with financial institutions; ability to retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; changes in relationships with strategic partners and reliance on strategic partners for the performance of critical activities under collaborative arrangements; changes in accounting practices or interpretation of accounting requirements; customer inventory practices and consolidations; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks, war and civil unrest; ability to identify, complete and realize the full benefits of potential acquisitions; and general business, political and economic conditions. These and other factors that could cause the forward-looking statements to be materially different are described in greater detail in our filings with the Securities and Exchange Commission, including our registration statements and our Annual Report on Form 10-K for the year ended December 31, 2003. Although forward-looking statements help to provide information about future prospects, they may not be reliable. The forward-looking statements are made as of the date of this Report and we undertake no duty to update these statements.

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

Overview

Our Company operates primarily in the worldwide $22 billion *in vitro* diagnostics business. We develop, manufacture and market oral fluid specimen collection devices using proprietary oral fluid technologies, diagnostic products including immunoassays, and other *in vitro* diagnostic tests. We also manufacture and sell a medical device for the removal of warts and other benign skin lesions by cryosurgery, or freezing.

Our diagnostic product offerings primarily target the infectious disease and substance abuse testing segments of the *in vitro* diagnostic market, and are used in both laboratories as well as the emerging, and rapidly growing, point-of-care marketplace. Our OraSure® and Intercept® oral fluid collection devices, and their related assays, are processed in a laboratory, while the OraQuick® rapid HIV antibody test and UPlink® oral fluid rapid drug detection system are designed for use at the point-of-care. Our cryosurgical product, which is sold under the names Histofreezer® and Freeze Off™, is also used at the point-of care.

In vitro diagnostics have traditionally used blood or urine as the bodily fluids upon which tests are conducted. However, we have targeted the use of oral fluid in our products as a differentiating competitive factor, and believe that it provides a significant competitive advantage over blood and urine. Our oral fluid tests have sensitivity and specificity comparable to blood and/or urine tests and, when combined with their ease of use, non-invasive and dignified nature, and cost effectiveness, represent a competitive alternative to the more traditional testing methods in the diagnostic space.

During the first quarter of 2004, we continued to increase our sales and gain market acceptance for our products.

Sales into the infectious disease testing market during the first quarter of 2004 increased significantly due to the continued market acceptance of our OraQuick® device. This resulted largely from sales directly to various public health organizations, sales to the Centers for Disease Control and Prevention ("CDC") for further distribution in the public health market, and sales to Abbott Laboratories for distribution primarily to hospitals. There were also international sales of this product during the quarter.

In 2003, the CDC placed purchase orders totaling approximately $4.0 million for 500,000 OraQuick® devices, with equal amounts to be shipped in 2003 and 2004. We expect that the CDC, and perhaps other federal governmental agencies, will make future bulk purchases of OraQuick® devices for further distribution to the public health and other markets throughout the United States.

In October 2003, we announced the termination of our agreement with Abbott for the distribution of OraQuick®. Abbott disputed our termination, and this dispute was resolved in February 2004 by an arbitrator who ruled that the agreement was not terminated and will continue in effect. Consistent with the arbitrator's ruling, we notified Abbott that the agreement was converted from co-exclusive to non-exclusive.

We also announced our intent to establish an internal sales force for selling OraQuick® directly into the hospital market. We have made progress in establishing this sales force with the recent hiring of a new Director, Hospital Sales to lead it, as well as the hiring of a small team of field salespeople to reach the larger metropolitan markets in the United States. The success of this effort will impact the future sales of OraQuick®. We also intend to address the market potential of physicians' offices by engaging one or more distribution partners, as we believe it would be impractical to build and sustain an internal sales force large enough to adequately service that market. We believe that the combination of our direct sales efforts and sales to Abbott and our other distribution partners will help us gain significant market penetration with OraQuick® in the hospital, physicians' office and other markets for rapid HIV testing.

During 2003, two competitors received U.S. Food and Drug Administration ("FDA") approval for rapid HIV tests. Based on their current FDA approvals, we expect that these tests will be sold, and will compete with our OraQuick® test, primarily in the hospital market in the United States.

During March 2004, we received FDA approval to use the OraQuick® test to detect antibodies to HIV-2 in finger stick whole blood and venipuncture whole blood samples. We also received FDA approval to use the test to detect HIV-1 antibodies in oral fluid samples and to detect antibodies to both HIV-1 and HIV-2 in plasma samples. We expect to submit data to the FDA in the near future in support of a request for approval to detect HIV-2 antibodies in oral fluid and to obtain a CLIA (Clinical Laboratory Improvements Amendments of 1988) waiver for use of OraQuick® with oral fluids. We believe these approvals will give us the most versatile rapid HIV test in the world and provide a significant advantage over our competitors.

Sales to the substance abuse testing market also increased during the first quarter of 2004, reflecting the growing acceptance of our Intercept® collection device and related oral fluid drug assays, as companies and criminal justice customers are increasingly shifting to oral fluid and away from traditional urine-based drug testing. We expect continuing growth in the utilization of our Intercept® product line, primarily in the United States and United Kingdom. This increase was partially offset by lower sales of our drug assays to the forensic toxicology market.

In March 2004, the FDA responded to our application for 510(k) clearance of the UP*link*® oral fluid rapid drugs of abuse detection system, by indicating that additional performance data would be needed in order to obtain clearance. We will need to obtain 510(k) clearance of this device to optimally penetrate the workplace and criminal justice markets in the United States. However, the absence of 510(k) clearance will not affect our ability to sell the UP*link*® system internationally. In April 2004, we launched our UP*link*® system in Germany and other European countries, primarily in the roadside testing market, with our partner, Dräger Safety.

Sales to the cryosurgical systems market during the first quarter of 2004 have grown substantially, largely because we entered the consumer or over-the-counter ("OTC") market. The cryosurgical systems market represents sales of Histofreezer® into both the domestic and international physicians' office markets and sales of the OTC formulation of this product, called Freeze Off™, to our partner, MedTech Holdings, Inc. ("MedTech"). MedTech distributes Freeze Off™ to consumers under its Compound W® trademark.

While we are pleased with the level of Freeze Off™ sales and hope that they continue at the same or higher levels, these sales were received in anticipation of the wart season in the U.S., which runs from Spring to Fall. Since the sales of Freeze Off™ during the first quarter of 2004 reflect the seasonality of this product, they may not continue at the same level during each of the remaining quarters in 2004.

Sales to the insurance risk assessment market continued to decline in the first quarter of 2004, primarily as a result of the loss of urine assay sales to our largest customer, Lab*One*. These products have experienced substantial competitive pressure from "home-brew" assays internally developed by this customer. Sales of these products are not expected to recover. We anticipate little growth and we may continue to experience declines in this market until we are successful in developing new oral fluid based diagnostic tests for additional predictive health markers desired by the insurance industry.

In March 2004, we received the final FDA approval to transfer the manufacture of our Intercept® and OraSure® collection devices and our oral fluid Western blot HIV-1 confirmatory test from Oregon to our facilities in Bethlehem, Pennsylvania. Commercial lots of each of these products are now being produced in Bethlehem. We expect that the completion of this transfer will reduce our annual operating expenses and improve our ability to control the quality of our products.

Because of the regulatory approvals needed for most of our products, we often are required to rely on sole source providers for critical components and materials. This is particularly true for our OraQuick® test and oral fluid Western blot HIV-1 confirmatory product. If we are unable to obtain necessary components or materials from these sole sources, the time required to develop replacements and obtain the required FDA approvals could disrupt our ability to sell the affected products. In addition, any delay or interruption in our ability to manufacture the oral fluid Western blot HIV-1 confirmatory test would adversely affect sales of our OraSure® oral fluid collection device, as our customers are not expected to purchase OraSure® devices if an oral fluid Western blot HIV-1 confirmatory test is not readily available.

Results of Operations

Total revenues increased 44% to approximately $12.4 million in the first quarter of 2004 from approximately $8.6 million in the comparable quarter in 2003, primarily as a result of increased sales of our Freeze Off™ and Histofreezer® cryosurgical products, OraQuick® rapid HIV-1 antibody test and Intercept® oral fluid drug test, partially offset by lower sales in the insurance risk assessment market. Product revenues for the first quarter of 2004 increased 47% to approximately $12.3 million compared to approximately $8.3 million for the first quarter of 2003. International sales accounted for 12% of total revenues in the first quarter of 2004.

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

	Three Months Ended March 31,				
	Dollars		Percent Change Inc. (Dec.)	Percentage of Total Revenues	
	2004	2003		2004	2003
Market revenues					
Insurance risk assessment	$ 2,284	$3,000	(24)%	18%	35%
Infectious disease testing	3,338	2,768	21	27	32
Substance abuse testing	2,194	1,598	37	18	19
Cryosurgical systems	4,473	977	358	36	11
Product revenues	12,289	8,343	47	99	97
Licensing and product development	120	268	(55)	1	3
Total revenues	$12,409	$8,611	44%	100%	100%

Sales to the insurance risk assessment market decreased 24% to approximately $2.3 million in the first quarter of 2004 as a result of lower urine assay and reagent sales and lower OraSure® oral fluid collection device sales. We expect that sales of our insurance assays and reagents will continue to come under competitive pressure. Our laboratory customers have reduced and are expected to continue to reduce their purchases of these products and instead use lower cost, internally-developed (i.e., “home-brew’) assays or reagents or testing products purchased from our competitors. We do not expect to recover this business, and our revenues are expected to be negatively impacted by as much as $1.0 million in 2004, when compared to 2003 revenues in the insurance risk assessment market.

Sales to the infectious disease testing market increased 21% to approximately $3.3 million in the first quarter of 2004, primarily as a result of the continued strength of our OraQuick® rapid HIV-1 antibody test in the public health marketplace, partially offset by lower sales of our OraSure® oral fluid collection device. OraQuick® sales totaled approximately $2.2 million and $1.4 million in the first quarters of 2004 and 2003, respectively. OraSure® sales totaled approximately $1.1 million and $1.4 million in the first quarters of 2004 and 2003, respectively.

In order to improve penetration of our OraQuick® test in the hospital market, we have expanded our internal sales force so that we can sell directly to hospitals, which was a primary market targeted by Abbott Laboratories, our non-exclusive distribution partner in the U.S. We believe that expanding our direct sales efforts will provide us with greater control over distribution and a higher margin contribution from this product, and will allow us to provide marketing support for hospital customers. We are also evaluating the use of one or more distributors to help us penetrate the physicians’ office market.

In the first quarter of 2004, we recorded OraQuick® sales of approximately $750,000 to Abbott and approximately $700,000 to the CDC. We also had approximately $500,000 in direct sales of OraQuick® to the U.S. public health market, and approximately $200,000 to the international market. We did not have any OraQuick® revenues from the hospital market during the first quarter from our new direct sales force, which was not deployed until early in the second quarter of 2004. We expect revenues from the infectious disease market to continue to expand throughout 2004 as we further penetrate the public health market, both directly and through sales to the CDC, and penetrate the hospital marketplace with our direct sales force.

Although sales of our OraQuick® test are expected to increase, such sales are expected to negatively impact sales of our OraSure® oral fluid collection device in the infectious disease testing market. Customers who now or in the future may purchase our OraSure® device for HIV-1 testing may elect instead to purchase our OraQuick® test. It is not possible at this time, however, to estimate the timing or extent of such change in purchasing patterns or the financial impact of replacing OraSure® sales with sales of our OraQuick® test.

In March 2004, we received approval from the FDA for use of the OraQuick® device to detect antibodies to HIV-2 in finger stick and venipuncture whole blood specimens. We secured this approval in anticipation of obtaining access to an HIV-2 patent license from Bio-Rad Laboratories ("Bio-Rad"), the holder of certain HIV-2 patents. During March 2004, we also received approval from the FDA for use of the OraQuick® device for detecting HIV-1 antibodies in oral fluid and antibodies to HIV-1 and HIV-2 in plasma samples. We are currently working with the FDA to obtain the necessary clinical data to secure approval of the OraQuick® device for detecting HIV-2 antibodies in oral fluid and to receive a CLIA waiver for the use of the OraQuick® device with oral fluid.

We believe that an OraQuick® device which is approved for detecting antibodies to both HIV-1 and 2 on multiple sample types, especially oral fluids, would enhance the versatility of our OraQuick® test, provide a significant competitive advantage, and allow us to more fully implement a strategy to sell OraQuick® internationally. However, there is no assurance that we will receive FDA approval of an HIV-2 oral fluid claim or waiver under CLIA for use of the device with oral fluids.

Sales to the substance abuse testing market increased 37% to approximately $2.2 million in the first quarter of 2004, primarily as a result of increased sales of our Intercept® oral fluid drug testing service in the U.S. workplace testing market. Sales into the U.S. workplace market increased approximately 120% to approximately $650,000 in the first quarter of 2004. Partially offsetting these increases were lower than expected sales of our drug assays into the forensic toxicology market, which were down 15% compared to the comparable period in 2003.

Additionally, in April 2004 we launched our UP*link*® rapid point-of-care oral fluid drug detection system, including assays for the detection of drugs of abuse commonly identified by the National Institute for Drug Abuse ("NIDA") as the NIDA-5, i.e. cocaine, opiates, amphetamines/methamphetamines, PCP and marijuana, with our partner, Dräger Safety. This product will be initially sold to the roadside testing market in Europe. Revenues from this product approximated $144,000 in the first quarter of 2004.

Sales of our products in the cryosurgical systems market (which includes both the physicians' office and OTC markets) increased 358% to approximately $4.5 million in the first quarter of 2004. This increase was primarily the result of $3.1 million in sales of our OTC cryosurgical system, called Freeze Off™, to MedTech, the owner of the Compound W® line of wart removal products. In 2003, we entered into a distribution agreement with MedTech following receipt of FDA 510(k) clearance for the sale of Histofreezer® in the OTC market in the U.S. Since this product was not launched by MedTech until the third quarter of 2003, there were no sales to MedTech in the comparable period in 2003.

The Freeze Off™ product is being sold under MedTech's Compound W® trademark. The five-year distribution agreement with MedTech requires minimum purchases of at least $2.0 million each year over the life of the contract in order for MedTech to maintain its exclusive distribution rights to the OTC market in the U.S. However, based on additional purchase orders received to date, we expect sales of Freeze Off™ to MedTech to reach at least $6.0 million during the first half of 2004.

Sales of our Histofreezer® product to physicians' offices in the U.S. market increased 76% to approximately $1.0 million in the first quarter of 2004, when compared to the same period in 2003, primarily as a result of higher distributor sales. We are investing in promotional programs to raise the brand awareness of Histofreezer® in the U.S. marketplace and expect our 2004 full-year revenues for this product to increase over 2003. Sales of Histofreezer® in the international market declined by 2% to approximately $387,000 and are expected to remain at approximately the 2003 levels until we are able to secure additional distributors in countries where the product is currently not sold.

It is possible that sales of the Freeze Off™ product in the U.S. OTC market may reduce the number of individuals that will seek to obtain treatment of their warts by a physician, which in turn could negatively affect sales of our Histofreezer® product in the professional market. To date we have not seen evidence of this and it is not possible at this time to estimate the timing or financial impact of such a change, if it occurs at all.

Licensing and product development revenues decreased by 55% to $120,000 during the first quarter of 2004, compared to the same period in 2003, primarily as a result of lower payments for our collaborative UP*link*™ and oral fluid research project with The University of Pennsylvania, under a grant awarded by the National Institutes of Health. The current phase of this grant expires in June 2004 and we expect to receive approximately $72,000 in additional revenues through that date. Additional revenues under this grant beyond June 2004 will depend on progress achieved in the research and future funding awarded by the National Institutes of Health.

Gross margin in the first quarter of 2004 was approximately 58%, which was unchanged from the first quarter of 2003. Gross margin was positively affected by more efficient utilization of the Company's manufacturing capacity, offset by increased foreign currency exchange costs associated with the purchase of our cryosurgical products. The Company's Freeze Off™ and Histofreezer® products are purchased from a contract manufacturer in The Netherlands and are paid for in Euros.

Research and development expenses decreased 14% to approximately $1.8 million in the first quarter of 2004 from approximately $2.1 million in the same period in 2003, primarily as a result of a decrease in expenses during 2004 related to both the transfer of manufacturing operations to our Bethlehem, Pennsylvania facilities, and certain clinical testing, which were incurred in the first quarter of 2003.

Sales and marketing expenses increased 63% to approximately $3.7 million in the first quarter of 2004 from approximately $2.2 million in the same period in 2003. This increase was primarily the result of higher product advertising expenditures, recruiting fees for the hospital sales team, compensation and travel expenses. Included in advertising expenses for the first quarter of 2004 was $551,000 payable to MedTech as reimbursement for marketing expenses incurred for the Freeze Off™ product. Pursuant to our agreement with MedTech, we will continue to co-invest in MedTech's marketing activities for the Freeze Off™ product, and we will reimburse MedTech, on a declining basis over the first four years of the agreement, for a portion of MedTech's out-of-pocket costs of advertising and promoting this product in the OTC market. We expect sales and marketing expenses to increase substantially during 2004 as a result of the deployment of our new hospital sales force and additional investment required to increase sales and acceptance of our OraQuick®, Intercept® and Histofreezer® products.

General and administrative expenses increased 14% to approximately $2.1 million in the first quarter of 2004 from approximately $1.9 million in the same period in 2003. This increase was primarily attributable to increased legal fees related to patent prosecution matters and our arbitration proceedings with Abbott. General and administrative expenses are expected to increase further in 2004 as a result of the additional costs to comply with the requirements of the Sarbanes-Oxley Act of 2002, higher professional fees and the anticipated transition costs for the planned retirement of our current Chief Executive Officer and potential additional costs of hiring and relocating a new Chief Executive Officer.

Interest expense decreased to $31,000 in the first quarter of 2004 from $49,000 in the same period in 2003 primarily as a result of lower outstanding debt balances. Interest income increased to $206,000 in the first quarter of 2004 from $86,000 in the same period in 2003, as a result of substantially larger balances available for investment.

During the first quarters of 2004 and 2003, a provision for foreign income taxes of approximately $5,000 was recorded.

Liquidity and Capital Resources

	March 31, 2004	December 31, 2003
	(In thousands)	
Cash and cash equivalents	$11,051	$ 30,695
Short-term investments	52,703	33,329
Working capital	67,326	67,171

The Company's cash, cash equivalents and short-term investments decreased approximately $271,000 during the first quarter of 2004 to approximately $63.8 million at March 31, 2004, primarily as a result of the Company's purchase of approximately $346,000 of equipment and approximately $282,000 of debt repayments, partially offset by approximately $229,000 in proceeds from the exercise of stock options and $139,000 in positive cash flow from operations. At March 31, 2004, the Company's working capital was approximately $67.3 million.

Net cash provided by operating activities was approximately $139,000 in the first quarter of 2004. The $139,000 of cash provided by operating activities resulted from an decrease of approximately $803,000 in accounts receivable, primarily related to increased collection efforts, depreciation and amortization of approximately $597,000 and non-cash charges of approximately $204,000 related to stock-based compensation expense and provisions for excess and obsolete inventories, offset by the approximate $162,000 loss for the period, inventory increases of $464,000, prepaid expense increases of $146,000 and a reduction of accounts payable and accruals of $694,000. Accounts receivable are expected to grow as our sales increase and the proportion of sales increase to parties such as the CDC and MedTech, which have 60-day payment terms.

Net cash used in investing activities during the first quarter of 2004 was approximately $19.7 million. We purchased approximately $346,000 of property and equipment and purchased a net amount of $19.4 million of short-term investments.

Capital expenditures are anticipated to increase during 2004 to approximately $3.0 million as a result of additional commitments we have made for the purchase and installation of manufacturing and research and development equipment. We also expect to purchase additional information systems equipment and to upgrade certain older equipment in 2004.

Net cash used in financing activities was approximately $53,000, reflecting the proceeds of $229,000 received from the sale of common stock, offset by approximately $282,000 of loan principal repayments.

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

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

The $887,000 mortgage loan matures in September 2012, bears interest at an annual floating rate equal to Comerica's prime rate (4% at March 31, 2004), and is repayable in fixed monthly principal and interest installments of $7,426 through September 2007, at which time the interest rate and fixed monthly repayment amount will be reset for the remaining 60 monthly installments. The outstanding balance of the loan at March 31, 2004 was $806,771.

The $3.0 million term loan matures in March 2006, bears interest at a fixed rate of 4.99% and is repayable in forty-two consecutive equal monthly principal payments of $71,429, plus interest. The outstanding balance of the loan at March 31, 2004 was $1,714,286.

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

As of March 31, 2004, we had an outstanding balance of $452,643 under the Original Non-Revolving Line consisting of four individual loans of (i) $119,857 with a fixed annual interest rate of 5.07%, (ii) $167,662 with a floating annual interest rate equal to Comerica's prime rate of 4.0% at March 31, 2004, (iii) $81,512 with a floating annual interest rate equal to Comerica's prime rate of 4.0% at March 31, 2004, and (iv) $83,612 with a floating annual interest rate equal to Comerica's prime rate of 4.0% at March 31, 2004.

Under the revolving working capital line of credit, we can borrow up to $4.0 million to finance working capital and other needs. Interest on outstanding borrowings accrues at a rate, selected at our option, equal to Comerica's prime rate less 0.25%, or 30-day LIBOR plus 2.55%, determined at the time of the initial borrowing. Borrowings are repayable by September 10, 2004, with interest payable monthly. We had no outstanding borrowings under this facility at March 31, 2004.

All borrowings under the Credit Facility are collateralized by a first priority security interest in all of our assets, including present and future accounts receivable, chattel paper, contracts and contract rights, equipment and accessories, general intangibles, investments, instruments, inventories, and a mortgage on our manufacturing facility in Bethlehem, Pennsylvania. Borrowings under the equipment and software non-revolving line and the revolving working capital line are limited to commercially standard percentages of equipment and software purchases and accounts receivable, respectively. The Credit Facility contains certain covenants that set forth minimum requirements for our quick ratio, liquidity, and tangible net worth. We were in full compliance with all covenants at March 31, 2004 and expect to remain in compliance with all covenants during 2004. The Credit Facility also restricts our ability to pay dividends, to make certain investments, to incur additional indebtedness, to sell or otherwise dispose of a substantial portion of assets, and to merge or consolidate operations with an unaffiliated entity, without the consent of Comerica.

We have entered into a ten-year facility lease with Tech III Partners, LLC ("Tech Partners"), an entity owned and controlled by two of our executive officers. Under the terms of this operating lease, we began leasing a 48,000 square-foot facility in October 2002 at a base rent of $780,000 per year, increasing to $858,240 per year, during the initial ten-year term. The base rental may be increased after the fifth year of the initial term in order to reflect changes in the interest rate on debt incurred by Tech Partners to finance construction of the leased facilities. We have not guaranteed any debt incurred by Tech Partners. The lease also provides us with options to renew the lease for an additional five years at a rental rate of $975,360 per year, and to purchase the facility at any time during the initial ten-year term based on a formula set forth in the lease. We are evaluating whether to exercise our option under the lease to purchase the facility.

The combination of our current cash position and available borrowings under our Credit Facility is expected to be sufficient to fund our operating and capital needs for at least the next twelve months. However, our cash requirements may vary materially from those now planned due to many factors, including, but not limited to, the scope and timing of strategic acquisitions, the cost and timing of the expansion of our manufacturing capacity, the progress of our research and development programs, the scope and results of clinical testing, the magnitude of capital expenditures, changes in existing and potential relationships with business partners, the time and cost of obtaining regulatory approvals, the costs involved in obtaining and enforcing patents, proprietary rights and any necessary licenses, the cost and timing of expansion of sales and marketing activities, the timing of commercial launch of new products, market acceptance of new products, competing technological and market developments, the potential exercise of our options to purchase one, or both, of our leased facilities in Bethlehem, Pennsylvania, and other factors.

Certain Relationships and Related Transactions

In connection with the announcement that Mike Gausling, our President and Chief Executive Officer will retire from the Company by the end of 2004, we entered into a transition agreement with Mr. Gausling, which replaced and terminated his employment agreement. Pursuant to the transition agreement, Mr. Gausling will continue to serve as President and Chief Executive Officer and as a member of the Board until requested to retire by the Board.

Regardless of his retirement date, Mr. Gausling will continue to be employed by the Company until December 31, 2004, unless his employment is terminated for cause (as defined therein). During 2004, Mr. Gausling will receive an annual base salary of $325,000, will be entitled to full executive benefits under our group health and other benefit arrangements, and will be entitled to a cash bonus under our 2004 Self-Funding Annual Bonus Plan payable, if at all, at the same time as other executives participating in the Plan receive bonuses. Mr. Gausling was also granted a non-qualified option to purchase 100,000 shares of common stock, pursuant to our 2000 Stock Award Plan.

During 2005, Mr. Gausling will receive salary continuation payments in an aggregate amount of $325,000, payable in four equal installments at the end of each fiscal quarter during 2005. However, if a “change of control” (as defined in the transition agreement) occurs either (i) before September 29, 2004 or (ii) between September 30, 2004 and December 31, 2004 and we have not hired a successor President and Chief Executive Officer, Mr. Gausling will continue to be paid an annual base salary of $325,000 for a period of 36 months from the date of the notice of the change in control, except that if Mr. Gausling continues to work for the Company or any of its subsidiaries, then any amounts Mr. Gausling receives as compensation following the event shall be credited against the amounts payable as a result of the change of control. If Mr. Gausling elects to obtain continuing coverage under our health benefit plan pursuant to COBRA beginning January 1, 2005, the Company will reimburse Mr. Gausling for the cost of his COBRA premiums for the 12-month period ending December 31, 2005.

Summary of Contractual Obligations

A summary of our obligations to make future payments under contracts existing at December 31, 2003 is included in Item 7, Management’s Discussion and Analysis of Financial Condition and Results of Operations, of our Annual Report on Form 10-K for the year ended December 31, 2003. As of March 31, 2004, there were no significant changes to this information except for the additional obligation arising from the pending retirement of our Chief Executive Officer. Pursuant to his transition agreement, and in addition to the contractual obligations previously disclosed, our contractual obligations from employment agreements have increased by $419,441 with $81,250 and $338,191 payable by December 31, 2004 and 2005, respectively.

Critical Accounting Policies and Estimates

Management’s Discussion and Analysis of Financial Condition and Results of Operations discusses our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires that we make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. On an on-going basis, we evaluate our judgments and estimates, including those related to bad debts, inventories, investments, intangible assets, accruals, income taxes, revenue recognition, restructuring costs, contingencies, and litigation. We base our judgments and estimates on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in Note 2 to the financial statements included in our 2003 Annual Report on Form 10-K filed with the Securities and Exchange Commission. We consider the following accounting estimates, which have been discussed with our Audit Committee, to be most critical in understanding the more complex judgments that are involved in preparing our financial statements and the uncertainties that could impact our results of operations, financial condition, and cash flows.

Revenue Recognition. We follow U.S. Securities and Exchange Commission Staff Accounting Bulletin No. 104, “Revenue Recognition in Financial Statements” (“SAB 104”). This bulletin draws on existing accounting rules and provides specific guidance on revenue recognition of up-front non-refundable licensing and development fees. We license certain products or technology to outside third parties, in return for which we receive up-front licensing fees. Some of these fees can be significant. In accordance with SAB 104, we are required to defer immediate recognition of these fees as revenue and instead ratably recognize this revenue over the related license period.

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

We recognize product revenues when there is persuasive evidence that an arrangement exists, the price is fixed or determinable, title has passed and collection is reasonably assured. Product revenues are net of allowances for any discounts or rebates. We do not grant price protection or product return rights to our customers, except for warranty returns. Where a product fails to comply with its limited warranty, we can either replace the product or provide the customer with a refund of the purchase price or credit against future purchases. Historically, returns arising from warranty issues have been infrequent and immaterial. Accordingly, we expense warranty returns as incurred. While such returns have been immaterial in the past, we cannot guarantee that we will continue to experience the same rate of warranty claims as we have in the past. Any significant increase in product warranty claims could have a material adverse impact on our operating results for the period in which the claims occur.

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

Based upon historical experience and any specific customer collection issues that are identified, we use our judgment to establish and evaluate the adequacy of our allowance for estimated credit losses, which was $361,397 at March 31, 2004. While credit losses have been within our expectations and the allowance provided, these losses can vary from period to period (approximately $89,000, $213,000, and $5,000 for the years ended December 31, 2003, 2002 and 2001, respectively). Furthermore, there is no assurance that we will experience credit losses at the same rates as we have in the past. Also, at March 31, 2004, approximately $3.0 million or 41% of our accounts receivable were due from two major customers. Any significant changes in the liquidity or financial position of these customers, or others, could have a material adverse impact on the collectibility of our accounts receivable and future operating results.

Inventories. Our inventories are valued at the lower of cost or market, determined on a first-in, first-out basis, and include the cost of raw materials, labor and overhead. The majority of our inventories are subject to expiration dating. We continually evaluate the carrying value of our inventories and when, in the opinion of management, factors indicate that impairment has occurred, either the inventories’ carrying value is reduced or the inventories are completely written off. We base these decisions on the level of inventories on hand in relation to our estimated forecast of product demand, production requirements over the next twelve months and the expiration dates of raw materials and finished goods. During the years ended December 31, 2003, 2002 and 2001, we wrote-off inventory which had a cost of approximately $500,000, $1.4 million, and $600,000, respectively, as a result of manufacturing scrap levels and product expiration issues. Forecasting product demand can be a complex

process, especially for a new product such as our OraQuick® rapid HIV-1 antibody test. Although we make every effort to ensure the accuracy of our forecasts of future product demand, any significant unanticipated changes in demand could have a significant impact on the carrying value of our inventories and reported operating results.

Long-lived and Intangible Assets. Our long-lived assets are comprised of property and equipment and an investment in a nonaffiliated entity, and our intangible assets primarily consist of patents and product rights. Together, these assets have a net book value of approximately $8.7 million or 10% of our total assets at March 31, 2004. Our investment in a privately-held nonaffiliated company is recorded under the cost method of accounting, because we do not have a controlling interest in this company nor do we have the ability to exert significant influence over the operating and financial policies of this investee company. Property and equipment, patents and product rights are amortized on a straight-line basis over their useful lives, which we determine based upon our estimate of the period of time over which each asset will generate revenues. An impairment of long-lived or intangible assets could occur whenever events or changes in circumstances indicate that the net book value of these assets may not be recoverable. Events which could trigger an asset impairment include significant underperformance relative to expected historical or projected future operating results, significant changes in the manner of our use of an asset or in our strategy for our overall business, significant negative industry or economic trends, shortening of product life-cycles or changes in technology, and negative financial performance of our nonaffiliated investee company. If we believe impairment of an asset has occurred, we measure the amount of such impairment by comparing the net book value of the affected assets to the fair value of these assets, which is generally determined based upon the present value of the expected cash flows associated with the use of these assets. If the net book value exceeds the fair value of the impaired assets, we would incur an impairment expense equal to this difference. We currently believe the future cash flows to be received from our long-lived and intangible assets will exceed their book value and, as such, we have not recognized any impairment losses through March 31, 2004. Any unanticipated significant impairment in the future, however, could have a material adverse impact on our balance sheet and future operating results.

Deferred Tax Assets. At December 31, 2003, we have federal net operating loss (“NOL”) carryforwards of approximately $76.6 million. The deferred tax asset associated with these NOLs and other temporary differences is approximately $31.7 million at December 31, 2003. In assessing the realizability of deferred tax assets, we consider whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the period in which those temporary differences become deductible. We consider the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. Based upon our cumulative and recent history of losses and projections for future taxable income over the periods in which the deferred tax assets are deductible, we believe that a full valuation allowance is necessary at this time. Our level of future profitability could cause us to conclude that all or a portion of the deferred tax asset will be realizable. Upon reaching such a conclusion, we would immediately record the estimated net realizable value of the deferred tax asset and would begin to provide for income taxes at a rate equal to our combined federal and state effective rates, which we believe would approximate 40%. Subsequent revisions to the estimated net realizable value of the deferred tax asset could cause our provision for income taxes to vary significantly from period to period.

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

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We do not hold any amounts of derivative financial instruments or derivative commodity instruments and accordingly, we have no material market risk to report under this Item.

Our holdings of financial instruments are comprised of certificates of deposit, commercial paper, U.S. government and agency obligations, state and local government agency obligations, corporate bonds, and asset-backed obligations. All such instruments are classified as available for sale securities. Our debt security portfolio represents funds held temporarily pending use in our business and operations. We seek reasonable assuredness of the safety of principal and market liquidity by investing in rated fixed income securities while at the same time seeking to achieve a favorable rate of return. Market risk exposure consists principally of exposure to changes in interest rates. If changes in interest rates would affect the investments adversely, we could decide to hold the security to maturity or sell the security. Our holdings are also exposed to the risks of changes in the credit quality of issuers. We typically invest in the shorter end of the maturity spectrum.

We do not currently have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. We have operations in The Netherlands which are subject to foreign currency fluctuations. As currency rates change, translation of the statement of operations for this operation from euros to U.S. dollars affects year-to-year comparability of operating results. Sales denominated in a foreign currency represented approximately $415,000 or 3.3% of our total revenues for the three months ended March 31, 2004. We do not expect the risk of foreign currency fluctuations to be material.

Item 4. CONTROLS AND PROCEDURES.

(a) Evaluation of Disclosure Controls and Procedures. The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures as of March 31, 2004. Based on that evaluation, the Company's management, including such officers, concluded that the Company's disclosure controls and procedures were effective in timely alerting them to material information relating to the Company, which is required to be included in its periodic filings with the Securities and Exchange Commission.

(b) Changes in Internal Control Over Financial Reporting. The evaluation referred to in paragraph (a) of this Item did not identify any change in the Company's internal control over financial reporting that occurred during the quarter ended March 31, 2004 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS.

In June 2002, Abbott Laboratories became a co-exclusive distributor of our OraQuick® rapid HIV-1 antibody test in the United States under a five-year agreement, which required minimum monthly purchases totaling approximately $4 million during a 15-month period following initial FDA approval of the product. The OraQuick® test received initial FDA approval in November 2002.

Abbott failed to meet its minimum purchase obligations under the agreement, and we asserted that the agreement was therefore terminated. Abbott disputed the termination, and in October 2003, it invoked the arbitration procedure for resolution of disputes under the agreement. In February 2004, the arbitrator ruled that the agreement did not terminate, and that our remedy is limited to revoking Abbott's status as a co-exclusive distributor. We have notified Abbott that, based on the magnitude of its purchases, we have decided to convert Abbott's distribution rights to non-exclusive. As a further result of the arbitrator's rulings, we will be required to fulfill Abbott's purchase orders at the agreed upon price contained in the original agreement.

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

(a) Exhibits.

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

(b) Reports on Form 8-K.

Current Report on Form 8-K, dated March 26, 2004, reporting the Company's announcement (i) that it will need to submit additional performance data to the U.S. Food and Drug Administration ("FDA") in order to obtain 510(k) clearance of its UP*link*® Oral Fluid Drug Detection System and (ii) that the FDA has approved oral fluid and plasma claims for the Company's OraQuick® Rapid HIV-1/2 Antibody Test.

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SIGNATURES

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

ORASURE TECHNOLOGIES, INC.

/s/ Ronald H. Spair

Date: May 7, 2004

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

/s/ Mark L. Kuna

Date: May 7, 2004

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

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EXHIBIT INDEX

Exhibit	
10	Transition Agreement and Release, dated as of March 8, 2004, between Michael J. Gausling and OraSure Technologies, Inc.*
31.1	Certification of Michael J. Gausling required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Ronald H. Spair required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
32.1	Certification of Michael J. Gausling required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Ronald H. Spair required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Management contract or compensatory plan or arrangement.

Exhibit 10

TRANSITION AGREEMENT AND RELEASE

THIS TRANSITION AGREEMENT AND RELEASE (the "Agreement") is entered into on this 8th day of March 2004 (the "Effective Date"), by and between Michael J. Gausling ("Executive") and OraSure Technologies, Inc., a Delaware corporation, together with each and every of its predecessors, successors (by merger or otherwise), parents, subsidiaries, affiliates, divisions and related entities directors, officers, executives, attorneys and agents, whether present or former, (the "Company").

WHEREAS, Executive is currently employed by the Company as its President and Chief Executive Officer ("CEO") pursuant to an Employment Agreement dated September 29, 2000 ("Employment Agreement");

WHEREAS, Executive desires to retire from his employment with the Company and position with the Company's Board of Directors (the "Board");

WHEREAS, pursuant to the terms of the Employment Agreement, Company has provided Executive notice of Company's intention not to renew the Employment Agreement;

WHEREAS, the parties desire to enter into this Agreement whereby Executive will assist in the transition of his job duties to a successor President and CEO;

WHEREAS, the parties desire to part on an amicable basis;

NOW THEREFORE, in consideration of these premises and the mutual promises contained herein, and intending to be legally bound hereby, the parties agree as follows:

1. Contract Termination. By mutual agreement of the parties the Employment Agreement is hereby terminated effective the date of this Agreement.

2. Executive's Duties. Notwithstanding the termination of the Employment Agreement, Executive agrees to continue to devote his entire business skill, time and effort as President and CEO of the Company until December 31, 2004 ("Transition Period") or until such time as the Board directs differently, but not later than December 31, 2004. Executive will continue to serve on the Board until December 31, 2004 unless the Board requests his earlier retirement. Executive agrees that, if so directed by the Board, he will retire from his position as President and CEO and from any and all positions held on the Board prior to December 31, 2004. At such time, Executive will be relieved of all specific job duties and will no longer have authority to act on behalf of the Company. However, the Company and Executive further agree that, should the Board direct his retirement prior to December 31, 2004, he will remain an employee of the Company but need not be present in the office on a daily basis. Executive will cooperate on an as-needed basis with any requests from the Board or from a successor President and/or CEO during the Transition Period to assist in the transition of responsibilities to his successor.

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3. Termination for Cause. The Company may terminate Executive's employment under this Agreement at any time for cause. Only the following actions, failures, or events by or affecting Executive shall constitute "cause" for termination of Executive by the Company:

a. willful and continued failure by Executive to substantially perform his duties provided herein after a written demand for substantial performance is delivered to Executive by the Chairman of the Board, which demand identifies with reasonable specificity the manner in which Executive has not substantially performed his duties, and Executive's failure to comply with such demand within a reasonable time;

b. the engaging by Executive in gross misconduct or gross negligence materially injurious to the Company;

c. the commission of any act in direct competition with or materially detrimental to the best interests of the Company; or

d. Executive's conviction of having committed a felony.

Notwithstanding the foregoing, Executive shall not be deemed to have been terminated by the Company for cause unless and until there shall have been delivered to him a copy of a resolution duly adopted by the affirmative vote of not less than a majority of the entire membership of the Board finding that, in the good faith opinion of the Board, the Company has cause for the termination of the employment of Executive as set forth in any of clauses (a) through (d) above and specifying the particulars thereof in reasonable detail.

4. Compensation During Transition Period. Provided that Executive complies with the terms of this Agreement, Executive will receive the following:

a. base salary through the Transition Period at its present level paid in accordance with the Company's normal payroll process;

b. full executive benefits for Executive, his spouse and their dependents under the Company's group health and other benefit arrangements at the current level and rates through the Transition Period;

c. year 2004 cash bonus payable, if at all, at the same time as bonus payments are made to the other bonus plan participants, which cash bonus shall be calculated pursuant to the terms of the 2004 Self-Funding Annual Bonus Plan, provided however, that the personal performance factor to be used in the Executive's bonus calculation will not be less than personal performance factor used for the Executive in 2003; and

d. upon Executive's execution of this Agreement, pursuant to the Company's 2000 Stock Award Plan ("2000 Award Plan"), the Company will grant to Executive a non-qualified stock option to purchase 100,000 shares of the Company's common stock at a per share exercise price equal to the fair market value of such shares (defined as the average of the high and low sales prices as reported on the NASDAQ Stock Market) on the date of the grant (the "2004 Option"); which options shall vest in full on December 31, 2004 provided that (i)

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Executive does not exercise his right of revocation as set forth in paragraph 13 of this Agreement, and (ii) Executive has complied with this Agreement and has continuously been an employee of the Company from the date of this Agreement through December 31, 2004. Notwithstanding the generality of the foregoing sentence, the 2004 Option shall immediately lapse if the Executive's employment with the Company ceases for any reason prior to December 31, 2004 other than due to a "change of control" (as defined in Section 6.4.3 of Executive's terminated employment agreement, which is incorporated herein only for purposes of defining a "change of control"). Executive (or his personal representative) must exercise the 2004 Option, if ever, on or before December 31, 2009.

The Company's obligations to provide the compensation stated above in subparagraphs 4(a) – 4(d) shall not be relieved or diminished by the death or disability of Executive during the Transition Period.

5. Stock Options. Options previously granted to Executive pursuant to the Incentive Stock Option Award dated December 15, 1999 are fully vested and the Incentive Stock Option Awards and Nonqualified Stock Option Awards dated December 13, 2000, January 31, 2003, and January 14, 2004, will continue to vest pursuant to the terms of each grant and the Company's 2000 Award Plan for a period of ninety (90) days after Executive's last date of employment with the Company. The foregoing option awards are referred to as the 'Existing Option Awards." Executive (or his personal representative) must exercise the Existing Option Awards within one year following his last date of employment with the Company, except for the Incentive Stock Option Award dated December 15, 1999 which must be exercised by December 15, 2004.

6. Salary Continuation Payments. Provided that Executive has complied with the terms of this Agreement, at the conclusion of the Transition Period, Executive agrees to sign and deliver to the Company a release in the form attached hereto as Exhibit A. In consideration for that release and the covenants in paragraph 8 of this Agreement, the Company will provide Executive with salary continuation payments for the period January 1, 2005 through December 31, 2005 ("Salary Continuation Period") as set forth in subparagraphs (a) and (b), below. However, if Executive fails to comply with paragraphs 8 or 11.b of this Agreement during the Transition Period or Salary Continuation Period, the Company's obligation to continue Executive's salary continuation payments shall end on the date of non-compliance and Executive shall return to the Company all monies paid to him by the Company pursuant to this paragraph. The Company's obligations to continue salary continuation payments shall not be relieved or diminished by the Executive's death or disability prior to, or during, the Salary Continuation Period. Should the Company cease payments under this paragraph due to Executive's failure to comply with paragraphs 8 or 11.b, all other rights or obligations of the parties under this Agreement shall remain in full force and effect.

a. The Company will continue to pay Executive's base salary at its present rate during the Salary Continuation Period in an aggregate amount of $325,000. These payments will be made in four (4) equal amounts at the end of each fiscal quarter during 2005, subject to all local, state, and federal income tax withholding; provided, however, that if a

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"change of control" (as defined in Section 6.4.3 of Executive's terminated Employment Agreement, which is referenced herein only for purposes of defining a "change of control") of the Company occurs either (i) before September 29, 2004 or (ii) between September 30, 2004 and December 31, 2004 so long as the Company has not hired a successor President and CEO, the "Salary Continuation Period" shall be as follows: Executive shall continue to be paid base salary at the rate of $325,000, in the manner and at the times at which regular compensation was paid to Executive during the term of his employment, for a period of 36 months from the date of notice of the change of control, except that if Executive continues to work for the Company or any of its subsidiaries, then any amounts Executive receives as compensation following the event shall be credited against the amounts payable to Executive under this subparagraph. In no other respect shall the amount of any payment provided for in this subparagraph be reduced by any compensation or benefits earned by Executive as a result of employment after his termination.

b. Under COBRA, Executive is eligible for continuing coverage under the Company's health benefit plan for a period of eighteen months from January 1, 2005. If Executive takes the necessary steps to elect COBRA continuation coverage, the Company will reimburse Executive for the cost of his COBRA premiums for the 12-month period ending December 31, 2005. Executive will be responsible for all local, state, and federal income tax withholding and payments for these amounts. For the remaining COBRA period, Executive will be responsible for paying the applicable COBRA premiums.

7. Release. In exchange for the payments referenced in paragraphs 2 and 4 of this Agreement and the other consideration set forth in this Agreement, Executive on behalf of himself, his spouse, dependents, heirs, executors, legal representatives and assignees hereby generally releases and discharges (collectively, the "Releasor") the Company, together with each and every of its predecessors, successors (by merger or otherwise), parents, subsidiaries, affiliates, divisions and related entities, directors, officers, executives, attorneys and agents, whether present or former (collectively the "Releasees"), from any and all suits, causes of action, complaints, obligations, demands, or claims of any kind, whether in law or in equity, direct or indirect, known or unknown, suspected or unsuspected (hereinafter "claims"), which the Executive ever had or now has arising out of or relating to any matter, thing or event occurring up to and including the date of this Agreement. Except as otherwise expressly provided in this Agreement, Executive's Release specifically includes, but is not limited to:

a. any and all claims for wages and benefits including, without limitation, salary, stock, options, commissions, royalties, license fees, health and welfare benefits, severance pay, vacation pay, incentives, and bonuses;

b. any and all claims for wrongful discharge, breach of contract (whether express or implied), or for breach of the implied covenant of good faith and fair dealing;

c. any and all claims for alleged employment discrimination on the basis of age, race, color, religion, sex, national origin, veteran status, disability and/or handicap and any and all other claims in violation of any federal, state or local statute, ordinance, judicial precedent or executive order, including but not limited to claims under the following statutes:

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Title VII of the Civil Rights Act of 1964, as amended, 42 U.S.C. §2000e et seq., the Civil Rights Act of 1866, 42 U.S.C. §1981, the Age Discrimination in Employment Act, 29 U.S.C. §621 et seq., the Older Workers Benefit Protection Act, 29 U.S.C. §626(f), the Americans with Disabilities Act, 42 U.S.C. §12101 et seq., the Family and Medical Leave Act of 1993, the Fair Labor Standards Act, the Executive Retirement Income Security Act of 1974, or any comparable statute of any other state, country, or locality except as required by law, but excluding claims for vested benefits under the Company's pension plans;

d. any and all claims under any federal, state or local statute or law;

e. any and all claims in tort (including but not limited to any claims for misrepresentation, defamation, interference with contract or prospective economic advantage, intentional or negligent infliction of emotional distress, duress, loss of consortium, invasion of privacy and negligence);

f. any and all claims for attorneys' fees and costs;

g. any and all other claims for damages of any kind; and

h. any and all claims relating to or arising out of the Employment Agreement.

Notwithstanding the foregoing, nothing contained in this paragraph shall apply to, or shall release the Company from, (i) any obligation of the Company under this Agreement; (ii) any accrued or vested benefit of the Executive pursuant to any executive benefit plan of the Company, (iii) any obligation of the Company under Existing Option Awards, or (iv) the Executive's rights to indemnification and contribution related to his service as an officer or director of the Company under the Indemnification Agreement between the Company and the Executive, dated September 29, 2000, or pursuant to the Company's Certificate of Incorporation or Bylaws.

8. Non-Competition. During the Transition and/or Salary Continuation Periods, Executive agrees that, unless he obtains written agreement from the Board of Directors, he will not:

a. recruit, solicit, or hire any Executive or employee of the Company;

b. induce or solicit any current of prospective customer, client, or supplier of the Company to cease being a customer, client or supplier or divert Company business away from any customer, client, or supplier of the Company;

c. own, manage, control, work for, or provide services to any entity which competes with the Company in the market for oral fluid or rapid point-of-care diagnostic testing in the United States.

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9. Directors' and Officers' Liability Insurance. To the extent the Company maintains liability insurance coverage for its directors and officers, the Company agrees to make reasonable best efforts to continue to maintain coverage for the Executive under such policy or policies through January 31, 2007, in accordance with its or their terms, to the maximum extent of the coverage provided under such policy or policies in effect for any other director or officer of the Company.

10. Cooperation Agreement. Executive agrees that, subject to prompt reimbursement by the Company of reasonable out-of-pocket costs and expenses, he will cooperate fully with the Company and its counsel with respect to any matter (including litigation, investigation, or governmental proceeding) which relates to matters with which Executive was involved during the term of employment with the Company. The Company agrees to provide Executive with reasonable notice, as practicable, that it requires Executive's assistance. Executive will render such cooperation in a timely manner and at such times and places as may be mutually agreeable to the parties. It is agreed that the Company will only require Executive to provide such cooperation at reasonable times and that such cooperation will not interfere with other employment or other business ventures that Executive may choose to undertake. Should such cooperation be required after December 31, 2005, the Company will pay Executive a per diem of Fifteen Hundred ($1,500.00) Dollars for each day or part thereof.

11. Return of Employer Property and Confidential Information.

a. On or prior to December 31, 2004, Executive will return to the Company in good working order all Company property within his possession, custody, and control. Such property includes, but is not limited to, keys, software, calculators, equipment, computers, credit cards, forms, files, documents, manuals, correspondence, business cards, personnel data, lists of or other information regarding customers, contacts and/or executives, contracts, agreements, leases, plans, financial data or documents, brochures, catalogues, training materials, computer tapes, and diskettes or other portable media.

b. Executive acknowledges that during his employment with the Company he had personal contact with and otherwise became aware of business data and other records that are confidential and proprietary to the Company or any of its present or former directors, officers, or executives. Executive further acknowledges that the confidential and proprietary information was entrusted to him as an executive of the Company. Executive affirms that he understands his obligation to keep confidential the business and proprietary information of the Company or any of its present or former directors, officers, or executives, including all confidential and proprietary information and agrees not to disclose it to, or allow it to become known by, any person who is not an executive of the Company or its affiliates, subsidiaries or agents. It is the parties' understanding, agreement and expectation that this confidentiality provision shall apply to the fullest extent permissible by law.

12. Acknowledgment. Executive understands that his Release extends to all of the aforementioned claims and potential claims which arose on or before the date of this Agreement, whether now known or unknown, suspected or unsuspected, and that this constitutes

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an essential term of the Release. Executive further understands and acknowledges the significance and consequence of the Release and of each specific release and waiver, and expressly consents that the Release shall be given full force and effect according to each and all of its express terms and provisions, including those relating to unknown and unsuspected claims, demands, obligations, and causes of action, if any, as well as those relating to any other claims, demands, obligations or causes of action herein above-specified.

13. Advice of Counsel; Revocation Period. Executive is hereby advised to seek the advice of counsel. Executive acknowledges that he has, in fact, sought the advice of counsel, and is acting of his own free will, that the Executive has been afforded a reasonable time to read and review the terms of this Agreement and the Release, and that the Executive is voluntarily entering into this Agreement and the Release with full knowledge of its provisions and effects. Executive intends that this Agreement and the Release shall not be subject to any claim for duress. Executive further acknowledges that the Executive has been given at least twenty-one (21) days within which to consider the Release and that if the Executive decides to execute this Agreement and the Release before the twenty-one day period has expired, the Executive does so voluntarily and waives the opportunity to use the full review period. Executive also acknowledges that he has seven (7) days following his execution of this Agreement and the Release to revoke acceptance of the Release of age discrimination claims, with the Release of age discrimination claims not becoming effective until the revocation period has expired. If Executive chooses to revoke his acceptance of the Release, he should provide written notice to:

Jonathan Kane, Esquire
Pepper Hamilton LLP
899 Cassatt Road
400 Berwyn Park
Berwyn, PA 19312

14. No Admissions. Neither the execution of this Agreement nor the terms hereof constitute an admission by the Company of liability to Executive.

15. No Disparagement. Executive agrees to refrain from making disparaging comments about the Company, and further agrees not to disrupt the Company's business activities in any manner whatsoever, and not to take any action that might affect adversely the professional or business reputation of the Company. The Company agrees not to disparage the Executive.

16. Confidentiality. Except to the extent otherwise required by law, rule or regulation, the parties hereto will not disclose, in whole or in part, the existence, negotiation, or any of the terms of this Agreement. However, the parties may disclose the terms of this Agreement to their legal and financial advisors (and Executive may disclose the terms of this Agreement to his spouse), provided that the parties take all reasonable measures to assure that those individuals do not disclose the terms of this Agreement to a third party except as otherwise required by law.

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17. Miscellaneous.

a. Successors and Assigns. This Agreement shall inure to the benefit of and be binding upon the Company and Executive and their respective successors, executors, administrators, heirs and/or permitted assigns; provided, however, that neither Executive nor the Company may make any assignments of this Agreement or any interest herein, by operation of law or otherwise, without the prior written consent of the other party, except that, without such consent, the Company may assign this Agreement to any successor to all or substantially all of its assets and business by means of liquidation, dissolution, merger, consolidation, transfer of assets, or otherwise. The Company shall cause any successor to all or substantially all of its assets to assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform it if no succession had taken place. In the event of Executive's death or disability during either the Transition or Salary Continuation Periods the Company shall make any payments due Executive in accordance with written instructions from Executive's executor or personal representative.

b. Notice. Any notice or communication required or permitted under this Agreement shall be made in writing and (a) sent by overnight courier, (b) mailed by certified or registered mail, return receipt requested or (c) sent by telecopier, addressed as follows:

If to Executive:

Michael J. Gausling
1512 Colesville Road,
Bethlehem, PA 18015

with a copy to:

Tallman, Hudders & Sorrentino, P.C.
Attn: Matthew R. Sorrentino, Esq.
Suite 300, 1611 Pond Road
Allentown, PA 18104

If to Company:

OraSure Technologies, Inc.
Attn: Jack E. Jerrett. Esq.
220 E. First Street
Bethlehem, PA 18015
Fax: (610) 882-2275

with a copy to:

Pepper Hamilton LLP
899 Cassatt Road
400 Berwyn Park

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Berwyn, PA 19312
Attn: Jonathan Kane, Esquire
Fax: 610-640-7835

or to such other address as either party may from time to time duly specify by notice given to the other party in the manner specified above.

c. Entire Agreement; Amendments. This Agreement contains the entire agreement and understanding of the parties hereto relating to the subject matter hereof, and merges and supersedes all prior and contemporaneous discussions, agreements and understandings of every nature relating to the employment of Executive by the Company. This Agreement may not be changed or modified, except by an Agreement in writing signed by each of the parties hereto.

d. Waiver. Any waiver by either party of any breach of any term or condition in this Agreement shall not operate as a waiver of any other breach of such term or condition or of any other term or condition, nor shall any failure to enforce any provision hereof operate as a waiver of such provision or of any other provision hereof or constitute or be deemed a waiver or release of any other rights, in law or in equity.

e. Governing Law. This Agreement shall be governed by, and enforced in accordance with, the laws of the Commonwealth of Pennsylvania without regard to the application of the principles of conflicts of laws.

f. Severability. Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision or the effectiveness or validity of any provision in any other jurisdiction, and this Agreement will be reformed, construed and enforced in such jurisdiction as if such invalid, illegal or unenforceable provision had never been contained herein.

g. Section Headings. The section headings in this Agreement are for convenience only; they form no part of this Agreement and shall not affect its interpretation.

h. Consent to Suit. Any legal proceeding arising out of or relating to this Agreement shall be instituted in the United States District Court for the Eastern District of Pennsylvania, or if such court does not have jurisdiction or will not accept jurisdiction, in any court of general jurisdiction in the county in Pennsylvania in which the Company maintains its principal place of business, and Executive and the Company hereby consent to the personal and exclusive jurisdiction of such court and hereby waive any objection that Executive or the Company may have to personal jurisdiction, venue, and any claim or defense of inconvenient forum.

i. Counterparts and Facsimiles. This Agreement may be executed, including execution by facsimile signature, in one or more counterparts, each of which shall be deemed an original, and all of which together shall be deemed to be one and the same instrument.

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IN WITNESS WHEREOF, the Company has caused this Agreement to be executed by its duly authorized officer, and Executive has executed this Agreement, in each case on the date first above written.

OraSure Technologies, Inc.

By: /s/ *Douglas G. Watson*

Name: Douglas G. Watson
Title: Chairman of the Board

/s/ Michael J. Gausling

Michael J. Gausling

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EXHIBIT A

SEPARATION AGREEMENT AND RELEASE

THIS SEPARATION AGREEMENT AND RELEASE (the "Agreement") is entered into on this 31st day of December 2004, by and between Michael J. Gausling ("Executive") and OraSure Technologies, Inc., a Delaware corporation, together with each and every of its predecessors, successors (by merger or otherwise), parents, subsidiaries, affiliates, divisions and related entities directors, officers, Executives, attorneys and agents, whether present or former (collectively the "Company");

WHEREAS, Executive executed a Transition Agreement and Release ("Transition Agreement"), on March __, 2004 and agrees to continue to abide by the terms of the Transition Agreement;

WHEREAS, Executive agrees to execute this Separation Agreement and Release it relates to the Transition Agreement;

WHEREAS, capitalized terms not otherwise defined in this Agreement shall have the meanings set forth in the Transition Agreement; and

NOW, THEREFORE, the parties agree as follows, in consideration of the mutual covenants and obligations contained herein, and intending to be legally held bound:

1. Consideration. In consideration for Executive's agreement to abide by the promises and covenants set forth in the foregoing Transition Agreement, the Company agrees to abide by the promises and covenants set forth in the Transition Agreement. Executive acknowledges that the consideration set forth in the Transition Agreement constitutes consideration to which Executive would not otherwise be entitled.

2. Executive's Release. In exchange for the salary continuation payments referenced in paragraph 6 of the Transition Agreement, Executive hereby generally releases and discharges the Company, together with each and every of its predecessors, successors (by merger or otherwise), parents, subsidiaries, affiliates, divisions and related entities, directors, officers, executives, attorneys and agents, whether present or former (collectively the "Releasees"), from any and all suits, causes of action, complaints, obligations, demands, or claims of any kind, whether in law or in equity, direct or indirect, known or unknown, suspected or unsuspected (hereinafter "claims"), which the Executive ever had or now has arising out of or relating to any matter, thing or event occurring up to and including the date of this Agreement. Except as otherwise expressly provided in this Agreement, Executive's release specifically includes, but is not limited to:

a. any and all claims for wages and benefits including, without limitation, salary, stock, options, commissions, royalties, license fees, health and welfare benefits, separation pay, vacation pay, incentives, and bonuses;

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b. any and all claims for wrongful discharge, breach of contract (whether express or implied), or for breach of the implied covenant of good faith and fair dealing;

c. any and all claims for alleged employment discrimination on the basis of age, race, color, religion, sex, national origin, veteran status, disability and/or handicap and any and all other claims in violation of any federal, state or local statute, ordinance, judicial precedent or executive order, including but not limited to claims under the following statutes: Title VII of the Civil Rights Act of 1964, as amended, 42 U.S.C. §2000e et seq., the Civil Rights Act of 1866, 42 U.S.C. §1981, the Age Discrimination in Employment Act, 29 U.S.C. §621 et seq., the Older Workers Benefit Protection Act, 29 U.S.C. §626(f), the Americans with Disabilities Act, 42 U.S.C. §12101 et seq., the Family and Medical Leave Act of 1993, the Fair Labor Standards Act, the Executive Retirement Income Security Act of 1974, or any comparable statute of any other state, country, or locality except as required by law, but excluding claims for vested benefits under the Company's pension plans;

d. any and all claims under any federal, state or local statute or law;

e. any and all claims in tort (including but not limited to any claims for misrepresentation, defamation, interference with contract or prospective economic advantage, intentional or negligent infliction of emotional distress, duress, loss of consortium, invasion of privacy and negligence);

f. any and all claims for attorneys' fees and costs;

g. any and all other claims for damages of any kind; and

h. any and all claims relating to or arising out of the Employment Agreement.

Notwithstanding the foregoing, nothing contained in this paragraph shall apply to, or shall release the Company from, (i) any obligation of the Company under this Agreement; (ii) any accrued or vested benefit of the Executive pursuant to any executive benefit plan of the Company, (iii) any obligation of the Company under the Existing Option Awards, or (iv) the Executive's rights to indemnification and contribution related to his service as an officer or director of the Company under the Indemnification Agreement between the Company and the Executive, dated September 29, 2000, or pursuant to the Company's Certificate of Incorporation or Bylaws.

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3. Acknowledgment. Executive understands that his release extends to all of the aforementioned claims and potential claims which arose on or before the date of this Agreement, whether now known or unknown, suspected or unsuspected, and that this constitutes an essential term of this Agreement. Executive further understands and acknowledges the significance and consequence of this Agreement and of each specific release and waiver, and expressly consents that this Agreement shall be given full force and effect according to each and all of its express terms and provisions, including those relating to unknown and unsuspected claims, demands, obligations, and causes of action, if any, as well as those relating to any other claims, demands, obligations or causes of action herein above-specified.

4. Remedies. All remedies at law or in equity shall be available to the Company for the enforcement of this Agreement . This Agreement may be pleaded as a full bar to the enforcement of any claim that Executive may assert against the Company in violation of this Agreement .

5. No Admissions. Neither the execution of this Agreement by the Company, nor the terms hereof, constitute an admission by the Company of liability to Executive.

6. Confidentiality. To the extent not otherwise made public by the Company, Executive shall not disclose or publicize the terms or fact of this Agreement, directly or indirectly, to any person or entity, except to Executive's attorney, spouse, and to others as required by law. Executive is specifically prohibited from disclosing the facts or terms of this Agreement to any former or present executive of the Company except as required by law.

7. Entire Agreement This Agreement, together with the terms of the Transition Agreement, contain the entire agreement of the parties with respect to the subject matter hereof, supersede any prior agreements or understandings with respect to the subject matter hereof, and shall be binding upon their respective heirs, executors, administrators, successors and assigns.

9. Severability. If any term or provision of this Agreement shall be held to be invalid or unenforceable for any reason, the validity or enforceability of the remaining terms or provisions shall not be affected, and such term or provision shall be deemed modified to the extent necessary to make it enforceable.

10. Advice of Counsel; Revocation Period. Executive is hereby advised to seek the advice of counsel. Executive acknowledges that he is acting of his own free will, that he has been afforded a reasonable time to read and review the terms of this Agreement, and that Executive is voluntarily entering into this Agreement with full knowledge of its provisions and effects. Executive intends that this Agreement shall not be subject to any claim for duress. Executive further acknowledges that he has been given at least twenty-one (21) days within which to consider this Agreement and that if Executive decides to execute this Agreement before the twenty-one day period has expired, Executive does so voluntarily and waives the opportunity to use the full review period. Executive also acknowledges that he has seven (7) days following his execution of this Agreement to revoke acceptance of this Agreement, with the Agreement not becoming effective until the revocation period has expired. If Executive chooses to revoke his acceptance of this Agreement, he should provide written notice to:

Jonathan Kane, Esquire
Pepper Hamilton LLP
899 Cassatt Road
400 Berwyn Park
Berwyn, PA 19312

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11. Amendments. Neither this Agreement nor any term hereof may be orally changed, waived, discharged, or terminated, and may be amended only by a written agreement between the parties hereto.

12. Governing Law. This Agreement shall be governed by the laws of the Commonwealth of Pennsylvania, without regard to the conflict of law principles of any jurisdiction.

13. Legally Binding. The terms of this Agreement contained herein are contractual, and not a mere recital.

IN WITNESS WHEREOF, the parties, acknowledging that they are acting of their own free will, have caused the execution of this Agreement as of this day and year written below.

OraSure Technologies, Inc.

By: _____

Name: _____

Title: _____

/s/ Michael J. Gausling

Michael J. Gausling

Initial _____

Exhibit 31.1

Certification

I, Michael J. Gausling, certify that:

1. I have reviewed this report on Form 10-Q of OraSure Technologies, Inc;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d –15(e)) for the registrant and have:
    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within the entity, particularly during the period in which this report is being prepared;
    b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2004

/s/ Michael J. Gausling

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

Exhibit 31.2

Certification

I, Ronald H. Spair, certify that:

1. I have reviewed this report on Form 10-Q of OraSure Technologies, Inc;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d –15(e)) for the registrant and have:
    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within the entity, particularly during the period in which this report is being prepared;
    b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2004

/s/ Ronald H. Spair

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

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. §1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of OraSure Technologies, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael J. Gausling, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Michael J. Gausling

Michael J. Gausling
President and Chief Executive Officer

May 7, 2004

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. §1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of OraSure Technologies, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ronald H. Spair, Executive Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Ronald H. Spair

Ronald H. Spair
Executive Vice President and
Chief Financial Officer

May 7, 2004