UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2005.

OR

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

For the transition period from _____ to _____.

Commission File Number 001-16537

ORASURE TECHNOLOGIES, INC.

(Exact Name of Registrant as Specified in Its Charter)

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

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

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

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

Number of shares of Common Stock, par value $.000001 per share, outstanding as of July 29, 2005: 45,287,396

Item 1. FINANCIAL STATEMENTS

ORASURE TECHNOLOGIES, INC.
BALANCE SHEETS
(Unaudited)

	June 30, 2005	December 31, 2004
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 20,728,862	$ 10,121,208
Short-term investments	50,734,444	56,602,248
Accounts receivable, net of allowance for doubtful accounts of $349,424 and $345,257	8,752,806	7,073,988
Inventories	4,127,297	4,951,979
Prepaid expenses and other	1,192,181	1,195,085
Total current assets	85,535,590	79,944,508
PROPERTY AND EQUIPMENT, net	5,143,715	5,551,261
PATENTS AND PRODUCT RIGHTS, net	1,706,817	2,080,363
OTHER ASSETS	465,427	488,192
	$ 92,851,549	$ 88,064,324
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	$ 904,464	$ 1,122,455
Accounts payable	2,009,217	2,360,214
Accrued expenses	7,800,302	7,552,279
Total current liabilities	10,713,983	11,034,948
LONG-TERM DEBT	992,731	1,334,236
OTHER LIABILITIES	249,927	118,135
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, 45,038,466 and 44,631,731 shares issued and outstanding	45	45
Additional paid-in capital	212,939,311	209,948,075
Deferred compensation	(3,592,367)	(2,916,503)
Accumulated other comprehensive loss	(326,152)	(324,669)
Accumulated deficit	(128,125,929)	(131,129,943)
Total stockholders' equity	80,894,908	75,577,005
	$ 92,851,549	$ 88,064,324

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.
STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
REVENUES:				
Product	$17,304,419	$13,122,039	$33,048,395	$25,410,907
Licensing and product development	125,763	92,674	210,077	212,414
	17,430,182	13,214,713	33,258,472	25,623,321
COSTS OF PRODUCTS SOLD	7,970,140	5,524,736	14,340,763	10,715,266
Gross profit	9,460,042	7,689,977	18,917,709	14,908,055
COSTS AND EXPENSES:				
Research and development	1,254,100	1,513,617	2,452,634	3,280,774
Sales and marketing	4,456,310	3,780,765	8,323,789	7,431,481
General and administrative	2,787,627	2,446,174	5,964,207	4,572,146
	8,498,037	7,740,556	16,740,630	15,284,401
Operating income (loss)	962,005	(50,579)	2,177,079	(376,346)
INTEREST EXPENSE	(25,274)	(39,981)	(52,599)	(71,394)
INTEREST INCOME	466,783	230,022	838,844	435,781
OTHER, NET	—	—	420	—
FOREIGN CURRENCY GAIN	39,162	7,625	40,270	1,332
Income (loss) before income taxes	1,442,676	147,087	3,004,014	(10,627)
INCOME TAXES	—	4,961	—	9,461
NET INCOME (LOSS)	$ 1,442,676	$ 142,126	$ 3,004,014	$ (20,088)
EARNINGS (LOSS) PER SHARE:				
BASIC AND DILUTED	$ 0.03	$ 0.00	$ 0.07	$ (0.00)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING:				
BASIC	44,783,546	44,465,017	44,714,521	44,368,443
DILUTED	45,871,551	45,334,105	45,475,167	44,368,443

The accompanying notes are an integral part of these statements.

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

	Six Months Ended June 30,	
	2005	**2004**
OPERATING ACTIVITIES:		
Net income (loss)	$ 3,004,014	$ (20,088)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Stock-based compensation expense	917,871	197,952
Depreciation and amortization	1,228,634	1,204,290
Provision for loss on property and equipment	196,011	6,599
Provision for excess and obsolete inventories	1,712,724	327,866
Changes in assets and liabilities:		
Accounts receivable	(1,678,818)	1,425,037
Inventories	(888,042)	(1,087,112)
Prepaid expenses and other current assets	71,726	(64,269)
Accounts payable, accrued expenses, and other liabilities	280,266	(112,410)
Net cash provided by operating activities	4,844,386	1,877,865
INVESTING ACTIVITIES:		
Purchases of short-term investments	(28,147,550)	(36,322,110)
Proceeds from maturities and redemptions of short-term investments	34,047,419	16,874,400
Purchases of property and equipment	(522,236)	(599,789)
Expenditures for patents and in-process technology	(300,000)	—
Increase in other assets	(50,000)	(623)
Net cash provided by (used in) investing activities	5,027,633	(20,048,122)
FINANCING ACTIVITIES:		
Repayments of long-term debt	(559,496)	(563,644)
Proceeds from issuance of common stock	1,756,812	1,491,606
Retirement of common stock	(428,133)	—
Net cash provided by financing activities	769,183	927,962
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	(33,548)	(16,047)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	10,607,654	(17,258,342)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	10,121,208	30,695,177
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 20,728,862	$ 13,436,835

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. One of our products is also sold in the United States over-the-counter or consumer retail market.

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, 2004. Results of operations for the three-month and six-month periods ended June 30, 2005 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 June 30, 2005 and December 31, 2004, cash equivalents consisted of commercial paper, U.S. government 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 agency obligations, state and local government agency obligations, asset-backed obligations, and corporate bonds, all 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 June 30, 2005 and December 31, 2004:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
June 30, 2005				
Certificates of deposit	$16,489,500	$ —	$ (881)	$16,488,619
Commercial paper	2,559,275	—	(822)	2,558,453
Government agency bonds	18,710,652	—	(59,227)	18,651,424
State and local government agency obligations	861,900	234	(596)	861,537
Corporate bonds	12,206,789	434	(32,814)	12,174,411
Total available-for-sale securities	$50,828,116	$ 668	$ (94,340)	$50,734,444
December 31, 2004				
Certificates of deposit	$18,702,211	$ 56	$ (29,411)	$18,672,856
Commercial paper	4,281,910	185	—	4,282,095
Government agency bonds	21,112,676	113	(61,631)	21,051,158
State and local government agency obligations	629,322	162	(1,059)	628,425
Asset-backed obligations	1,002,116	—	(866)	1,001,250
Corporate bonds	10,999,750	431	(33,717)	10,966,464
Total available-for-sale securities	$56,727,985	$ 947	$(126,684)	$56,602,248
At June 30, 2005, maturities of investments were as follows:				
Less than one year	$50,828,116	$ 668	$ (94,340)	$50,734,444
1 – 2 years	—	—	(—)	—
Total available-for-sale securities	$50,828,116	$ 668	$ (94,340)	$50,734,444

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

	June 30, 2005	December 31, 2004
Raw materials	$2,406,442	$3,405,578
Work-in-process	798,232	659,304
Finished goods	922,623	887,097
	$4,127,297	$4,951,979

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. For the three-month period ended June 30, 2005, three individual customers accounted for 16, 11, and 10 percent of total revenues as compared to 25, 10, and 0 percent for the same period of 2004. For the six-month period ended June 30, 2005, these customers accounted for 21, 12, and 5 percent of total revenues as compared to 25, 13, and 0 percent for the same period of 2004. The same customers also accounted for approximately 13, 8, and 20 percent of accounts receivable as of June 30, 2005 and 23, 8, and 0 percent of accounts receivable as of December 31, 2004.

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 component of accumulated other comprehensive loss within stockholders' equity.

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Net income (loss)	$ 1,442,676	$ 142,126	$ 3,004,014	$ (20,088)
Weighted average shares of common stock outstanding:				
Basic	44,783,546	44,465,017	44,714,521	44,368,443
Dilutive effect of stock options, warrants and restricted shares	1,088,005	869,088	760,646	—
Diluted	45,871,551	45,334,105	45,475,167	44,368,443
Earnings (loss) per share:				
Basic	$ 0.03	$ 0.00	$ 0.07	$ (0.00)
Diluted	$ 0.03	$ 0.00	$ 0.07	$ (0.00)

For the three-month and six-month periods ended June 30, 2005 and 2004, outstanding common stock options, warrants, and unvested restricted stock, representing 347,792, 388,251, 1,800,335 and 5,777,270 shares, respectively, were excluded from the computation of diluted earnings (loss) per share, 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 Emerging Issues Task Force 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-based 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 stock-based awards been determined based upon the fair value of the awards at the date of grant, our net income (loss) for the three-month and six-month periods ended June 30, 2005 and 2004 would have been impacted as follows:

	Three months ended June 30,		Six months ended June 30,	
	2005	2004	2005	2004
Net income (loss):				
As reported	$ 1,442,676	$ 142,126	$ 3,004,014	$ (20,088)
Add: stock-based employee compensation expense included in net income (loss)	450,457	134,180	917,871	197,952
Deduct: total stock-based employee compensation expense determined under the fair value-based method for all awards	(1,234,705)	(1,392,745)	(2,569,714)	(2,641,239)
Pro forma	$ 658,428	$ (1,116,439)	$ 1,352,171	$ (2,463,375)
Basic and diluted income (loss) per share:				
As reported	$ 0.03	$ 0.00	$ 0.07	$ (0.00)
Pro forma	$ 0.01	$ (0.03)	$ 0.03	$ (0.06)

In May 2005, we modified the term of two individual Stock option grants. As a result, compensation expense of $33,992 was recorded during the three-month and six-month periods ended June 30, 2005. No such expense was recorded for the comparable periods in 2004.

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.

Recent Accounting Pronouncements. In November 2004, the Financial Accounting Standards Board ("FASB") issued SFAS No. 151, "Inventory Costs." SFAS No. 151 clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material and requires such costs to be recognized as current-period charges. Additionally, SFAS No. 151 requires that allocation of fixed production overhead costs be based on normal capacity. SFAS No. 151 is effective for years beginning after June 15, 2005, with early adoption permitted. The implementation of SFAS No. 151 is not expected to have a material effect on our financial position, results of operations or cash flows.

In December 2004, the FASB issued SFAS No. 123 Revised, "Share-Based Payment" ("SFAS No. 123R"). SFAS No. 123R requires employee stock options to be accounted for in the statement of operations based on their fair values on the date of grant, and eliminates the ability to account for these instruments under the intrinsic value method prescribed by APB Opinion No. 25. SFAS No. 123R requires the use of an option pricing model for estimating fair value, which is amortized to expense over the service period. The requirements of SFAS No. 123R are effective for annual periods beginning after June 15, 2005. SFAS No. 123R allows for either prospective recognition of compensation expense or retrospective recognition. The Company is considering the potential implementation of different valuation models to determine the fair value of stock-based compensation and, therefore, has not yet completed evaluating the impact of adopting SFAS No. 123R on its results of operations. If the Company had applied the provisions of SFAS No. 123R to the financial statements for the three-month and six-month periods ended June 30, 2005, net income would have been reduced by approximately $784,000 and $1.7 million, respectively.

3. Accrued Expenses:

	June 30, 2005	December 31, 2004
Payroll and related benefits	$2,344,783	$2,069,309
Royalties	2,012,206	1,069,932
Deferred revenue	1,521,220	1,353,711
Advertising	839,102	603,009
Professional fees	390,018	1,227,087
Laboratory testing fees	226,986	249,041
License fees	—	300,000
Other	465,987	680,190
	$7,800,302	$7,552,279

At June 30, 2005, accrued payroll and related benefits increased primarily as a result of an increase in accrued commissions and payroll, partially offset by the payment of annual bonuses during the first quarter. Accrued royalties and advertising expenses at June 30, 2005 and December 31, 2004 are primarily related to our OraQuick® and Freeze Off™ products. Deferred revenue at June 30, 2005 and December 31, 2004 consisted primarily of customer prepayments, totaling $1,101,868 and $1,041,711, respectively. Professional fees at June 30, 2005 decreased primarily as a result of the payment of legal fees related to current litigation. License fees at December 31, 2004 are related to a sublicense agreement for certain HIV-2 patents held by a third party, which we entered into in June 2004 and were payable, and paid, in June 2005.

4. Stockholders' Equity

During the six-month period ended June 30, 2005, we granted 292,188 restricted shares of our common stock to certain key officers and members of management. These shares are nontransferable and are subject to three-year vesting requirements. Upon granting of these restricted shares, deferred compensation cost equivalent to the market value at the date of grant was charged to stockholders' equity and is subsequently being amortized over the three-year period during which the restrictions lapse. In connection with these restricted share grants, we initially recorded $1,635,668 of deferred compensation, which was subsequently reduced by $75,925 due to restricted stock forfeitures, during the six-month period ended June 30, 2005. Amortization of deferred compensation related to these and previous grants was $450,457, $134,180, $883,879 and $197,952 during the three-month and six-month periods ended June 30, 2005 and 2004, respectively.

In connection with the vesting of restricted shares during the three-month and six-month periods ended June 30, 2005, we withheld and immediately retired 43,699 and 46,751 shares with aggregate values of $408,157 and $428,133, respectively.

5. Geographic Area 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 June 30,		Six months ended June 30,	
	2005	2004	2005	2004
United States	$16,180	$11,797	$30,321	$22,722
Europe	973	908	2,286	1,984
Other regions	277	510	651	917
	$17,430	$13,215	$33,258	$25,623

6. Provision for Loss on Assets

During the first six months of 2005, the Company explored options with respect to one of its products, including transitioning the manufacturing of the product to the Company's distribution partner. The Company was not able to determine an outlet for this product and as a result, recorded a $1,512,898 charge in June 2005 to reflect the provision for loss on inventory and fixed assets related to this product.

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 may include statements about our expected revenues, earnings, expenses, cash flow or other financial performance or development, expected regulatory filings and approvals, planned business transactions, views of future industry, competitive or market conditions, and other factors that could affect our future operations, results of operations or financial position. These statements often include the words "believes," "expects," "anticipates," "intends," "plans," "estimates," "may," "will," "should," "could," or similar expressions. Forward-looking statements are not guarantees of future performance or results. Known and unknown 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 other new products or technology; ability to fund research and development and other projects and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical product components; availability of related products produced by third parties; ability to obtain and timing of obtaining necessary regulatory approvals; ability to comply with applicable regulatory requirements; history of losses and ability to achieve sustained profitability; volatility of our stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; 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, patent infringement, 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; customer consolidations and inventory practices; 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 political, business and economic conditions. These and other factors that could cause the forward-looking statements to be materially different are described in greater detail in 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, 2004. Although forward-looking statements help to provide complete 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 is 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 six months of 2005, we continued to increase sales and gain market acceptance for our products. As a result, we reported strong financial results for the first half of 2005. Our total revenues were $33.3 million, or an increase of 30% over the comparable period in 2004, and our net income was $3.0 million, representing an improvement of more than $3.0 million over the first half of 2004. Our liquidity also improved, as we reported $4.8 million in cash flow from operations during the first six months of 2005 and had $71.5 million in cash, cash equivalents and short-term investments as of June 30, 2005.

Sales into the infectious disease testing market increased significantly during the first six months of 2005 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, sales to the Substance Abuse and Mental Health Services Administration ("SAMHSA") for further distribution to drug treatment centers and other clinics, and sales both directly and through Abbott Laboratories into the hospital market.

In 2004, the CDC and SAMHSA placed purchase orders totaling $6.3 million for OraQuick® devices and related testing materials. Both of these orders were for the OraQuick® *ADVANCE*™ rapid HIV-1/2 antibody test only. We expect that federal governmental agencies will make future bulk purchases of OraQuick® *ADVANCE*™ for further distribution to the public health and other markets throughout the United States.

In February 2005, we entered into a new agreement for the distribution of OraQuick® *ADVANCE*™ with Abbott Laboratories. Under this agreement, Abbott was appointed as our exclusive distributor in the U.S. hospital market and as a non-exclusive distributor in the U.S. physicians' office marketplace. As our exclusive distributor to hospitals, Abbott will sell OraQuick® *ADVANCE*™ to federal hospitals under the terms and conditions of our Federal Supply Schedule that is filed with the U.S. General Services Administration. We have retained exclusive rights to all other markets, including the public health and criminal justice markets, the military, the CDC, SAMHSA and other government agencies. In 2004, we deployed a small sales force that provided direct access to and marketing support for the sales of our OraQuick® test into the hospital market. This sales force now supports Abbott and works together with Abbott sales representatives to maximize the penetration of OraQuick® *ADVANCE*™ in the hospital market.

The markets for rapid HIV testing are very competitive and the level of competition is expected to increase, which could affect sales of our OraQuick® tests. For example, the Ortho Diagnostics division of Johnson & Johnson and Bio-Rad Laboratories each sell competing laboratory-based HIV-1 enzyme immunoassays, and Calypte, Inc. sells an HIV-1 screening test for urine, in the United States. In addition, MedMira and Trinity Biotech have each received U.S. Food and Drug Administration ("FDA") approval to sell competing rapid HIV-1 blood tests and Bio-Rad recently received FDA approval for a rapid HIV-1/2 blood test. We believe these tests, under their current FDA approvals, will compete with our OraQuick® tests in the hospital or other laboratory settings. In addition, Trinity Biotech has received CLIA waiver for its rapid finger stick HIV-1 blood test, and we believe that this test will compete with our OraQuick® tests in the public health and other markets outside of the traditional hospital and laboratory settings. These companies, or others, may continue to expand the bodily fluids with which a rapid HIV test may be performed or develop and commercialize new rapid tests, either of which would provide further competition for our OraQuick® tests.

Sales to the substance abuse testing market also increased during the second quarter of 2005, reflecting the growing acceptance of our Intercept® collection device and related oral fluid drug assays, as corporate and criminal justice customers continued to shift 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.

In April 2004, SAMHSA published proposed guidelines that would, if adopted, include oral fluid testing as an accepted drug testing method for federal employees. We have responded to SAMHSA's proposed guidelines with a comment letter and await the final guidelines that will apply to both our Intercept® and UPlink® drugs of abuse testing products. We are unable to predict at this time whether additional modifications may be required to bring our

UP*link*® or Intercept® products into compliance with the guidelines when finally adopted or what affect, if any, non-compliance with the final guidelines will have on our product offerings. Compliance with the guidelines will be required in order for us to sell our drug testing products to federal employees and possibly other industries that are influenced by the federal guidelines in structuring their drug testing programs.

As part of the strategic business review we completed in late 2004, we concluded that the roadside drugs of abuse testing market for UP*link*® may not be as attractive as a number of other opportunities we are pursuing. During the first six months of 2005, we explored our options with respect to the UPlink® product, including transitioning the manufacturing of the product to our distribution partner, Dräger Safety. Throughout this period, we were not able to reach an agreement with Dräger Safety or determine an alternative outlet for this product. In addition, we were advised that Dräger will no longer promote the sale of the UP*link*® product. As a result, we recorded a $1.5 million charge in June 2005 to reflect a provision for loss on inventory and fixed assets related to our UP*link*® product.

Sales to the cryosurgical systems market during the second quarter of 2005 have decreased slightly. The cryosurgical systems market represents sales of Histofreezer® into both the domestic and international physicians' office markets and sales of the over-the-counter ("OTC") formulation of this product, called Freeze Off™, to our partner, Medtech Holdings, Inc. ("Medtech"), a wholly-owned subsidiary of Prestige Brands Holdings, Inc. Medtech distributes Freeze Off™ to consumers under its Compound W® trademark in the OTC market in the United States and is the owner of both tradenames.

In June 2005, we entered into an agreement with SSL International plc ("SSL") under which we will manufacture and supply, and SSL will distribute on an exclusive basis, the Company's cryosurgical wart removal product in the OTC footcare market in Europe, Australia and New Zealand. The product will be manufactured and sold under SSL's Scholl and Dr. Scholl trademarks, and is expected to be made initially available for retail purchase in pharmacies and retail outlets in the United Kingdom, France, Germany, Spain, and Italy in the fall of 2005 and in other European countries, Australia and New Zealand beginning in early 2006.

In July 2004, we filed a lawsuit against Schering-Plough Healthcare Products, Inc. ("Schering-Plough") for infringement of several of our patents relating to the technology for the cryosurgical removal (i.e., freezing) of warts and other benign skin lesions. The suit was commenced in the United States District Court for the Eastern District of Pennsylvania, and alleges that Schering-Plough's manufacture and sale of its Dr. Scholl's® Freeze Away™ cryosurgical wart removal product in the over-the-counter market infringes three of our patents. We are seeking injunctive relief and the payment of damages, and Schering-Plough has raised several defenses, including that their Freeze Away™ device does not infringe our patents and that one or more of our patents are either invalid or unenforceable. We currently expect that a final trial on the merits in this matter will occur during the fourth quarter of 2005.

Sales to the insurance risk assessment market remained consistent in the second quarter of 2005. We anticipate little growth in the insurance risk assessment market until we are successful in developing new oral fluid based diagnostic tests for additional predictive health markers desired by the insurance industry.

In January 2005, the lease on our Oregon facility expired and all operations at that location have now ceased. The absence of this lease has reduced and will continue to reduce our operating expenses.

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 and on related products supplied by third parties. This is particularly true for our OraQuick® tests, our OraSure® oral fluid collection device and our 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. 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. In addition, if the HIV-1 enzyme immunoassay approved by the FDA for use with our OraSure® collection device, which is manufactured by a third party, is either unavailable or experiences quality or performance problems, sales of our OraSure® device could be adversely affected.

Results of Operations

Three months ended June 30, 2005 compared to June 30, 2004

Total revenues increased 32% to approximately $17.4 million in the second quarter of 2005 from approximately $13.2 million in the comparable quarter in 2004, primarily as a result of increased sales of our OraQuick® *ADVANCE*™ rapid HIV-1/2 antibody test and our Intercept® oral fluid drug test, partially offset by lower sales in the cryosurgical systems market. International sales accounted for 7% of total revenues in the second quarter of 2005.

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 June 30,				
	Dollars		Percent Change Inc. (Dec.)	Percentage of Total Revenues	
	2005	2004		2005	2004
Market revenues					
Insurance risk assessment	$ 1,974	$ 1,905	4%	11%	14%
Infectious disease testing	7,509	3,970	89	43	30
Substance abuse testing	3,540	2,389	48	20	18
Cryosurgical systems	4,281	4,858	(12)	25	37
Product revenues	17,304	13,122	32	99	99
Licensing and product development	126	93	35	1	1
Total revenues	$17,430	$13,215	32%	100%	100%

Sales to the insurance risk assessment market in the second quarter of 2005 increased slightly as compared to the second quarter of 2004. We currently expect that our 2005 revenues in this market segment will remain at approximately the levels attained in 2004.

Sales to the infectious disease testing market increased 89% to approximately $7.5 million in the second quarter of 2005, primarily as a result of the increasing strength of our OraQuick® *ADVANCE*™ rapid HIV-1/2 antibody test. OraQuick® sales totaled approximately $6.3 million and $2.3 million in the second quarters of 2005 and 2004, respectively. OraSure® sales totaled approximately $1.2 million and $1.6 million in the second quarters of 2005 and 2004, respectively.

In the second quarters of 2005 and 2004, we recorded approximately $2.2 million and $720,000, respectively, in direct sales of OraQuick® to the U.S. public health market and approximately $879,000 and $923,000, respectively, to the CDC. We also had OraQuick® sales of approximately $1.7 million and $0 to SAMHSA, approximately $939,000 and $401,000 to Abbott, approximately $371,000 and $228,000 to the international marketplace, and approximately $203,000 and $67,000 directly to hospital customers, in the second quarters of 2005 and 2004, respectively. Sales of OraQuick® *ADVANCE*™ in the United States totaled $4.6 million, or 80% of total U.S. OraQuick® sales in the second quarter of 2005.

We believe that our OraQuick® *ADVANCE*™ device, which is FDA-approved for detecting antibodies to both HIV-1 and 2 in oral fluid, fingerstick and venous whole blood, and plasma samples, and is CLIA-waived for use with all sample types except plasma, provides a significant competitive advantage and will allow us to more fully implement a strategy to sell OraQuick® internationally. We are currently pursuing CE marking for our OraQuick® *ADVANCE*™ product which would allow us to sell our product in Europe. Our goal is to obtain a CE mark for OraQuick® *ADVANCE*™ in the third quarter of 2005, and obtain several country-specific registrations thereafter allowing us to launch the product in Europe in late 2005.

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

Sales to the substance abuse testing market increased 48% to approximately $3.5 million in the second quarter of 2005, primarily as a result of increased sales of our Intercept® oral fluid drug testing service in the U.S. workplace and international markets. Sales into the U.S. workplace and international markets increased 162% and 23% to approximately $1.7 million and $477,000, respectively, in the second quarter of 2005. We expect continued growth in Intercept® sales through the remainder of 2005 as customers continue to shift from urine-based to oral fluid-based drug testing methods.

Revenues from our UP*link*® rapid point-of-care oral fluid drug detection system approximated $30,000 and $129,000 in the second quarter of 2005 and 2004, respectively. As part of the strategic business review we completed in late 2004, we concluded that the roadside drugs of abuse testing market for UP*link*® may not be as attractive as a number of other opportunities we are pursuing. During the first six months of 2005, we explored our options with respect to the UP*link*® product, including transitioning the manufacturing of the product to our distribution partner, Dräger Safety. Throughout this period, we were not able to reach an agreement with Dräger Safety or determine an alternative outlet for this product. In addition, we were advised that Dräger will no longer promote the sale of the UP*link*® product. As a result, we recorded a $1.5 million charge in June 2005 to reflect a provision for loss on inventory and fixed assets related to our UP*link*® product.

Sales of our products in the cryosurgical systems market (which includes both the physicians' office and OTC markets) decreased 12% to approximately $4.3 million in the second quarter of 2005. This decrease was primarily the result of a reduction in sales of our OTC cryosurgical product, called Freeze Off™, to Medtech, the owner of the Compound W® line of wart removal products, to $2.8 million in the second quarter of 2005, compared to $3.3 million during the comparable period in 2004.

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 United States.

In June 2005, we entered into an agreement with SSL under which we will manufacture and supply, and SSL will distribute on an exclusive basis, the Company's cryosurgical wart removal product in the OTC footcare market in Europe, Australia and New Zealand. The product will be manufactured and sold under SSL's Scholl and Dr. Scholl trademarks, and is expected to be made initially available for retail purchase in pharmacies and retail outlets in the United Kingdom, France, Germany, Spain, and Italy in the fall of 2005 and in the other licensed countries outside the Americas (i.e., North America, South America and Central America) beginning in early 2006. We expect sales of domestic and international OTC cryosurgery products to approximate $2.8 million in the third quarter of 2005.

Sales of our Histofreezer® product to physicians' offices in the U.S. and international markets decreased 5% and 7% to $1.1 million and $329,000, respectively, in the second quarter of 2005. Despite this decrease, we anticipate that U.S. and international sales of Histofreezer® in the professional market will increase slightly during 2005, as compared to 2004, particularly as we secure additional distributors in countries where the product is currently not sold.

Although it is not our experience to date in the U.S. professional marketplace, it is possible that sales of our OTC cryosurgical products may reduce the number of individuals that will seek to obtain treatment of their warts by a physician, which in turn could negatively affect sales of our Histofreezer® product in the professional market. However, it is not possible at this time to estimate the timing or financial impact of such a change, if it occurs at all.

Medtech accounted for approximately 16% and 25% of total revenues for the second quarter of 2005 and 2004, respectively. Lab*One*, Inc. accounted for approximately 11% and 10% of total revenues for the second quarter of 2005 and 2004, respectively. SAMHSA accounted for approximately 10% and 0% of total revenues for the second quarter of 2005 and 2004, respectively.

Licensing and product development revenues increased by 35% to $126,000 during the second quarter of 2005, from $93,000 in the comparable period in 2004. Licensing and product development revenues are primarily related to our collaborative UP*link*® and oral fluid research project, under a grant awarded by the National Institutes of Health. The current annual phase of this grant expired in June 2005. Further revenues under this grant beyond June 2005 will depend on progress achieved in the research and future funding awarded by the National Institutes of Health.

Gross margin in the second quarter of 2005 was approximately 54%, compared to 58% for the second quarter of 2004. Gross margin was negatively affected, by approximately 9 percentage points, due to the $1.5 million charge associated with the UP*link*® assets. This decrease was partially offset by more efficient utilization of the Company's manufacturing capacity.

Research and development expenses decreased 17% to approximately $1.3 million in the second quarter of 2005 from approximately $1.5 million in the same period in 2004, primarily as a result of lower overall staffing costs and lower consulting fees. Research and development costs are expected to increase for the full year during 2005, as compared to 2004, primarily as a result of costs associated with the development of new product offerings and product enhancements for the infectious disease and substance abuse testing markets.

Sales and marketing expenses increased 18% to approximately $4.5 million in the second quarter of 2005 from approximately $3.8 million in the same period in 2004. This increase was primarily the result of increased consulting fees, commissions, travel expenses, compensation and levels of staffing, partially offset by lower advertising expenses. Included in advertising expenses for the second quarters of 2005 and 2004 were $466,000 and $736,000, respectively, 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.

General and administrative expenses increased 14% to approximately $2.8 million in the second quarter of 2005 from approximately $2.4 million in the same period in 2004. This increase was primarily attributable to increased legal fees associated with the Schering-Plough patent litigation, increased amortization of restricted stock grants to management, and increased staffing related expenses. This increase was partially offset by a reduction in rent expense due to the transfer of manufacturing operations to Bethlehem and the expiration of the lease for our Oregon facilities in January 2005. General and administrative expenses are expected to increase further in 2005 versus 2004 as a result of higher legal fees associated with the Schering-Plough litigation.

Interest expense decreased to $25,000 in the second quarter of 2005 from $40,000 in the same period in 2004, primarily as a result of lower outstanding debt balances. Interest income increased to $467,000 in the second quarter of 2005 from $230,000 in the same period in 2004, as a result of higher yields on our investment portfolio.

Although there was income before income taxes during the second quarter of 2005, there was no provision for income taxes primarily due to the utilization of previously unbenefitted net operating loss carryforwards. The utilization of such tax attributes results in a corresponding decrease in deferred tax assets and the related valuation allowance. There also was no provision for foreign income taxes recorded during the second quarter of 2005. During the second quarter of 2004, a provision for foreign income taxes of approximately $5,000 was recorded.

Results of Operations

Six months ended June 30, 2005 compared to June 30, 2004

Total revenues increased 30% to approximately $33.3 million for the six months ended June 30, 2005 from approximately $25.6 million in the comparable period in 2004, primarily as a result of increased sales of our OraQuick® *ADVANCE*™ rapid HIV-1/2 antibody test, our Intercept® oral fluid drug test, and our Freeze Off™ and Histofreezer® cryosurgical products. International sales accounted for 9% of total revenues during the first six months of 2005.

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.

	Six Months Ended June 30,				
	Dollars		Percent Change Inc. (Dec.)	Percentage of Total Revenues	
	2005	2004		2005	2004
Market revenues					
Insurance risk assessment	$ 4,089	$ 4,190	(2)%	12%	16%
Infectious disease testing	12,635	7,307	73	38	29
Substance abuse testing	6,465	4,583	41	19	18
Cryosurgical systems	9,859	9,331	6	30	36
Product revenues	33,048	25,411	30	99	99
Licensing and product development	210	212	(1)	1	1
Total revenues	$33,258	$25,623	30%	100%	100%

Sales to the insurance risk assessment market were slightly lower in the first six months of 2005, compared to the first six months of 2004. We currently expect that our 2005 revenues in this market segment will remain at approximately the levels attained in 2004.

Sales to the infectious disease testing market increased 73% to approximately $12.6 million in the first six months of 2005, primarily as a result of the increasing strength of our OraQuick® *ADVANCE*™ rapid HIV-1/2 antibody test. OraQuick® sales totaled approximately $10.3 million and $4.5 million in the first six months of 2005 and 2004, respectively. OraSure® sales totaled approximately $2.3 million and $2.8 million in the first six months of 2005 and 2004, respectively.

In the first six months of 2005 and 2004, we recorded approximately $3.8 million and $1.2 million, respectively, in direct sales of OraQuick® to the U.S. public health market and approximately $1.7 million and $1.6 million, respectively, to the CDC. We also had OraQuick® sales of approximately $1.7 million and $0 to SAMHSA, approximately $1.6 million and $1.2 million to Abbott, approximately $714,000 and $450,000 to the international marketplace, and approximately $734,000 and $67,000 directly to hospital customers, in the first six months of 2005 and 2004, respectively. Sales of OraQuick® *ADVANCE*™ in the United States totaled $6.6 million, or 72% of total U.S. OraQuick® sales in the first six months of 2005.

We believe that our OraQuick® *ADVANCE*™ device, which is approved for detecting antibodies to both HIV-1 and 2 in oral fluid, fingerstick and venous whole blood, and plasma samples, and is CLIA-waived for use with all sample types except plasma, provides a significant competitive advantage and will allow us to more fully implement a strategy to sell OraQuick® internationally. We are currently pursuing CE marking for our OraQuick® *ADVANCE*™ product which would allow us to sell our product in Europe. Our goal is to obtain a CE mark for OraQuick® *ADVANCE*™ in the third quarter of 2005, and obtain several country-specific registrations thereafter allowing us to launch the product in Europe in late 2005.

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

Sales to the substance abuse testing market increased 41% to approximately $6.5 million in the first six months of 2005, primarily as a result of increased sales of our Intercept® oral fluid drug testing service in the U.S. workplace and criminal justice markets. Sales into the U.S. workplace and criminal justice markets increased 128% and 54% to approximately $2.8 million and $1.3 million, respectively, in the first six months of 2005. We expect continued growth in Intercept® sales through the remainder of 2005 as customers continue to shift from urine-based to oral fluid-based drug testing methods.

Revenues from our UP*link*® rapid point-of-care oral fluid drug detection system approximated $267,000 and $273,000 in the first six months of 2005 and 2004, respectively. As part of the strategic business review we completed in late 2004, we concluded that the roadside drugs of abuse testing market for UP*link*® may not be as attractive as a number of other opportunities we are pursuing. During the first six months of 2005, we explored our options with respect to UP*link*®, including transitioning the manufacturing of the product to our distribution partner, Dräger Safety. Throughout this period, we were not able to reach an agreement with Dräger Safety or determine an alternative outlet for this product. In addition, we were advised that Dräger will no longer promote the sale of the UP*link*® product. As a result, we recorded a $1.5 million charge in June 2005 to reflect a provision for loss on inventory and fixed assets related to our UP*link*® product.

Sales of our products in the cryosurgical systems market (which includes both the physicians' office and OTC markets) increased 6% to approximately $9.9 million in the first six months of 2005. This increase was primarily the result of an increase in sales of our OTC cryosurgical product, called Freeze Off™, to Medtech, the owner of the Compound W® line of wart removal products, to $6.8 million in the first six months of 2005, compared to $6.4 million during the comparable period in 2004.

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 United States.

In June 2005, we entered into an agreement with SSL under which we will manufacture and supply, and SSL will distribute on an exclusive basis, the Company's cryosurgical wart removal product in the OTC footcare market in Europe, Australia and New Zealand. The product will be manufactured and sold under SSL's Scholl and Dr. Scholl trademarks, and is expected to be made initially available for retail purchase in pharmacies and retail outlets in the United Kingdom, France, Germany, Spain, and Italy in the fall of 2005 and in the other licensed countries outside the Americas (i.e., North America, South America and Central America) beginning in early 2006. We expect domestic and international sales of OTC cryosurgery products to our distributors to approximate $2.8 million in the third quarter of 2005.

Sales of our Histofreezer® product to physicians' offices in the U.S. market decreased 2% to $2.1 million in the first six months of 2005, while sales in the international market increased 19% to $882,000 in the first six months of 2005. We anticipate that U.S. and international sales of Histofreezer® in the professional market will increase slightly during 2005, as compared to 2004, particularly as we secure additional distributors in countries where the product is currently not sold.

Although it is not our experience to date in the U.S. professional marketplace, it is possible that sales of our OTC cryosurgical products may reduce the number of individuals that will seek to obtain treatment of their warts by a physician, which in turn could negatively affect sales of our Histofreezer® product in the professional market. However, it is not possible at this time to estimate the timing or financial impact of such a change, if it occurs at all.

Medtech accounted for approximately 21% and 25% of total revenues for the first six months of 2005 and 2004, respectively. Lab*One* accounted for approximately 12% and 13% of total revenues for the first six months of 2005 and 2004, respectively. SAMHSA accounted for approximately 5% of total revenues for the first six months of 2005. There were no sales to SAMHSA in the first six months of 2004.

Licensing and product development revenues during the first six months of 2005, were essentially flat compared to 2004. Licensing and product development revenues are primarily related to our collaborative UP*link*® and oral fluid research project, under a grant awarded by the National Institutes of Health. The current annual phase of this grant expired in June 2005. Further revenues under this grant beyond June 2005 will depend on progress achieved in the research and future funding awarded by the National Institutes of Health.

Gross margin for the first six months of 2005 was approximately 57%, compared to 58% for the first six months of 2004. Gross margin was negatively affected, by approximately 4 percentage points, due to the $1.5 million charge associated with the UP*link*® assets. This decrease was partially offset by more efficient utilization of the Company's manufacturing capacity.

Research and development expenses decreased 25% to approximately $2.5 million in the first six months of 2005 from approximately $3.3 million in the same period in 2004, primarily as a result of lower overall staffing costs and lower costs associated with transferring our manufacturing operations from Oregon to Bethlehem, Pennsylvania. Research and development costs are expected to increase for the full year during 2005, as compared to 2004, primarily as a result of costs associated with the development of new product offerings and product enhancements for the infectious disease and substance abuse testing markets.

Sales and marketing expenses increased 12% to approximately $8.3 million in the first six months of 2005 from approximately $7.4 million in the same period in 2004. This increase was primarily the result of increased levels of consulting, staffing, compensation, commissions, and travel expenses, partially offset by lower advertising expenses. Included in advertising expenses for the six months of 2005 and 2004 were $1.0 million and $1.3 million, respectively, 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.

General and administrative expenses increased 30% to approximately $6.0 million in the first six months of 2005 from approximately $4.6 million in the same period in 2004. This increase was primarily attributable to increased legal fees associated with the Schering-Plough patent litigation, increased amortization of restricted stock grants to management, and increased staffing related expenses. This increase was partially offset by a reduction in rent expense due to the transfer of manufacturing operations to Bethlehem and the expiration of the lease for our Oregon facilities in January 2005. General and administrative expenses are expected to increase further in 2005 versus 2004 as a result of legal fees associated with the Schering-Plough litigation.

Interest expense decreased to $53,000 in the first six months of 2005 from $71,000 in the same period in 2004, primarily as a result of lower outstanding debt balances. Interest income increased to $839,000 in the first six months of 2005 from $436,000 in the same period in 2004, as a result of higher yields on our investment portfolio.

Although there was income before income taxes during the first six months of 2005, there was no provision for income taxes primarily due to the utilization of previously unbenefitted net operating loss carryforwards. The utilization of such tax attributes results in a corresponding decrease in deferred tax assets and the related valuation allowance. There also was no provision for foreign income taxes recorded during the first six months of 2005. During the first six months of 2004, a provision for foreign income taxes of approximately $9,500 was recorded.

Liquidity and Capital Resources

	June 30, 2005	December 31, 2004
	(In thousands)	
Cash and cash equivalents	$20,729	$ 10,121
Short-term investments	50,734	56,602
Working capital	74,822	68,910

Our cash, cash equivalents, and short-term investments increased approximately $4.7 million during the first six months of 2005 to approximately $71.5 million at June 30, 2005, primarily as a result of $4.8 million in positive cash flow from operations and approximately $1.8 million in proceeds from the exercise of stock options, partially offset by the purchase of approximately $522,000 of property and equipment, approximately $559,000 of loan principal repayments, approximately $428,000 of payments related to the retirement of common stock, an expenditure of $300,000 for patent license rights, and an increase of $50,000 in other assets. At June 30, 2005, our working capital was approximately $74.8 million.

Net cash provided by operating activities was approximately $4.8 million in the first six months of 2005. The $4.8 million of cash provided by operating activities resulted from net income of approximately $3.0 million, depreciation and amortization of approximately $1.2 million and non-cash charges of approximately $2.8 million related to stock-based compensation expense, provisions for excess and obsolete inventories, and provisions for loss on property and equipment, a decrease of $72,000 in prepaid expenses and other current assets, and an increase of $280,000 in accounts payable and accrued expenses, offset by inventory increases of $888,000, and an increase of approximately $1.7 million in accounts receivable. Accounts receivable are expected to grow as our sales increase and as the proportion of sales increase to parties such as the CDC and Medtech, which have 60-day payment terms.

Net cash provided by investing activities during the first six months of 2005 was approximately $5.0 million. We purchased approximately $522,000 of property and equipment, sold a net amount of $5.9 million of short-term investments, paid $300,000 for patent license rights, and had an increase of $50,000 in other assets.

Capital expenditures are anticipated to increase during 2005 to approximately $3.2 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 2005.

Net cash provided by financing activities was approximately $769,000, reflecting the proceeds of $1.8 million received from the issuance of common stock pursuant to stock option exercises, offset by approximately $559,000 of loan principal repayments and approximately $428,000 of payments related to the retirement of common stock.

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. In April 2005, the Credit Facility was amended further to extend the maturity date of our revolving working capital line of credit to April 29, 2006.

The $887,000 mortgage loan matures in September 2012, bears interest at an annual floating rate equal to Comerica's prime rate (6.25% at June 30, 2005), and is repayable in fixed monthly principal and interest installments of $7,426 through September 2007, at which time the interest rate and fixed monthly repayment amount will be reset for the remaining 60 monthly installments. The outstanding balance of the loan at June 30, 2005 was $742,532.

The $3.0 million term loan matures in March 2006, bears interest at a fixed rate of 4.97% and is repayable in forty-two consecutive equal monthly principal payments of $71,429, plus interest. The outstanding balance of the loan at June 30, 2005 was $642,857.

As of June 30, 2005, we had an outstanding balance of $250,382 under the Original Non-Revolving Line consisting of four individual loans of (i) $59,929 with a fixed annual interest rate of 5.07%, (ii) $91,451 with a floating annual interest rate equal to Comerica's prime rate (6.25% at June 30, 2005), (iii) $51,453 with a floating annual interest rate equal to Comerica's prime rate (6.25% at June 30, 2005), and (iv) $47,549 with a floating annual interest rate equal to Comerica's prime rate (6.25% at June 30, 2005).

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 April 29, 2006, with interest payable monthly. We had no outstanding borrowings under this facility at June 30, 2005.

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 revolving working capital line are limited to commercially standard percentages of accounts receivable. 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 June 30, 2005 and expect to remain in compliance with all covenants during the remainder of 2005. 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.

As of June 30, 2005, we also had a $261,424 note payable to the Pennsylvania Industrial Development Authority related to the purchase of one of our facilities in Bethlehem, Pennsylvania in 1998. This note is secured by a second lien on our building, bears interest at 2% per year, and requires monthly installments of principal and interest of $4,893 through March 2010.

The combination of our current cash position, cash flow from operations, and available borrowings under our Credit Facility is expected to be sufficient to fund our operating, licensing, and capital needs for the remaining six months of 2005. 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 market 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.

Recent Accounting Pronouncements

In November 2004, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 151, "Inventory Costs," which amends the guidance in Accounting Research Bulletin No. 43. SFAS No. 151 clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material and requires such costs to be recognized as current-period charges. Additionally, SFAS No. 151 requires that allocation of fixed production overhead costs be based on normal capacity. SFAS No. 151 is effective for years beginning after June 15, 2005, with early adoption permitted. The implementation of SFAS No. 151 is not expected to have a material effect on our financial position, results of operations or cash flows.

In December 2004, the FASB issued SFAS No. 123 Revised, "Share-Based Payment" ("SFAS No. 123R"). SFAS No. 123R requires employee stock options to be accounted for in the statement of operations based on their fair values on the date of the grant, and eliminates the ability to account for these instruments under the intrinsic value method prescribed by Accounting Principles Board Opinion No. 25. SFAS No. 123R requires the use of an option pricing model for estimating fair value, which is amortized to expense over the service period. The requirements of SFAS No. 123R are effective for annual periods beginning after June 15, 2005. SFAS No. 123R allows for either prospective recognition of compensation expense or retrospective recognition. The Company is considering the potential implementation of different valuation models to determine the fair value of stock-based compensation and, therefore, has not yet completed evaluating the impact of adopting SFAS No. 123R on its results of operations. If the Company had applied the provisions of SFAS No. 123R to the financial statements for the three-month and six-month periods ending June 30, 2005, net income would have been reduced by approximately $784,000 and $1.7 million.

Summary of Contractual Obligations and Commercial Commitments

The following sets forth our approximate aggregate obligations at June 30, 2005 for future payments under contracts and other contingent commitments, for the years 2005 and beyond:

		Payments due by December 31,					
Contractual Obligations	**Total**	**2005[6]**	**2006**	**2007**	**2008**	**2009**	**Thereafter**
Long-term debt[1]	$ 1,897,195	$ 558,897	$ 465,840	$ 125,400	$ 109,958	$ 114,385	$ 522,715
Operating leases[2]	6,329,364	684,580	880,864	783,062	798,810	814,262	2,367,786
Employment contracts[3]	2,169,579	968,818	995,761	205,000	—	—	—
Purchase obligations[4]	2,485,131	2,485,131	—	—	—	—	—
Minimum commitments under contracts[5]	8,429,167	212,500	625,000	725,000	725,000	650,000	5,491,667
Total contractual obligations	$ 21,310,436	$ 4,909,926	$ 2,967,465	$ 1,838,462	$ 1,633,768	$ 1,578,647	$ 8,382,168

1 Represents principal repayments required under notes payable to our lenders.
2 Represents payments required under our operating leases.
3 Represents salary or retention bonus payments payable under the terms of employment agreements executed by us with certain officers and employees.
4 Represents payments required by non-cancelable purchase orders related to inventory, capital expenditures and other goods or services.
5 Represents payments required pursuant to certain research, licensing and royalty agreements executed by the Company.
6 In August 2005, the Company entered into a licensing agreement with third parties, pursuant to which we are required to pay $1.5 million in August 2005 and may be obligated to pay additional licensing fees in the future.

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 2004 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" ("SAB No. 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 No. 104, we 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 $349,424 at June 30, 2005. While credit losses have been within our expectations and the allowance provided, these losses can vary from period to period (approximately $3,541, $88,659, and $213,188 in 2004, 2003 and 2002, respectively). Furthermore, there is no assurance that we will experience credit losses at the same rates as we have in the past. Also, at June 30, 2005, approximately $3.6 million, or 41% of our accounts receivable, were due from three 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 2004, 2003, and 2002, we wrote-off inventory which had a cost of approximately $839,000, $540,000, and $1.4 million, respectively, as a result of scrap levels and product expiration issues. During the six months ended June 30, 2005, we wrote-off inventory which had a cost of approximately $1.7 million, of which $1.3 million related to a provision for loss on our UP*link*® product. During the first six months of 2005, we explored options with respect to the UP*link*® product, however, we were not able to determine an outlet for

this product. As a result, we recorded this $1.3 million charge to reflect a provision for loss on the UP*link*® inventory. 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 $7.2 million or 8% of our total assets at June 30, 2005. Our investment in the 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. During June 2005, we recorded a $196,000 provision for loss on our UP*link*® fixed assets as a result of our inability to reach an agreement to transfer these assets to our distribution partner or determine an alternative outlet for these assets. We currently believe the future cash flows to be received from all other long-lived and intangible assets will exceed their book value and, as such, we have not recognized any additional impairment losses through June 30, 2005. 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, 2004, we had federal net operating loss (“NOL”) carryforwards of approximately $74.9 million. The deferred tax asset associated with these NOLs and other temporary differences is approximately $31.5 million at December 31, 2004. 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, at that time. 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 SFAS No. 5, “Accounting for Contingencies.” SFAS No. 5 requires us to record an estimated loss contingency when information available prior to issuance of our financial statements indicates that it is probable that an asset has been impaired or a liability has been incurred at the date of the financial statements and the amount of the loss can be reasonably estimated. Accounting for contingencies arising from contractual or legal proceedings requires that we use our best judgment when estimating an accrual related to such contingencies. As additional information becomes known, our accrual for a loss contingency could fluctuate, thereby creating variability in our results of operations from period to period. Likewise, an actual loss arising from a loss contingency which significantly exceeds the amount accrued for in our financial statements could have a material adverse impact on our operating results for the period in which such actual loss becomes known.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We do not hold any 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 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 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 $329,000 and $883,000 or 2% and 3% of our total revenues for the three months and six months ended June 30, 2005, respectively. We do not expect the risk of foreign currency fluctuations to be material.

Item 4. CONTROLS AND PROCEDURES.

(a) Evaluation of Disclosure Controls and Procedures. The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) as of June 30, 2005. Based on that evaluation, the Company's management, including such officers, concluded that the Company's disclosure controls and procedures are adequate and effective to ensure that information required to be disclosed by the Company in the reports that we file or submit under the Securities Exchange Act of 1934 is accumulated and communicated to the Company's management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure and is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission.

(b) Changes in Internal Control Over Financial Reporting. There was no change in the Company's internal control over financial reporting identified in connection with the evaluation referred to in paragraph (a) above 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

On July 23, 2004, we filed a lawsuit against Schering-Plough Healthcare Products, Inc. for infringement of several of our patents relating to technology for the cryosurgical removal (i.e., freezing) of warts and other benign skin lesions. The suit was commenced in the United States District Court for the Eastern District of Pennsylvania, and alleges that Schering-Plough's manufacture and sale of its Dr. Scholls® Freeze Away™ cryosurgical wart removal product in the United States over-the-counter market infringes the following United States patents: Nos. 5,738,682; 6,092,527 and 4,865,028. We are requesting permanent injunctive relief and the payment of damages. Schering-Plough has asserted various defenses in this matter, including that its Dr. Scholls® Freeze Away™ product does not infringe our patents and that one or more of our patents are invalid or unenforceable.

In August 2004, we filed an application for a preliminary injunction against Schering-Plough. In September 2004, the Court scheduled an early trial in this matter for February 2005. Because such a trial would include a final determination of our request for permanent injunctive relief in lieu of our previously-filed request for a preliminary injunction, we withdrew our request for a preliminary injunction. The parties then engaged in extensive discovery through January 2005.

In November 2004, the Court held a Markman hearing in order to determine as a matter of law the meaning of certain terms and phrases in the claims in our patents that are relevant to an infringement determination. Since the Court had not issued its Markman decision by February 2005, however, it vacated the original trial schedule. In July 2005, the Court issued a decision from the Markman hearing. Shortly after issuing the Markman decision, the Court entered an order establishing a new trial schedule. Based on this new schedule, a final trial on the merits in this matter is expected to occur in November 2005.

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

At our 2005 Annual Meeting of Stockholders ("Annual Meeting") held on May 17, 2005, the following individuals were elected by the votes indicated as Class II directors of the Company for terms expiring at the 2008 Annual Meeting of Stockholders:

Nominee	Votes For	Votes Withheld
Ronny B. Lancaster	40,448,792	329,305
Roger L. Pringle	39,661,665	1,116,432

The terms of the following directors continued after the Annual Meeting: Frank G. Hausmann, Douglas A. Michels, and Douglas G. Watson.

At the Annual Meeting, stockholders also ratified the appointment of KPMG LLP as our independent registered public accounting firm to audit and report upon our financial statements and internal control over financial reporting for the period January 1, 2005 through December 31, 2005. Voting results on this matter were as follows: 40,589,855 shares were voted for ratification; 88,916 shares were voted against ratification; and 99,326 shares abstained.

Item 6. EXHIBITS

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

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: August 5, 2005

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

/s/ Mark L. Kuna

Date: August 5, 2005

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

EXHIBIT INDEX

Exhibit	
10.1	Distribution Agreement, dated as of June 1, 2005, between OraSure Technologies, Inc. and SSL International plc. *
10.2	Third Amendment to Loan and Security Agreement, dated as of April 21, 2005, between OraSure Technologies, Inc. and Comerica Bank, is incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K, filed April 27, 2005.
10.3	Written Description of OraSure Technologies, Inc. 2005 Self-Funding Management Incentive Plan.**
31.1	Certification of Douglas A. Michels 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 Douglas A. Michels 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.

* Portions of this exhibit were omitted pursuant to an application for confidential treatment and filed separately with the Securities and Exchange Commission.

** Management contract or compensatory plan or arrangement.

EXHIBIT 10.1

*Portions of this Exhibit were omitted and filed separately with the Secretary of the Commission pursuant to an application for confidential treatment filed with the Commission pursuant to Rule 406 under the Securities Act of 1933. Such omissions are designated as ***.*

Execution Copy

DISTRIBUTION AGREEMENT

THIS DISTRIBUTION AGREEMENT (this "Agreement") is made and entered into this 1st day of June 2005, by and between SSL International plc, a limited liability company organized under the laws of England with principal offices at Venus, No. 1 Old Park Lane, Manchester England M41 7HA ("Distributor"), and OraSure Technologies, Inc., a corporation organized under the laws of the State of Delaware, U.S.A., with principal offices at 220 East First Street, Bethlehem, Pennsylvania 18015-1360 ("OSUR").

BACKGROUND

OSUR has exclusive rights to develop, manufacture, market, sell and distribute the Product (as defined below) for the treatment of ordinary warts and plantar warts (verrucas) by means of a refrigerant. OSUR desires to grant to Distributor the right to import, market, sell and distribute the Product under the Distributor Trademarks (as defined below) on an exclusive basis in certain markets within certain geographic territories, and Distributor desires to accept such rights, all in accordance with the terms and subject to the conditions contained in this Agreement.

NOW, THEREFORE, in consideration of the foregoing, and of the mutual promises and covenants contained in this Agreement, OSUR and Distributor, intending to be legally bound, hereby agree as follows:

1. DEFINITIONS.

1.1. "Affiliate" means, when used with reference to either Distributor or OSUR, any person or entity directly or indirectly controlling, controlled by or under common control with Distributor or OSUR, as the case may be. For purposes of this Agreement, "control" (including with correlative meanings "controlling," "controlled by," or "under common control with") means: (a) the direct or indirect ownership, in the aggregate, of at least 50% of the outstanding voting securities of an entity; (b) the right to receive directly or indirectly, in the aggregate, at least 50% of the profits or earnings of an entity; or (c) the right or power, directly or indirectly, to direct or cause the direction of the policy decisions of an entity, whether by ownership of voting securities, contract or otherwise.

1.2. "Assembly Contractor" means the contractors designated by OSUR to manufacture and assemble the Product purchased hereunder.

1.3. “Business Day” means any day other than a Saturday, Sunday or day on which the Federal Reserve Bank of Philadelphia, Pennsylvania, U.S.A., is closed, or which constitutes a national holiday in the United Kingdom.

1.4. “Competing Product” shall have the meaning set forth in Section 3.1.5(a).

1.5. “Claims” shall have the meaning set forth in Section 9.2.1.

1.6. “Contract Year” means, with respect to the first Contract Year, the period beginning on the Effective Date and ending on December 31, 2005 and, with respect to each subsequent Contract Year, the calendar year beginning on the date immediately following the end of the preceding Contract Year.

1.7. “Country” means any of the countries within the Territory, as listed in Exhibit A.

1.8. “Distributor Components” shall have the meaning set forth in Section 4.2.

1.9. “Effective Date” means the date first written above.

1.10. “Improved Product” shall have the meaning set forth in Section 4.4.4(b).

1.11. “Index” shall have the meaning set forth in Section 4.4.2.

1.12. “Initial Term” shall have the meaning set forth in Section 12.1.

1.13. “ISO Standards” shall have the meaning set forth in Section 4.8.2.

1.14. “Losses” shall have the meaning set forth in Section 9.2.1.

1.15. “Medical Device Directive” shall have the meaning set forth in Section 6.1.

1.16. “OTC Market” means the over-the-counter or consumer market within the Territory for selling Product through retail outlets or wholesalers serving such retail outlets, in the Territory solely for ultimate purchase and home use by consumers in the Territory without any prescription from, a medical professional or health care practitioner.

1.17. “Passive Sales” shall have the meaning set forth in Section 2.2.

1.18. “Price” shall have the meaning set forth in Section 4.4.1.

1.19. “Price Adjustment Notice” shall have the meaning set forth in Section 4.4.2.

1.20. “Product” means the patented cryosurgical removal system that is developed, assembled, manufactured, marketed and sold by OSUR or its Affiliates or designees pursuant to this Agreement, for the purpose of treating ordinary warts and plantar warts, and meets the Specifications.

1.21. “Prohibited Entity” shall have the meaning set forth in Section 12.2.5.

1.22. “Purchase Order” shall have the meaning set forth in Section 4.5.

1.23. “QSR” shall have the meaning set forth in Section 4.8.2.

1.24. “Quarterly Period” means each successive period of three (3) months in a Contract Year with the first such three (3) month period beginning on the first day of such Contract Year.

1.25. “Renewal Term” shall have the meaning set forth in Section 12.1.

1.26. “Replacement Product” shall have the meaning set forth in Section 4.9.

1.27. “Specifications” means the Product specifications set forth in Exhibit B to this Agreement, as such specifications may be modified or amended pursuant to Section 4.4.4 of this Agreement.

1.28. “Term” shall have the meaning set forth in Section 12.1.

1.29. “Territory” means all of the Countries listed in Exhibit A to this Agreement.

1.30. “Territory A Countries” means the ***.

1.31. “Territory A Minimum Quantity” means, with respect to each Contract Year, the quantity of Units of Product for each of the Territory A Countries as set forth in Exhibit C, which are required to be purchased by Distributor during such Contract Year.

1.32. “Territory B Countries” means all Countries in the Territory except for the Territory A Countries.

1.33. “Third Party Supplier” shall have the meaning set forth in Section 4.9.

1.34. “Total Territory Minimum Quantity” means, with respect to each Contract Year, the aggregate quantity of Units of Product for all Countries in the Territory as set forth in Exhibit C, which are required to be purchased by Distributor during such Contract Year.

1.35. “Total Territory B Minimum Quantity” means, with respect to each Contract Year, the aggregate quantity of Units of Product for all Territory B Countries as set forth in Exhibit C, which are required to be purchased by Distributor during such Contract Year.

1.36. “Unit” means a single unit of Product as described in the Specifications.

1.37. “United Kingdom” means England, Scotland, Wales and Northern Ireland.

1.38. “Warranty Period” shall have the meaning set forth in Section 8.1.

2. APPOINTMENT.

2.1. Distribution Rights. In accordance with the terms and subject to the conditions contained in this Agreement, OSUR hereby grants to Distributor, on an exclusive basis during the Term, the right to market, promote, import, sell and distribute the Product solely in the OTC Market in the Territory, and Distributor hereby accepts such rights.

2.2. Reservation of Rights. OSUR expressly reserves to itself the exclusive right to import, market, promote, use, sell or distribute the Product, directly or indirectly, outside the Territory and in any market other than the OTC Market, including without limitation to physicians and other medical or healthcare professionals (the "Professional Market") within the Territory. Furthermore, Distributor acknowledges and agrees that nothing in this Agreement shall preclude OSUR from manufacturing or assembling the Product, or having the Product manufactured or assembled, in any jurisdiction either within or outside of the Territory. The parties acknowledge that OSUR currently manufactures and imports, markets, sells and distributes its Histofreezer® cryosurgical removal product to the Professional Market in the Territory and elsewhere, and nothing in this Agreement shall preclude OSUR from importing, marketing, manufacturing, promoting, using, selling or distributing its Histofreezer® product, either directly or indirectly through one or more distributors, sub-distributors or agents, in the Professional Market in any Country or other territory or in any market outside of the OTC Market. OSUR will not sell any Product to any third party that OSUR knows or has reason to believe intends actively to sell the Product to the OTC Market in the Territory. Notwithstanding the foregoing, Distributor acknowledges that nothing in this Agreement is intended to preclude Passive Sales (as defined below) of the Product or the Histofreezer® products by OSUR, to the OTC Market in the European Union, within the meaning of Commission Regulation (EC) No. 2790/1999 of 22 December 1999 on the application of Article 81(3) of the Treaty to Categories of Vertical Agreements and Concerted Practices. For purposes of this Agreement, "Passive Sales" shall mean responding to unsolicited requests from individual customers for Product, such sales of Product to be made without actively approaching individual customers by for instance direct mail or visits, or through advertisements in media or other promotions specifically targeted at such customers, or by establishing a warehouse or distribution outlet in the territory in which such customers are located.

2.3. Sub-distributors. In exercising its rights hereunder, Distributor may engage sub-distributors or agents as provided in this Section 2.3. Distributor shall enter a written agreement with each sub-distributor or agent, requiring the sub-distributor or agent to comply with Distributor's obligations under this Agreement with respect to distribution of the Product in the OTC Market in the Territory, including, without limitation, Sections 3.1.2, 3.1.4, 5.1 and 5.2. Upon request, Distributor shall provide a copy of the sub-distributor or agent agreement to OSUR. Distributor's use of sub-distributors or agents does not relieve Distributor of any obligations under this Agreement.

2.4. Distributor's Compensation. Distributor has no right to any compensation from OSUR. Distributor's compensation, if any, will come from the margin between the Price it pays OSUR for the Product and the price at which it sells the Product under this Agreement into the OTC Market.

2.5. Independent Contractor. Distributor is an independent business and has no power, right, or authority to bind OSUR or to assume or to create any obligation or responsibility, express or implied, on behalf of OSUR. Distributor shall not take any action that could lead a third party to believe it has such authority. Nothing stated in this Agreement shall be construed as creating relationships of partners, employer and employee, franchiser and franchisee, or principal and agent between the parties.

2.6. Conversion to Non-Exclusive Rights. To the extent Distributor's rights to the Product hereunder are converted from exclusive to non-exclusive rights, OSUR shall be permitted to market, promote, import, sell and distribute the Product in the OTC Market in the Territory, directly or indirectly through one or more distributors, sub-distributors or agents.

3. OBLIGATIONS.

3.1. By Distributor.

3.1.1. Level of Effort. Distributor shall use all commercially reasonable efforts to market, promote, sell and distribute the Product in the OTC Market. In connection therewith, Distributor shall maintain, at its own expense and subject to OSUR's obligations under Section 3.2.2, an adequately trained staff to enable Distributor to fulfill its obligations under this Agreement.

3.1.2. Customer and Territorial Obligations. Distributor and OSUR acknowledge and agree that distribution of Product requires strict measures to ensure the proper identification, storage, tracking and transportation of the Product through its life cycle and significant commitments on the part of Distributor. For this reason, Distributor may market, promote and solicit sales of Product only to customers within the OTC Market in the Territory and to sub-distributors or agents who are licensed and contractually permitted, pursuant to the terms of this Agreement, to distribute Product in the OTC Market in the Territory. Distributor shall not sell the Product to customers who Distributor knows or has reason to believe intend to resell Products outside the OTC Market or Territory or whom OSUR or Distributor reasonably believes are facilitating such resale. Notwithstanding the above, OSUR acknowledges that nothing herein shall prohibit Passive Sales to non-OTC Market customers in the European Union, within the meaning of Commission Regulation (EC) No. 2790/1999 of 22 December 1999 on the application of Article 81(3) of the Treaty to Categories of Vertical Agreements and Concerted Practices. Distributor shall notify OSUR of any sale, order, resale or use of Product or other occurrence that violates this Section 3.1.2 promptly upon learning thereof.

3.1.3. Sales Leads Outside of the Territory or OTC Market.

(a) Without prejudice to Distributor's rights under Section 5.3 with respect to Distributor Trademarks and under Section 3.1.2 with respect to Passive Sales, Distributor shall

refer to OSUR all sales leads that come to its attention with respect to the sale or use of the Product outside of the Territory or OTC Market and, as soon as reasonably possible, inform OSUR of the identity of such sales lead. Distributor shall not be entitled to any commission, referral or finder fee or other remuneration for these referrals.

(b) Without prejudice to OSUR's rights under Section 2.2 with respect to Passive Sales, OSUR shall refer to Distributor all sales leads that come to OSUR's attention with respect to the sale or use of the Product in the OTC Market in the Territory and, as soon as reasonably possible, shall inform Distributor of the identity of such leads.

3.1.4. Compliance with Laws. Distributor shall comply with all applicable treaties, laws, rules and regulations in connection with its promotion, marketing, use, sale, import or distribution of the Product in the OTC Market, its supply of the Distributor Components hereunder and its performance of its obligations under this Agreement. Without limiting the generality of the foregoing, Distributor shall comply with all applicable regulatory approvals, clearances or registrations obtained for the import, promotion, marketing, sale or distribution of the Product in the OTC Market.

3.1.5. Exclusive Supply.

(a) During the period commencing on the Effective Date and ending on the last day of the sixth Contract Year and, subject to Section 3.1.5(b) below, during each subsequent Contract Year during the Term, Distributor and its Affiliates shall not, directly or indirectly, (a) import, market, manufacture, use, promote, sell, distribute or purchase any cryosurgical wart or lesion removal product that directly competes with the Product (a "Competing Product") or (b) engage in, provide services for or acquire or hold a controlling (as defined in Section 1.1) interest in any company, entity or business (as owner, stockholder, partner, co-venturer, director, officer, employee, consultant or otherwise) that imports, manufactures, markets, promotes, sells or distributes a Competing Product. If any provision of this Section 3.1.5 shall be held unenforceable because of scope, duration or area of its applicability, it shall be deemed modified to the extent necessary to make it enforceable, while preserving its intent.

(b) The obligations of Section 3.1.5(a), above, shall automatically renew and continue in full force and effect on an annual basis for successive Contract Years after the sixth Contract Year, unless Distributor elects to terminate such obligations in accordance with this Section 3.1.5(b). Effective on the first day of any Contract Year after the sixth Contract Year, Distributor shall have the right to terminate its obligations under Section 3.1.5(a) by giving OSUR written notice of its election to terminate not less than twelve (12) months prior to the effective date of termination. In the event Distributor exercises its right to terminate its obligations under Section 3.1.5(a) as provided above, OSUR may, either (i) terminate this Agreement or (ii) convert Distributor's rights hereunder to the Product from exclusive to non-exclusive rights, in each case effective as of the date Distributor's obligations under Section 3.1.5(a) are terminated. In order to exercise its right to terminate this Agreement or convert Distributor's rights, OSUR shall provide Distributor with written notice of such election within

sixty (60) days after receipt of Distributor's notice to terminate its obligations under Section 3.5.1(a). Notwithstanding anything to the contrary in this Agreement, if OSUR elects to terminate or convert Distributor's rights hereunder pursuant to this Section 3.1.5(b), nothing in this Agreement shall preclude OSUR from preparing to sell the Product, either directly or indirectly, into the OTC Market after this Agreement is terminated or Distributor's rights are converted, including without limitation conducting negotiations with new distributors and preparing marketing and promotional materials and plans. If OSUR elects to terminate this Agreement pursuant to this Section 3.1.5(b), Distributor shall pay OSUR a royalty which shall start at *** per unit of Competing Product sold by Distributor in the OTC Market in the Territory during the *** after the termination and shall be reduced by *** per unit for Competing Product sold during *** thereafter (i.e. the royalty rate shall be *** per unit during the *** period, *** per unit during the *** period, etc.); provided that Distributor shall no longer have any royalty obligation hereunder for any Competing Product sold after ***.

3.1.6. Marketing Plan. Distributor shall develop for each Contract Year a written annual plan for the marketing and sale of the Product in the OTC Market in each Country in the Territory. Distributor shall deliver such plan to OSUR for the first Contract Year within thirty (30) days after the Effective Date. Thereafter, Distributor shall deliver such a plan to OSUR for each subsequent Contract Year by September 1 of the preceding Contract Year. Additionally, Distributor shall provide OSUR with monthly updates of Distributor's sales of Product by Country and all marketing and promotional activities for each month. Distributor shall consult with OSUR in the preparation of each annual sales and marketing plan. In addition, Distributor shall provide OSUR with access to all market, sales and customer research and data obtained by Distributor which relates to the Product or the OTC Market.

3.1.7. Training. Distributor shall establish reasonable procedures to ensure that all new customers and sub-distributors or agents authorized hereunder in the OTC Market in the Territory are shown how to make proper use of the Product, in accordance with Product labeling, package inserts and instructions and applicable regulatory approvals in the Territory.

3.1.8. Technical Agreement. Distributor shall enter into and comply with a Technical Agreement with OSUR substantially in the form of attached Exhibit E, which is incorporated herein by reference.

3.2. By OSUR.

3.2.1. Compliance with Laws. OSUR shall comply with all applicable treaties, laws, rules and regulations in connection with its provision of the Product to Distributor and its performance of its obligations under this Agreement.

3.2.2. Training. OSUR shall provide technical support and training to Distributor in the use and performance of the Product at a level comparable to the support and training customarily provided by OSUR in the ordinary course of business to its distributors, which training shall be at times and places and for durations mutually agreed to by the parties.

3.2.3. Technical Support. OSUR shall provide and maintain, at its own expense, adequate support services and a staff properly trained in all aspects of the Product to provide Distributor with such levels of technical support during the Term that are commercially reasonable in light of the then current and reasonably anticipated sales volumes of the Product in the OTC Market.

3.2.4. Competition. Except as permitted by Section 2.2, during the Term OSUR shall not, directly or indirectly, import, market, manufacture, use, promote, actively sell or distribute any cryosurgical wart or lesion removal product that directly competes with the Product in the OTC Market in the Territory. Notwithstanding the foregoing, OSUR shall be released of its obligation to comply with this Section 3.2.4 in each Country where Distributor's rights to the Product are converted from exclusive to non-exclusive rights under this Agreement. If the provision of this Section 3.2.4 shall be held unenforceable because of scope, duration or area of its applicability, it shall be deemed modified to the extent necessary to make it enforceable, while preserving its intent.

3.2.5. Technical Agreement. OSUR shall enter into and comply with a Technical Agreement with Distributor substantially in the form of attached Exhibit E, which is incorporated herein by reference.

4. SUPPLY; ORDERING AND DELIVERY.

4.1. Requirements. In accordance with the terms and subject to the conditions contained in this Agreement, OSUR shall assemble (or cause to be assembled) and sell to Distributor, and Distributor shall purchase from OSUR, all of Distributor's requirements for the Product to be imported, marketed, sold, used or distributed in the OTC Market in the Territory. OSUR's obligation to assemble and supply Product to Distributor shall be subject to Distributor's compliance with its obligation to supply Distributor Components as set forth in Section 4.2 below.

4.2. Supply of Distributor Components. In accordance with the terms of this Section 4.2, Distributor shall supply, at its sole cost, the following components and deliver such components, or cause such components to be delivered, to the Assembly Contractor for use in packaging and assembling Products purchased hereunder (the "Distributor Components"):

(i) Four-sided box (with glued ends, tear strip and hook) in 6 colors for each Unit of Product, with labeling approved by OSUR;

(ii) One-color package insert or instructions for each Unit of Product, in form approved by OSUR;

(iii) Security detection devices (Checkpoint or SensorMatic), if required;

(iv) One shipper box; and

(v) One shipper label.

OSUR shall assist Distributor in selecting third-party vendors located in the United States for the manufacture and supply of the Distributor Components. Once such a vendor(s) have been selected by OSUR and approved by Distributor (which approval shall not be unreasonably withheld, delayed or conditioned), Distributor shall order Distributor Components directly from such vendor(s) and OSUR shall assist Distributor in placing such orders to ensure timely delivery of Distributor Components to the Assembly Contractor. Distributor Components shall be supplied with sufficient lead-times and in sufficient quantities as directed by OSUR to permit the packaging and assembly of Product purchased hereunder and delivery of such Product to Distributor in accordance with Distributor's Purchase Orders. Distributor shall directly pay each vendor for the Distributor Components supplied by such vendor. OSUR shall assist Distributor in ensuring that all Distributor Components are manufactured, stored and supplied in accordance with the Specifications and all applicable treaties, laws, rules and regulations within the Territory.

4.3. Terms and Conditions. The terms and conditions of this Agreement shall control all sales of Product by OSUR to Distributor. No different or additional terms and conditions on any purchase order, acknowledgment or other transmittal, whether a standard business form or otherwise, utilized by Distributor or OSUR in connection with the sale by OSUR of Product to Distributor shall be construed or deemed to be an amendment of or supplement to this Agreement or otherwise binding on either Distributor or OSUR.

4.4. Prices.

4.4.1. Product Price. Subject to Sections 4.4.2 and 4.4.4, below, Distributor shall pay OSUR the applicable price set forth in or determined pursuant to Exhibit D hereto, for each Unit purchased hereunder (the "Price"). The Price includes all costs of OSUR associated with the manufacture and packaging of the Products including raw materials and labor but excluding the cost of the Distributor Components. It is recognized that Products having different SKU or Part Numbers may be needed to reflect the use of language clusters for Product labeling and packaging and may result in different Prices for each separate SKU or Part Number. The need for separate SKU or Part Numbers and the appropriate Price therefore shall be determined by the parties and added to Exhibit D hereto. If Distributor requests, and OSUR agrees to provide, non-standard packaging for Product supplied hereunder, Distributor shall pay OSUR an additional fee for such packaging in accordance with OSUR's then existing pricing policies.

4.4.2. Price Increases. The applicable Price payable by Distributor for Product may be adjusted, at either party's option, at the beginning of *** and each *** thereafter during the Term, to an amount equal to the applicable Price then in effect, plus or minus the cumulative percentage increase or decrease, as the case may be, in the Index (as defined below) during the most recently completed 12-month period prior to delivery of the applicable Price Adjustment Notice (as defined below) for which the Index data (preliminary or final) is available. By December 1 of ***, the party desiring to exercise its right to adjust the Price hereunder will give the other party notice of any adjustment in the Price (the "Price Adjustment Notice") for Product to be purchased during ***. For purposes of this Agreement, "Index" shall mean the Consumer

Price Index of the Bureau of Labor Statistics of the U.S. Department of Labor for Urban Wage Earners and Clerical Workers (Base Year 1982-84=100) for All Urban Areas. In the event that the compilation and/or publication of the Index shall be transferred to any other governmental department, bureau, or agency, or shall be discontinued, then the index most nearly the same as the Index shall be used.

4.4.3. Taxes; Freight; Duties; Etc. Prices for Product are EX WORKS (Incoterms 2000) the Assembly Contractor's facilities and are exclusive of all sales, use, ad valorem and other similar taxes, customs, duties and other similar imports, fees and governmental charges, and freight, shipping and insurance charges. Any such charges shall be the sole responsibility of Distributor.

4.4.4. Product Improvement or Modification.

(a) *Pending Modification*. Distributor acknowledges that OSUR is currently developing a modified form of the Product. Based on the proposed design of such modified Product provided by OSUR to Distributor, it is agreed that it would be desirable to distribute the modified form of the Product, when available, into the OTC Market. Once the modified form of the Product is available, ***. The Specifications shall also be amended to reflect the foregoing modification. ***.

(b) *Other Changes*. OSUR may also, from time to time, without the prior consent of the Distributor, further improve any feature of the Product or change in any manner the technical specifications, features, design or performance of the Product (an "Improved Product"). OSUR shall not be obliged to make any improvement or modification to any Product or to make any Improved Product available for purchase by Distributor, except pursuant to Subsections (i) – (iii) below.

(i) Distributor shall have the right to submit suggested design changes and improvements for the Product to OSUR from time to time. OSUR shall consider such changes and improvements in good faith. In the event Distributor proposes any change or modification to the Product and OSUR is willing to make such change or modification, the parties shall determine in good faith appropriate changes to the Specifications, a sharing of costs to develop such change or modification if appropriate and a revised Price for the Product as so changed or modified. If the parties reach agreement on the foregoing matters with respect to an Improved Product, OSUR shall supply the Improved Product to the Distributor hereunder. It is recognized that Distributor has suggested that a modification be made to the Product. If such modification is warranted, OSUR agrees to use commercially reasonable efforts to develop the Product with such modification, subject to the foregoing provisions of this Section 4.4.4(b)(i). Notwithstanding the foregoing, any failure by OSUR to successfully develop or implement any change or improvement to the Product shall not constitute a breach of this Agreement or otherwise entitle Distributor to any compensation as a result thereof.

(ii) In the event that OSUR desires to make or makes a change or modification to the Product and desires to make such Improved Product available for purchase

by Distributor hereunder, OSUR shall notify Distributor of such change or modification and any proposed changes to the Price, the Specifications and the other terms and conditions of this Agreement required thereby. The Distributor shall have a period of not less than thirty (30) days from receipt of the foregoing notice from OSUR to decide whether or not to accept the Improved Product and the proposed changes to the Price, Specifications and other terms or conditions of this Agreement proposed by OSUR. If Distributor agrees to the foregoing, or the parties otherwise agree to include the Improved Product in this Agreement, then OSUR shall supply the Improved Product to the Distributor hereunder.

(iii) In the event that Distributor does not agree to an Improved Product proposed under Subsection (ii) above, and the parties otherwise fail to agree to include the Improved Product herein, OSUR may nevertheless supply the Distributor with such Improved Product hereunder, at the Price and under the other terms and conditions of this Agreement then in effect, so long as the improvement or change made to the Product in order to create such Improved Product is required for safety reasons or in order to comply with any applicable legal or regulatory requirements. The Specifications shall be modified to reflect such Improved Product.

(c) *Effect of Changed Product*. In the case of the modified Product under Section 4.4.4(a) or any Improved Product under Sections 4.4.4(b)(i), (ii) or (iii), any changes to the Price, Specifications or other terms and conditions of this Agreement related thereto shall be set forth in an amendment to this Agreement or other written instrument executed by the parties and shall thereafter be deemed to be the applicable Price, Specifications and other terms and conditions hereunder and such modified or Improved Product shall be deemed to be the Product hereunder. Once the modified or Improved Product is available, OSUR shall not be obliged to manufacture or supply the prior form of Product and the supply of such modified or Improved Product to Distributor shall satisfy in full OSUR's supply obligations hereunder. Notwithstanding the foregoing, OSUR and Distributor shall cooperate in determining a reasonable timing for launching the modified or Improved Product into the OTC Market in the Territory. Distributor shall be responsible for obtaining, at its cost, all regulatory approvals, clearances or registrations required in the OTC Market in the Territory, including a CE mark, that are required as a result of any modified or Improved Product, and OSUR shall cooperate with Distributor in such efforts, except that OSUR shall pay the costs of obtaining the approvals for the modified Product described in Section 4.4.4(a) and any Improved Product described in Section 4.4.4(b)(iii).

4.5. Purchases of Product.

(a) Distributor shall order Product by issuing binding purchase orders (each, a "Purchase Order") to OSUR pursuant to the terms of this Agreement. Each Purchase Order shall be subject to Section 4.3 and shall state the quantity and SKU or Part Number for the Product to be purchased, delivery date(s), routing instructions, destination(s) and confirmation of the applicable Price hereunder. OSUR shall indicate its acceptance or rejection of a Purchase Order within five (5) Business Days after receipt; provided that OSUR may reject a Purchase Order, in

whole or in part, only if: (i) the Purchase Order fails to comply with the terms and conditions of this Agreement; (ii) the delivery date or dates in such Purchase Order are less than ninety (90) days from the date of OSUR's receipt of the Purchase Order; (iii) Distributor shall have failed to forecast a sufficient quantity of canisters with sufficient lead times, as required under Section 4.5(b), to enable OSUR to assemble the Product covered by the Purchase Order; or (iv) the volume under the Purchase Order and all other accepted Purchase Orders covering the same period exceeds the volume in Distributor's then current forecast (delivered pursuant to Section 4.6) for such period by more than fifty percent (50%). If requested by Distributor following Distributor's receipt of OSUR's rejection notice under clause (iv) above, OSUR will use commercially reasonable efforts to deliver the excess volume of Product on the delivery dates specified in the rejected Purchase Order, but OSUR's failure to so deliver the excess volume shall not be a breach of this Agreement. In no event shall OSUR be liable to any third party for OSUR's failure to deliver Product to Distributor by any delivery due date set forth in any Purchase Order. Each Purchase Order shall be for a minimum of *** Units of Product and Distributor shall order not less than *** Units of any Product with a single or the same SKU or Part Number.

(b) In each monthly forecast delivered pursuant to Section 4.6, Distributor shall provide OSUR with the monthly quantity of canisters needed to fill all Purchase Orders issued under Section 4.5(a); provided that Distributor shall provide OSUR with a forecast for canisters needed to assemble the Units of Product to be purchased under each such Purchase Order at least *** (***) days in advance of the applicable delivery date or dates for such Units of Product. In the event this Agreement terminates or expires and OSUR has remaining inventory of canisters ordered in reliance on a forecast received from Distributor, the disposition of such excess canisters shall be governed by Section 12.3.4 hereof.

4.6. Forecasts. Within thirty (30) days after the Effective Date, Distributor shall provide to OSUR a written forecast of Distributor's anticipated monthly requirements for Product during the first Contract Year. Thereafter, by the fifteenth (15th) day of each month during the Term, Distributor shall provide OSUR with an additional, written forecast of Distributor's anticipated monthly requirements for the Product during the subsequent twelve (12) month period beginning with the next full month, including a forecast of the monthly quantities of canisters required to fill Purchase Orders issued by Distributor in accordance with Section 4.5(b). Subject to Section 4.5(b), each forecast required to be delivered by Distributor under this Section 4.6 shall be nonbinding except for the first three (3) months of such forecast, which shall constitute a binding commitment to purchase by Distributor.

4.7. Shipment. OSUR shall ship Products EX WORKS (Incoterms 2000) the Assembly Contractor's facilities. OSUR shall fill Purchase Orders that comply and are accepted in accordance with Section 4.5. All risk of loss, damage, spoilage, improper storage, mishandling and negligence for all Product shall pass to Distributor at the time of delivery to the shipper at the Assembly Contractor's facilities. At Distributor's request made in its Purchase Order, OSUR may, on Distributor's behalf, choose a carrier, arrange for transportation of the Product to Distributor or Distributor's customers, insure the Product during shipment, and pay any export or

import duties or other charges. OSUR shall charge Distributor for all such expenditures in addition to the Price of the Product. OSUR shall ensure that all Products are suitably packed for shipment in OSUR standard containers. OSUR shall provide to Distributor, not less than three (3) Business Days in advance of each shipment, all necessary information relating to such shipment, including without limitation, the number of Units, cases, pallets and lot numbers.

4.8. Records.

4.8.1. By Distributor. Distributor shall maintain accurate and complete records of each sale of the Product, including without limitation, the name and address of the purchaser, the date of purchase, quantity, type, batch numbers and SKU or Part Number of Product sold in each Country, total volume of Product sold in the Territory and in each Country, and information regarding other products that compete with any of the Products in the Territory known to Distributor. Distributor shall maintain such records for at least three years from the date of sale, or such longer period as reasonably requested by OSUR. In addition to the foregoing, Distributor shall comply with all record-keeping requirements imposed by regulatory or governmental authorities in each Country in the Territory. Upon request, Distributor shall provide OSUR with copies of any records required to be maintained under this Section 4.8.1, including such records as may be necessary for OSUR to comply with all regulatory approvals related to the import, marketing, sale, use or distribution of the Products in the Territory and any other requirements of any regulatory or governmental authority.

4.8.2. By OSUR. OSUR shall maintain accurate and complete records with respect to its performance under this Agreement with respect to the manufacture, supply and quality control of the Product necessary to comply with the Quality System Regulation as promulgated by the U.S. Food and Drug Administration ("QSR"), the Medical Device Directive and the requirements of the International Standards Organization ("ISO Standards"). OSUR shall maintain such records for at least three (3) years, or such longer period as may be required by the QSR, Medical Device Directive or ISO Standards. In addition, upon reasonable advance notice by Distributor, OSUR's records shall, upon request but in no event on more than one occasion during any Contract Year, be made available during normal business hours for inspection by Distributor. OSUR shall also use commercially reasonable efforts to cause the Assembly Contractor to comply with the foregoing record-keeping requirements and to make such records available to Distributor in accordance with this Section 4.8.2.

4.9. Failure to Supply. If, during any Contract Year, OSUR is unable for any reason (other than Distributor's failure to comply with Section 4.2 or 4.5(b)) to supply at least *** in accordance with the terms and conditions of this Agreement, ordered by binding Purchase Orders in compliance with the terms of Section 4.5 (which quantity shall not include excess quantities contemplated by Section 4.5(a)(iv)) for delivery in any calendar quarter, and such failure continues for at least ninety (90) days after the delivery date set forth in such Purchase Order, then Distributor may elect to obtain a supply of a replacement product (the "Replacement Product") from a third party (a "Third Party Supplier") in an amount equal to the quantity of Product OSUR is unable to supply. Distributor shall notify OSUR in writing of its election no

later than thirty (30) days after the end of the ninety (90) day period specified above. If Distributor exercises its right under this Section 4.9, such action shall be Distributor's sole and exclusive remedy in the event of a failure to supply OSUR. OSUR shall cooperate with Distributor in order to enable such Third Party Supplier to supply Replacement Product as required under this Section 4.9; provided that any such Third Party Supplier executes a confidentiality agreement in form and substance reasonably satisfactory to OSUR in order to maintain the confidentiality of any proprietary information provided by OSUR to such Third Party Supplier. Nothing in this Section 4.9 shall require OSUR to transfer (by license or otherwise) to a Third Party Supplier any patent or other intellectual property rights to the Product. During the period that a Third Party Supplier is manufacturing and supplying Replacement Product under this Section 4.9, OSUR agrees that it will not enforce any patent rights owned or licensed by OSUR against Distributor, the Third Party Supplier or any customer of Distributor in respect of the manufacture, marketing, distribution or sale of the Replacement Product in accordance with this Agreement. If Distributor exercises its right to have a Third Party Supplier manufacture and supply a Replacement Product pursuant to this Section 4.9 and thereafter during the Term OSUR desires to resume supplying Distributor with the Product (whether by OSUR, through another source or otherwise), then OSUR shall notify Distributor of such desire. Distributor shall then resume purchasing Product exclusively from OSUR for the remainder of the Term of this Agreement as soon as OSUR demonstrates to Distributor's reasonable satisfaction that OSUR (whether by OSUR, another source or otherwise) is capable of reestablishing a satisfactory supply of Product. Distributor agrees that it will not enter into any contracts with Third Party Suppliers in accordance with this Section 4.9 under which the Distributor cannot terminate its purchase commitments for Replacement Product within ninety (90) days in order to permit the resumption of supply by OSUR in accordance herewith.

4.10. Nondiscrimination. In supplying Product to the Distributor hereunder, OSUR shall supply such Product to the Distributor and OSUR's other customers in a nondiscriminatory manner.

5. INTELLECTUAL PROPERTY.

5.1. Branding and Packaging. Product labeling, packaging and package inserts and instructions shall be in the form approved by or which is in compliance with applicable regulatory authorities in the Territory, and shall use the "Scholl" trademark and trade dress of Distributor ("Distributor Trademarks"), in accordance with this Section 5.1. The parties shall cooperate in the design of the package labeling, packaging, inserts and instructions for Product, and the final Product labeling, packaging, inserts and instructions shall be subject to written approval by both parties, which shall not be unreasonably withheld or delayed. Distributor shall ensure that all Product purchased hereunder is distributed into the OTC Market in the Territory only with the labeling, packaging, inserts and instructions approved in writing by OSUR. Distributor shall be responsible for supplying adequate quantities of all packaging, labeling and package inserts and instructions in accordance with Section 4.2. Distributor hereby consents to OSUR's use of the Distributor Trademarks on labeling, package inserts and instructions and packaging used to assemble and ship the Product.

5.2. Promotional Materials. Distributor shall produce and use sufficient quantities of promotional materials, including sales aids, brochures, product briefs, advertisements and similar materials relating to the Product (including references and/descriptions on its website), which are in Distributor's reasonable judgment appropriate for each specific Country, for purposes of promoting, marketing, selling and distributing the Product in the OTC Market; provided that all such materials (in print, electronic or any other type of media) shall be subject to the written approval of OSUR prior to their use (which approval shall not be unreasonably withheld or delayed). In addition, Distributor shall provide appropriate customer support to maintain and foster customer satisfaction.

5.3. No Other Rights; Allocation of Goodwill. Except for the rights herein, neither party shall acquire any right, title, or interest in any trademark, trade name, logo or trade dress, copyright, patent, or any other intellectual property rights of the other party by reason of this Agreement.

5.4. Effect of Termination. Upon termination of this Agreement, both parties shall immediately cease all use of the other party's trademarks, trade names, logos and trade dress, except such use as is necessary to complete the manufacturing, assembly and sale of Product under open Purchase Orders at the time of termination, to complete the manufacturing and assembly of Product with OSUR's remaining inventory of components therefore and to sell off such party's Product inventory, as permitted under Section 4.5(b) or 12.3.4.

6. APPROVALS.

6.1. CE Mark. To the extent it has not done so prior to the Effective Date, Distributor shall obtain, as soon as reasonably practicable after the Effective Date, a CE Mark on the Product pursuant to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (the "Medical Device Directive") and shall maintain such CE Mark on the Product during the Term of this Agreement. Distributor shall be appointed as the European authorized representative for purposes of the Medical Device Directive and OSUR shall provide Distributor with all reasonable assistance with respect to obtaining and maintaining the CE Mark, at no cost for OSUR. Distributor shall comply with all obligations placed on the European authorized representative by the Medical Device Directive. Distributor shall provide OSUR with copies of all documents and significant correspondence sent or received in connection with obtaining authority to affix a CE Mark, including any agreement with a notified body.

6.2. Regulatory Approval and Compliance by Distributor. To the extent Distributor has not already done so prior to the Effective Date, Distributor shall obtain, as soon as reasonably practicable after a CE Mark has been obtained for the Product, all government approvals (other than the CE Mark) necessary to import the Product into and market and sell the Product in the OTC Market in the Territory. Distributor shall maintain all such approvals during the Term of this Agreement. Distributor shall, promptly upon receipt, provide OSUR with copies of all approvals and all significant correspondence with or from (including any notices from) any governmental agency with respect to the Product or such approvals. Distributor shall also immediately inform OSUR of any government invalidation of any approval to import, use, market, distribute or sell Product in the OTC Market in the Territory.

6.3. Clinical Trial Protocol. OSUR shall review and approve (which approval shall not be unreasonably withheld or delayed) each protocol for clinical testing or evaluation of the Product required in the Territory; provided that each such protocol shall comply with all applicable legal and regulatory requirements in the Territory. If required to obtain any governmental approval, Distributor shall perform or use its best efforts to cause the government of the Territory to undertake a clinical trial or evaluation in the Territory using the protocol approved by OSUR. Distributor shall obtain OSUR's written consent (not to be unreasonably withheld or delayed) prior to initiating any clinical trial with respect to the Product. Distributor agrees to assume any and all clinical trial or evaluation costs necessary to obtain such approvals (except to the extent necessitated by changes to the Product by OSUR pursuant to Section 4.4.4(a) or 4.4.4(b)(iii)) and act if necessary as the sponsor of such trial under applicable laws and assume all related obligations (including insurance obligations). OSUR shall have a non-exclusive, perpetual and royalty-free right to use the results of such trials for any commercial or other purpose. Immediately upon receipt of documentation confirming registration of the Product in the Territory, Distributor shall provide to OSUR written copies of such documentation issued by the relevant governing body in the Territory.

6.4. Technical Data. OSUR shall use commercially reasonable efforts to provide Distributor with all available technical data and assistance reasonably required by the government of any Country in the Territory in order to receive regulatory approval to market the Product in the OTC Market in such Country, provided that OSUR shall not be obligated to disclose such information if it cannot be assured that (i) the information will be treated confidentially in the manner described in Section 11 and (ii) the information will not be made publicly available.

6.5. New Indications. The Parties acknowledge that the Product is currently intended only for use in removing common warts and plantar warts (verrucas). In no event shall Distributor seek to obtain or obtain any regulatory approval or license, or otherwise distribute the Product, for removal of any other types of skin lesions, without the prior written consent of OSUR, which may be withheld or granted in OSUR's sole discretion.

7. PAYMENT TERMS; MINIMUM PURCHASE COMMITMENTS.

7.1. Payment Terms. Product shall be invoiced by OSUR upon shipment. Distributor shall pay OSUR all amounts due under this Agreement no later than forty-five (45) days from the date of an invoice from OSUR for such amounts. Overdue amounts shall bear interest at a rate of one percent (1%) per month or such lower rate required by law, until paid. Distributor shall not have any right to set off or withhold any amounts due OSUR hereunder arising out of, or based upon, any counter-claim, breach of contract, tort or other action against OSUR.

7.2. Total Territory Minimum Quantity. Distributor agrees to purchase during each Contract Year an aggregate quantity of Product sufficient to meet the Total Territory Minimum

Quantity for such Contract Year. To the extent Distributor purchases more than the Total Territory Minimum Quantity in any Contract Year, such excess shall not be counted towards meeting the Total Territory Minimum Quantity in any subsequent or prior Contract Year.

7.3. Territory A Minimum Quantities. Distributor agrees to purchase during each Contract Year a quantity of Product for sale in each Territory A Country, which is sufficient to meet the Territory A Minimum Quantity for such Territory A Country for such Contract Year. To the extent Distributor purchases more than the Territory A Minimum Quantity for any Territory A Country in any Contract Year, such excess shall not be counted towards meeting (i) the Territory A Minimum Quantity for such Territory A Country in any subsequent or prior Contract Year or (ii) the Territory A Minimum Quantity for any other Territory A Country.

7.4. Total Territory B Minimum Quantity. Distributor agrees to purchase during each Contract Year a quantity of Product for sale in the Territory B Countries which is sufficient to meet the Total Territory B Minimum Quantity for such Contract Year. To the extent Distributor purchases more than the Total Territory B Minimum Quantity in any Contract Year, such excess shall not be counted towards meeting (i) the Total Territory B Minimum Quantity for any prior or subsequent Contract Year or (ii) the Territory A Minimum Quantity for any Territory A Country.

7.5. Effect of Failure to Meet Minimums. In the event Distributor fails to meet any of the minimum purchase commitments set forth in Sections 7.2, 7.3 or 7.4, above, OSUR shall have the termination and conversion rights set forth in Section 12.2.3. The exercise of its rights under Section 12.2.3 shall be OSUR's sole and exclusive remedy in the event Distributor fails to meet any of the minimum purchase quantities set forth in Sections 7.2, 7.3 or 7.4, above.

7.6. Purchases. In order to determine whether a purchase of Product by Distributor occurs within a particular Contract Year for purposes of meeting the minimum purchase commitments set forth in Sections 7.2, 7.3 and 7.4, a purchase of Product shall be deemed to occur when such Product is delivered and title and risk of loss for such Product transfers to Distributor under Section 4.7.

7.7. Minimums During Renewal Terms. In the event this Agreement is extended for one or more Renewal Terms, the Total Territory Minimum Quantity, the Territory A Minimum Quantities, the Total Territory B Minimum Quantity and any other or different minimum purchase commitments for each Contract Year during such Renewal Term shall be subject to negotiation by the parties.

8. WARRANTIES.

8.1. Limited Product Warranties. OSUR warrants to Distributor that: (a) the Product, when shipped, will conform to the specifications as set forth in the Specifications; and (b) the Product shall be free from defects in materials and workmanship for a period equal to the stated shelf life for such Product (the "Warranty Period").

8.2. OSUR DISCLAIMER. THE EXPRESS LIMITED WARRANTIES FOR THE PRODUCT SET FORTH IN SECTION 8.1. OF THIS AGREEMENT AND THE ADDITIONAL REPRESENTATIONS AND WARRANTIES SET FORTH IN SECTION 9.1.2 OF THIS AGREEMENT ARE IN LIEU OF ALL OTHER REPRESENTATIONS AND WARRANTIES BY OSUR, WHETHER EXPRESSED OR IMPLIED. OSUR HEREBY DISCLAIMS ANY AND ALL OTHER REPRESENTATIONS AND WARRANTIES OF ANY KIND, EXPRESSED OR IMPLIED, WHETHER ARISING FROM A COURSE OF DEALING OR USAGE OF TRADE, INCLUDING, WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT.

8.3. Distributor's Warranty Remedies. During the Warranty Period, OSUR shall replace, at OSUR's expense, or at Distributor's option, refund or credit the purchase Price of, any Product that does not comply with the limited warranty set forth in Section 8.1 of this Agreement. OSUR's obligation to replace defective Products or provide a credit or refund pursuant to this Section 8.3 shall not apply to any Products that have been subjected to misuse, mishandling, storage in a manner inconsistent with labeling, neglect, modification or unusual physical or chemical stress after delivery to Distributor. This Section 8.3 states Distributor's sole and exclusive remedy for failure of any Product to comply with the limited warranties set forth in Sections 8.1.

9. REPRESENTATIONS AND ADDITIONAL WARRANTIES; INDEMNIFICATION.

9.1. Representations and Additional Warranties.

9.1.1. By Distributor. Distributor represents and warrants to OSUR as follows: (a) Distributor has full corporate power and authority to enter into and carry out its obligations under this Agreement; (b) the execution, delivery and performance of this Agreement will not conflict with, are not inconsistent with and will not result in any breach of any terms, conditions or provisions of, or constitute (with due notice or lapse of time, or both) a default under any agreement, contract, document or instrument to which Distributor is a party or by which it is otherwise bound; (c) this Agreement has been duly executed and delivered by Distributor and constitutes the legal, valid and binding obligation of Distributor, enforceable against Distributor in accordance with its terms; and (d) no authorization, consent, approval or similar action of or by any third party is required for or in connection with Distributor's authorization, execution, delivery or performance of this Agreement; and (e) the use of the Distributor Trademarks will not constitute an infringement or dilution of a third party's trademark rights in the Territory. In addition, Distributor recognizes that OSUR is not fully familiar with the laws, rules, regulations and policies of each jurisdiction within the Territory and that OSUR has entered into this Agreement with Distributor (and will perform this Agreement) in reliance upon the following representations and warranties made by Distributor on the date hereof and on each date that Product is shipped or sold that: (i) none of this Agreement, the relationship created hereby or the performance hereof is contrary to the laws, rules, regulations or policies of any government,

commission, agency or instrumentality having jurisdiction within the Territory; and (ii) Distributor has not refunded and will not refund, either directly or indirectly, any funds to any director, officer, employee or other representative of OSUR.

9.1.2. By OSUR. OSUR represents and warrants to Distributor as follows: (a) OSUR has full corporate power and authority to enter into and carry out its obligations under this Agreement; (b) the execution, delivery and performance of this Agreement will not conflict with, are not inconsistent with and will not result in any breach of any terms, conditions or provisions of, or constitute (with due notice or lapse of time, or both) a default under any agreement, contract, document or instrument to which OSUR is a party or by which it is otherwise bound; (c) this Agreement has been duly executed and delivered by OSUR and constitutes the legal, valid and binding obligation of OSUR, enforceable against OSUR in accordance with its terms; (d) the manufacture, sale and use of the Product will not infringe upon, or constitute a misappropriation of, any third party's intellectual property rights; and (e) no authorization, consent, approval or similar action of or by any third party is required for or in connection with OSUR's authorization, execution, delivery or performance of this Agreement.

9.2. Indemnification.

9.2.1. By Distributor. Distributor shall indemnify, defend and hold harmless OSUR, its Affiliates, and the respective directors, officers, employees, agents and representatives of each of the foregoing, from and against any and all claims, suits and proceedings by a person or entity (other than a party to this Agreement or such party's Affiliates) (individually and collectively, "Claims"), and any and all losses, obligations, damages, deficiencies, costs, penalties, liabilities, assessments, judgments, amounts paid in settlement, fines, and expenses (including court costs and reasonable fees and expenses of attorneys) in respect of any Claims (individually and collectively, "Losses"): (a) arising out of the negligence or willful misconduct of Distributor or its Affiliates, employees, agents or any other person for whose actions Distributor is legally liable; (b) for bodily injury, personal injury, death, property damage or other injury caused by or arising out of or in connection with the use, handling or storage of any Product by a consumer or other end-user in a manner inconsistent with the applicable package insert or labeling or instructions for such Product (including without limitation for any indication or intended use not explicitly described or claimed in the applicable Product insert) or any misuse, mishandling or improper storage of any Product by Distributor, any subdistributor or agent of Distributor; (c) arising out of or in connection with any promotional material, advertisement or claim made by Distributor or any sub-distributor or agent of Distributor or product labeling, insert, instructions or packaging, which is not approved in writing in advance by OSUR; (d) arising out of or in connection with a material breach by Distributor of any of its obligations under this Agreement including, without limitation, its obligations under Section 6 and any representations or warranties set forth in Section 9.1.1, or the acts or omissions of any distributor, sub-distributor or agent of Distributor or any person or entity claiming to be acting pursuant to authority from Distributor; (e) arising out of the failure to manufacture or supply Distributor Components in accordance with Section 4.2; or (f) arising out of any claim that any of the Distributor Trademarks constitutes an infringement or dilution of a third party's trademark

rights in the Territory; provided, however, that Distributor shall have no liability to OSUR for any Claims or Losses to the extent that such Claims or Losses result from or arise out of: (i) the negligence or willful misconduct of OSUR or its Affiliates, employees, agents or any person for whose actions OSUR is legally liable; (ii) a material breach by OSUR of any of its obligations under this Agreement or its representations or warranties set forth in Section 9.1.2; (iii) in the case of clause (e) above, any failure by OSUR to perform its obligations under Section 4.2; or (iv) any occurrence for which OSUR has liability to Distributor pursuant to Section 9.2.2.

9.2.2. By OSUR. OSUR shall indemnify, defend and hold harmless Distributor, its Affiliates, and the respective directors, officers, employees, agents and representatives of each of the foregoing, from and against any and all Claims and Losses: (a) for bodily injury, personal injury, death, property damage or other injury caused by the defective design or manufacture of the Product (excluding the Distributor Components) or the inadequacy, inaccuracy and insufficiency of any product labeling approved in writing or developed by OSUR prior to its use; (b) arising out of the negligence or willful misconduct of OSUR or its Affiliates, employees, agents or any other person for whose actions OSUR is legally liable; (c) arising out of or in connection with a material breach by OSUR of any of its obligations under this Agreement including any representations or warranties set forth in Section 9.1.2; or (d) arising out of a claim that any of the manufacture, marketing, import, sale or use of the Product infringes upon any lawful patent rights; provided, however, that OSUR shall have no liability to Distributor for any Claims or Losses to the extent that such Claims or Losses result from or arise out of: (i) the negligence or willful misconduct of Distributor or its Affiliates, subdistributors, employees, agents or any person for whose actions Distributor is legally liable; (ii) a material breach by Distributor of any of its obligations under this Agreement including any representations or warranties set forth in Section 9.1.1; or (iii) any occurrence for which Distributor has liability to OSUR pursuant to Section 9.2.1. In addition, OSUR shall have no liability to Distributor with respect to any Claims or Losses in connection with Product labeling under clause (a), above, if such labeling is not actually distributed with the Product without modification or alteration or Distributor fails to comply with its obligations hereunder with respect to Product packaging, labeling, inserts, instructions and promotional materials, including Sections 3.1.4, 4.2 and 5.1.

9.2.3. Indemnification Procedures. Each party shall provide prompt notice to the other of any actual or threatened Loss or Claim of which the other becomes aware; provided, that the failure to provide prompt notice shall only be a bar to recovering Losses or Claims to the extent that a party was prejudiced by such failure. In the event of any such actual or threatened Loss or Claim, each party shall provide the other information and assistance as the other shall reasonably request for purposes of defense, and each party shall receive from the other all necessary and reasonable cooperation in such defense including, but not limited to, the services of employees of the other party who are familiar with the transactions or occurrences out of which any such Loss or Claim may have arisen. It shall be a condition to indemnification that the indemnifying party be allowed to control the response to and any settlement or defense of any Claim, or the portion of any Claim, as to which indemnification is sought at the indemnifying party’s sole expense and with counsel of its own choosing. After notice from the indemnifying party to the indemnified party of its election to assume the defense of a Claim, the

indemnifying party will not be liable to the indemnified party for expenses incurred by the indemnified party in connection with such Claim under this Agreement, other than the indemnified party's reasonable costs of investigation or participation in such Claim, and except as provided below. The indemnified party shall have the right to employ its own counsel in any such Claim, but the fees and expenses of such counsel incurred after notice from the indemnifying party of its assumption of the defense of such Claim shall be at the expense of the indemnified party, unless (i) the employment of counsel by the indemnified party has been authorized by the indemnifying party, (ii) the indemnified party shall have reasonably concluded that there may be a conflict of interest between the indemnifying party and the indemnified party in the conduct of the defense of such Claim, or (iii) the indemnifying party shall not in fact have employed counsel to assume the defense of such Claim, in each of which cases the fees and expenses of the indemnified party's counsel shall be paid by the indemnifying party. Neither party shall have the right to settle any Claim or agree to the entry of any judgment or other relief without the prior consent of the other party, which consent shall not be withheld or delayed unreasonably; provided that the indemnifying party may settle any Claim or agree to the entering of any judgment or relief if such settlement, judgment or relief includes a complete release of the indemnified party from the Claims at issue.

9.3. Additional Rights for Claims of Infringement. Without limitation to any of the rights and obligations of OSUR and Distributor under this Agreement, including but not limited to Section 9.2, if a third party asserts or threatens any Claim asserting: (a) that any of the manufacture, marketing, sale, use or distribution of the Product infringes upon, or constitutes a misappropriation of, such third party's intellectual property rights in the Territory, then OSUR may, at its option (i) procure for Distributor a license to continue selling the Product, (ii) modify such items to make them non-infringing, or (iii) if neither of the foregoing is commercially practicable, terminate this Agreement with respect to sale of the infringing item in the jurisdiction in which infringement is asserted.

9.4. Insurance. Distributor and OSUR each represent, warrant, and covenant that during the Term, it shall maintain general liability insurance, including contractual liability coverage and products liability/completed operations coverage, at least sufficient to cover such party's respective indemnification obligations under this Agreement and with a minimum aggregate limit of *** and a minimum limit per occurrence of ***. Such insurance shall be evidenced by one or more certificates of insurance delivered to the other party on an annual basis, naming such other party as an additional insured (or other substantially equivalent protection) and providing that the other party shall receive at least thirty (30) days' prior written notice of cancellation or material change of any of the policies underlying such coverage. Any failure by Distributor to maintain the insurance coverage required by this Section 9.4 shall be a material breach of this Agreement.

10. RECALL; COMPLAINTS.

10.1. Recall. Each party shall immediately notify the other in writing should it become aware of any defect or condition that may render any Product in violation of any applicable

requirement of law or regulation in the Territory or that may constitute a deviation from the warranties made by OSUR in Section 8.1. Upon the reasonable determination of OSUR (after consultation with Distributor), or upon the reasonable determination by Distributor if required by applicable law or regulation in the Territory, to recall the affected Product, OSUR and Distributor shall carry out any recall or replacement in full compliance with applicable laws and regulations and in the manner reasonably agreed by OSUR and Distributor in as expeditious a manner as possible and in such a way as to cause the least disruption and to preserve customer goodwill and the reputation of OSUR and Distributor. OSUR shall reimburse Distributor in full for all reasonable, direct costs of the recall or replacement of a Product, but only if the recall or replacement results from a defect in the manufacture or packaging of the Product or from any OSUR breach of warranty, and not from any action taken or omitted by Distributor, its Affiliates or entities or persons directly controlled by Distributor or for which it is legally responsible or from the Distributor Components. The direct costs for which OSUR shall reimburse Distributor shall be limited to direct and out-of-pocket costs, such as mailing and printing costs, freight, supervised destruction and other amounts paid or credited to third parties. OSUR shall have no liability to Distributor (or others) for indirect costs of the recall or replacement, such as lost profits, employee time, or overhead.

10.2. Consumer Communications and Complaints.

10.2.1. Communications. Distributor shall receive, collect, classify and organize routine communications from customers and consumers. From time to time, but not less frequently than annually or when reasonably requested by OSUR, Distributor will provide OSUR with a summary report of such communications.

10.2.2. Complaints. Distributor shall notify OSUR of the receipt of any complaints, reports, adverse events or reactions related to the Product, including any non-serious adverse events or reactions, improper performance or other performance related communications related to the Product, and shall forward all such complaints, reports, adverse events and reactions to OSUR along with all related information available to Distributor, as soon as practicable and in no event later than thirty (30) days after each Quarterly Period in which they occur (with the form of any summary or compilation of information to be mutually agreed by the parties); provided that Distributor shall notify OSUR of any deaths or serious adverse events or reactions within two (2) Business Days after receipt by Distributor. Distributor shall be responsible for investigating, responding to and reporting to all relevant health authorities all such complaints, adverse events and reactions and reporting, in accordance with applicable law and regulatory approvals for the Product in the Territory. Distributor shall provide OSUR with copies of all reports or other communications with health authorities regarding complaints, reports, adverse events and reactions. Distributor and OSUR shall cooperate as necessary and useful, to investigate and respond to all complaints of any nature. Distributor shall share its investigations and conclusions with OSUR within 10 Business Days after receipt of a potentially reportable complaint. Information or data (if any) bearing on safety or performance of the Product in a material respect arising from sales outside the OTC Market or Territory by OSUR or any licensee or other party authorized by OSUR shall be summarized and provided to the Distributor as reasonably required by the mutual interests of the parties, but not less frequently than annually.

10.3. Regulatory Inspection. OSUR shall advise Distributor in writing as soon as practicable if any regulatory authority inspects the facilities of OSUR or (if known by OSUR) the Assembly Contractor and issues any findings or makes any determinations relating to the manufacture and supply of the Product which is reasonably likely to materially affect OSUR's ability to supply Product to Distributor under this Agreement.

10.4. Quality Audits. Upon reasonable advance written notice to OSUR, Distributor shall be entitled to perform quality audits of the facilities of OSUR or the Assembly Contractor where the Product is assembled in order to determine if the Product is manufactured and assembled in accordance with this Agreement; provided that any such audit shall occur during normal business hours and shall not interfere with the normal operations of the facility being audited. Distributor shall be permitted to perform a quality audit under this Section 10.4 no more frequently than once per Contract Year and shall provide OSUR with a written summary of the results of each such audit. The results of any audit and any information disclosed to Distributor during any audit shall be deemed to be Confidential Information of OSUR subject to the provisions of Section 11 hereof.

11. CONFIDENTIALITY AND NON-USE OF INFORMATION.

11.1. Confidential Information.

11.1.1. Definition of "Confidential Information." As used in this Agreement, the term "Confidential Information" shall, subject to Section 11.2 of this Agreement, mean all technical (including, without limitation, Product specifications, design, components, compositions and formulations), financial (including, without limitation, any information obtained under Section 4.8 of this Agreement), commercial (including, without limitation, customer lists and identities) or other information of Distributor (or any of Distributor's Affiliates) or OSUR (or any of OSUR's Affiliates), as applicable, irrespective of the form of communication and whether or not disclosed prior to or after the Effective Date, other than information that was generally known or otherwise generally available to the public or the industry before disclosure to the other party, or information that becomes generally known to the public or the industry after such disclosure through no wrongful act or omission of the receiving party. Failure to mark or otherwise identify any information as confidential or proprietary shall not adversely affect its status as "Confidential Information."

11.1.2. Obligations of Confidentiality and Non-Use.

(a) During the Term and at all times thereafter, neither Distributor nor OSUR shall disclose any of the other party's Confidential Information. The foregoing shall not prohibit disclosures: (i) made to such party's employees, agents or advisors who have a "need to know" the other party's Confidential Information to the extent necessary to perform such party's duties and obligations, or to enforce such party's rights, under this Agreement; or (ii) compelled to be

made by any requirement of law or pursuant to any legal or investigative proceeding before any court, or governmental or regulatory authority, agency or commission so long as the party so compelled to make disclosure of Confidential Information pertaining to the other party provides prior written notice (to the extent possible under applicable law) to such other party and uses its commercially reasonable efforts to cooperate with such other party to obtain a protective order or other similar determination with respect to such Confidential Information.

(b) During the Term and at all times thereafter, Distributor and OSUR shall not use any of the other party's Confidential Information for its own direct or indirect benefit, or the direct or indirect benefit of any third party, except that each of Distributor and OSUR may use the other party's Confidential Information to the extent necessary to perform its duties and obligations, or to enforce such party's rights, under this Agreement.

(c) Each of Distributor and OSUR shall (i) take reasonable steps, whether by instruction, agreement, or otherwise, to cause its employees, agents and advisors who may have access to Confidential Information of the other party, to comply with its obligations under this Section 11 and (ii) shall be liable for the breach of this Section 11 by any of its employees, agents or advisors who may have access to Confidential Information of the other party.

11.2. Exceptions. Confidential Information shall not include information that: (a) a party can prove on the basis of the written record, was known by the receiving party at time of disclosure; (b) the receiving party can prove on the basis of the written record to have been independently developed for the receiving party after the time of disclosure by employees or third parties who have not had access to corresponding Confidential Information; or (c) was received by the receiving party, without restriction, from a third party not under any obligation to the other party not to disclose it and otherwise not in violation of the other party's rights.

11.3. Remedies. Any breach of the restrictions contained in this Section 11 by either Distributor or OSUR is a material breach of this Agreement, which may cause irreparable harm to the other party entitling such other party to injunctive relief in addition to all other legal remedies.

11.4. Disclosure of this Agreement. The parties acknowledge that it is their intention to issue a press release concerning the execution of this Agreement. The parties shall cooperate in the preparation of such a release, which shall be subject to approval (not to be unreasonably withheld or delayed) of both parties. It is also understood that OSUR may need to publicly disclose and file a copy of this Agreement under applicable securities laws and regulations or the rules of a stock exchange, and OSUR shall be permitted to do so so long as it omits from such disclosure the financial terms and other competitively sensitive information contained in this Agreement to the extent permitted under applicable law. Distributor shall cooperate with OSUR in connection with the preparation and filing of such disclosure.

12. TERM AND TERMINATION.

12.1. Term. The term of this Agreement shall begin on the Effective Date and end on the last day of the tenth Contract Year or on such earlier date as this Agreement may be terminated pursuant to Section 12.2 of this Agreement (the "Initial Term"). The parties agree to consult with each other beginning three hundred sixty-five (365) days prior to the expiration of the Initial Term and any Renewal Term (as defined below) to decide whether to renew this Agreement for a successive period of five (5) years each (each, a "Renewal Term," and together with the Initial Term, the "Term"). If so renewed, the terms of Agreement for each Renewal Term shall, subject to Section 7.7, be subject to negotiation and agreement by the parties and this Agreement shall continue through the end of the applicable Renewal Term, unless earlier terminated pursuant to Section 12.2.

12.2. Termination.

12.2.1. By Reason of Material Breach. This Agreement may be terminated by either Distributor or OSUR upon notice if the other party materially breaches any term or condition of this Agreement (other than a breach covered by Section 12.2.2 or 12.2.5) and fails to remedy the breach within thirty (30) days after being given notice thereof.

12.2.2. By Reason of Failure to Pay Amounts Owing. Either OSUR or Distributor shall have the right to terminate this Agreement if the other party shall have failed to pay timely any amounts due under this Agreement which nonpayment has not been cured within fifteen (15) days of receipt of notice thereof.

12.2.3. Failure to Meet Minimum Purchase Commitments.

(a) Total Territory. In the event Distributor fails to purchase Product in any Contract Year sufficient to meet the Total Territory Minimum Quantity for such Contract Year, then OSUR shall have the right, upon thirty (30) days prior written notice, to terminate this Agreement in its entirety or convert Distributor's rights to the Product from exclusive to non-exclusive rights within the Territory.

(b) Territory A Countries. In the event Distributor fails to purchase Product in any Contract Year sufficient to meet the Territory A Minimum Quantity for any Territory A Country for such Contract Year, then OSUR shall have the right, upon thirty (30) days prior written notice, to terminate Distributor's rights to such Territory A Country and remove such Territory A Country from this Agreement or to convert Distributor's rights to the Product in such Territory A Country from exclusive to non-exclusive rights. In the event Distributor fails to purchase Product in any Contract Year sufficient to meet the Territory A Minimum Quantity for two (2) or more Territory A Countries for such Contract Year, then OSUR shall have the right, upon thirty (30) days prior written notice, to terminate this Agreement in its entirety or to convert Distributor's rights to the Product from exclusive to non-exclusive rights within the entire Territory.

(c) Territory B. Countries. In the event Distributor fails to purchase Product in any Contract Year sufficient to meet the Total Territory B Minimum Quantity for such Contract Year, then OSUR shall have the right, upon thirty (30) days prior written notice, (i) to terminate this Agreement in its entirety, (ii) terminate Distributor's rights with respect to the Territory B Countries and remove the Territory B Countries from this Agreement or (iii) convert Distributor's rights to the Product in the Territory B Countries from exclusive to non-exclusive rights.

12.2.4. By Reason of Bankruptcy or Similar Proceedings. This Agreement may be terminated in its entirety by either party upon notice if the other party becomes the subject of insolvency or bankruptcy proceedings, ceases doing business, makes an assignment of assets for the benefit of creditors, dissolves, or has a trustee appointed for all or a substantial portion of such party's assets.

12.2.5. By Reason of a Change of Control. The parties acknowledge and agree that this Agreement is entered into by OSUR in reliance upon the current management and ownership of Distributor. If the control (as defined in Section 1.1 herein) of Distributor changes and the surviving entity is a Prohibited Entity (as defined below) or Distributor is otherwise controlled (as defined by Section 1.1 herein) by a Prohibited Entity, OSUR may terminate this Agreement or convert Distributor's rights hereunder from exclusive to non-exclusive, in its sole discretion, upon not less than ninety (90) days' prior written notice to Distributor. If OSUR elects to exercise its right to terminate or convert under this Section 12.2.5 as a result of a change in control involving Distributor, OSUR must do so no later than sixty (60) days after receipt of written notice from Distributor that such a change in control has occurred or will occur. For purposes of this Agreement, the term "Prohibited Entity" shall mean a person or entity (i) that manufactures or sells any product(s) in any territories that directly or indirectly compete against the Product or any other product of OSUR or (ii) that has a financial or credit condition which, in the reasonable judgment of OSUR, is materially weaker than the financial or credit condition of Distributor at the time of the change of control.

12.3. Effect of Termination.

12.3.1. Subsisting Obligations. Termination or expiration of this Agreement shall not relieve the parties of any obligation arising prior to the effective date of such termination or expiration and shall not constitute a waiver of any right of the parties under this Agreement as a result of breach or default.

12.3.2. Remedies Upon Breach. If this Agreement is validly terminated by either Distributor or OSUR pursuant to Section 12.2. of this Agreement, then subject to the limitations set forth in Sections 7.5, 8.2, 8.3 and 13.5 of this Agreement, any and all rights and remedies available to the non-breaching party, whether under this Agreement, at law or in equity shall be preserved and survive the termination of this Agreement; provided, however, that Distributor shall not be entitled to a termination indemnity or penalty or similar damages or compensation if this Agreement is terminated in accordance with its terms.

12.3.3. Return of Confidential Information. Upon expiration of this Agreement or its termination by either party, each party, as the other may direct, shall destroy or return to the other promptly all tangible materials provided to it by the other that embody the other's Confidential Information and shall erase or delete all such Confidential Information embodied in any magnetic, optical or similar medium or stored or maintained on any information storage or retrieval device, and shall provide an officer's certificate regarding such destruction, return, erasure or deletion. Notwithstanding the foregoing, and subject to the provisions set forth in Section 11 of this Agreement, each party's outside legal counsel may retain one (1) copy of such materials for archival purposes.

12.3.4. Inventory. Following expiration of this Agreement or its termination by either party, (i) Distributor may continue selling any inventory of Product remaining in its possession in accordance with its past business practices for a period of six (6) months after such expiration or termination, (ii) OSUR may complete, or cause the Assembly Contractor to complete, assembly of Product required to fulfill all then outstanding Purchase Orders and Distributor shall purchase all such Product at the Price set forth herein and (iii) at OraSure's request, Distributor shall purchase all remaining components (including any excess canisters ordered by OSUR or the Assembly Contractor in reliance on a forecast from Distributor pursuant to Section 4.5(b)) not then assembled into Product remaining in OSUR's or the Assembly Contractor's inventory at OSUR's cost therefore. Distributor may sell the Product and components purchased under clauses (ii) and (iii) above for a period of six (6) months after delivery of such Product and components to Distributor.

12.3.5. Transfer of Approvals. Upon expiration of this Agreement or its termination by either party, Distributor shall transfer to OSUR or its designee (or provide OSUR with all necessary assistance to obtain such transfer, as the case may be) all approvals and registrations (other than registrations of the Distributor's Trademarks, including the SCHOLL mark) relating to the Product in the Territory which are in Distributor's name or control.

12.3.6. Survival. The following Sections shall survive expiration or termination of this Agreement for any reason: Section 1, 2.4, 2.5, 3.1.5(b), 4.3, 4.4.1, 4.4.3, 4.5(b), 4.7, 4.8, 5.3, 5.4, 7.1, 8, 9, 10, 11, 12.3 and 13.

13. GENERAL PROVISIONS.

13.1. Currency. All amounts payable under this Agreement shall be paid in U.S. dollars, unless otherwise agreed in writing.

13.2. Governing Law. This Agreement shall be governed by, and construed and interpreted in accordance with, the laws of the Commonwealth of Pennsylvania, U.S.A., without reference to conflict of laws principles of any jurisdiction.

13.3. Force Majeure. Notwithstanding anything to the contrary set forth herein, neither party shall be liable in damages, nor shall either party have the right to terminate this Agreement for any delay or default in performing any obligation hereunder, if such delay or default is

caused by conditions beyond the control of the relevant party, including but not limited to, acts of God, governmental restrictions or regulations, wars or insurrections, strikes, fire, floods, work-stoppages, lack of materials, and unforeseen occurrences or other occurrences beyond the control of the affected party; provided, however, that the party so affected shall employ such reasonable actions to avoid or to remove such cause of non-performance, and shall continue performance under this Agreement with the utmost dispatch whenever the relevant cause is abated; and further provided that if either party is unable to fulfill any relevant obligation under this Agreement due to any such cause, and this situation continues for a period of ninety (90) days, then the other party hereto shall have the right to terminate this Agreement by written notice.

13.4. Assignment. This Agreement may not be assigned or otherwise transferred, nor may any right or obligation under this Agreement be assigned or transferred, by either party to a third party without the prior written consent of the other party, which consent shall not be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing, either party may assign this Agreement without the other party's consent in connection with the transfer or sale of all or substantially all of its businesses or assets, the sale or transfer of the division or line of business of the assigning party that includes the Product, or a change in control (as defined in Section 1.1) of the assigning party, so long as (i) the assigning party provides the other party with at least thirty (30) days advance written notice of such assignment, (ii) the assignee or surviving entity assumes in a written instrument reasonably acceptable to the non-assigning party all of the assigning party's obligations hereunder, (iii) where Distributor is the assigning party, the assignee, surviving entity or controlling party is not a Prohibited Entity, and (iv) where OSUR is the assigning party solely in connection with the sale or transfer only of the division or line of business of OSUR that includes the Product, the assignee shall not be actively engaged, directly or indirectly, in the import, manufacture, sale or distribution of a Competing Product within the OTC Market in the Territory.

13.5. Limitation of Liability. NEITHER PARTY SHALL BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR INDIRECT DAMAGES ARISING IN ANY WAY OUT OF THIS AGREEMENT, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, INCLUDING, WITHOUT LIMITATION, PUNITIVE DAMAGES, LOST PROFITS AND THE COST OF REPLACEMENT PRODUCT OR GOODS. THIS LIMITATION WILL APPLY EVEN IF THE OTHER PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGE. NOTHING IN THIS SECTION 13.5 SHALL PRECLUDE THE INCLUSION OF SPECIAL, INCIDENTAL, CONSEQUENTIAL OR INDIRECT DAMAGES INCURRED BY ANY PARTY ENTITLED TO INDEMNIFICATION UNDER SECTION 9.2 OF THIS AGREEMENT IN CONNECTION WITH ANY THIRD PARTY CLAIM, SUIT OR ACTION AGAINST SUCH PARTY WITHIN THE AMOUNT OF LOSSES INCURRED AS A RESULT OF SUCH THIRD PARTY CLAIM OR ACTION.

13.6. No Third Party Beneficiaries. Distributor and OSUR intend that only Distributor and OSUR will benefit from, and are entitled to enforce the provisions of, this Agreement. No third party beneficiary is intended under this Agreement.

13.7. Modifications; Waiver. No modification to this Agreement shall be effective unless such modification is in a writing, which is signed by a duly authorized representative of each of Distributor and OSUR. No waiver of any rights or breach or default under this Agreement shall be effective unless assented to in writing by the party to be charged with such waiver. The waiver of any breach or default shall not constitute a waiver of any other right hereunder or any subsequent breach or default.

13.8. Notices. Any required notices under this Agreement shall be given in writing at the address of each party set forth above, or to such other address as either party may substitute by written notice to the other in the manner contemplated in this Section 13.8, and shall be deemed given (a) when personally delivered; (b) if sent by recognized overnight courier service, on the next business day after deposit with such courier, properly addressed and fee prepaid; (c) if sent by U.S. certified mail, return receipt requested, on the seventh (7th) Business Day after deposit in the U.S. mail, properly addressed and postage prepaid; or (d) if sent by facsimile, upon and after the receipt of a machine-generated written confirmation report corresponding to the notice given evidencing the proper facsimile number of the receiving party, provided a copy of such notice is also sent by regular first-class U.S. mail. All notices shall be sent to the attention of the recipient's president.

13.9. Descriptive Headings. The headings of the several sections of this Agreement are intended for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement.

13.10. Severability. In the event that any provision of this Agreement becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable or void, this Agreement shall continue in full force and effect without such provision; provided that this severability provision shall not be effective if it materially changes the economic benefit of this Agreement to either Distributor or OSUR.

13.11. Prohibited Acts. Distributor shall not make any payment or take any other action that would violate the United States Foreign Corrupt Practices Act, the United States Anti-Boycott Regulations or any other law of the United States or any Country in the Territory.

13.12. Official Language. The official language of this Agreement is English. Documents or notices not originally written in English shall have no effect under this Agreement until they have been translated into English, and the English translation shall then be the controlling form of such documentation or notice.

13.13. Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but both of which together shall constitute one and the same instrument. A facsimile transmission of a signed original shall have the same effect as delivery of the signed original.

13.14. Expenses. Except as otherwise expressly set forth in this Agreement, Distributor and OSUR shall bear their own respective expenses incident to the preparation, negotiation, execution and delivery of this Agreement and to the performance of their respective obligations under this Agreement.

13.15. Alternate Dispute Resolution.

13.15.1. Agreement to utilize Alternate Dispute Resolution. Except for matters which relate to the enforcement of Section 11 of this Agreement, which matters shall not be required to be submitted to mediation or arbitration, any controversy or claim between Distributor and OSUR arising out of or relating to this Agreement, or any breach of this Agreement, including without limitation, any claim that this Agreement, or any part thereof, is invalid, illegal or otherwise voidable or void, shall be submitted to neutral third party dispute resolution in the form of mediation before a mutually selected and agreed upon mediator who shall be neutral and experienced in the type of business contemplated herein. Should the parties be unable to agree on a mediator or should mediation fail, the parties shall then submit the dispute to arbitration before and in accordance with the then current commercial arbitration rules of the American Arbitration Association. Any mediation or arbitration shall take place in the New York County, NY, U.S.A. Judgment upon an arbitration award may be entered in any court having competent jurisdiction and shall be binding, final and non-appealable. No punitive or exemplary damages shall be awarded against either Distributor or OSUR. This Section 13.15.1 shall be deemed to be self-executing, and in the event either party fails to appear at any properly noticed arbitration proceeding, an award may be entered against such party notwithstanding said failure to appear. Such arbitration shall take place in a neutral location as the parties may mutually agree. Each party shall bear its own costs incurred in connection with the mediation or arbitration proceeding.

13.15.2. Right to Seek Injunctive Relief Preserved. Nothing in the Agreement shall be construed as limiting or precluding either party from bringing any action in any court of competent jurisdiction for injunctive or other extraordinary relief as such party deems necessary or appropriate to compel the other party to comply with its obligations under Section 11 of this Agreement.

13.16. Entire Agreement. This Agreement constitutes the entire and exclusive agreement and understanding between Distributor and OSUR with respect to the subject matter of this Agreement, and supersedes and cancels all previous negotiations, agreements, and commitments, whether oral or in writing, in respect to the subject matter of this Agreement.

IN WITNESS WHEREOF, the undersigned duly authorized officers of OSUR and Distributor, respectively, hereby execute this Agreement on the date first above written on behalf of OSUR and Distributor, respectively.

ORASURE TECHNOLOGIES, INC.

By: */s/ Douglas A. Michels*

Print Name: Douglas A. Michels
Title: President and Chief Executive Officer

SSL INTERNATIONAL PLC

By: */s/ Rob Gillingwater*

Print Name: Rob Gillingwater
Title: Footcare Supply & Procurement Director

By: */s/ M.J. Pilkington*

Print Name: M.J. Pilkington
Title: Group Supply Chain Director

Exhibit A

Territory

The following Countries constitute the Territory:

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EXHIBIT B

Product Specifications

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EXHIBIT C

Purchase Minimums

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EXHIBIT D

Prices*

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* This Exhibit shall be modified from time to time to include Prices for Product with different SKU or Part Numbers, pursuant to Section 4.4.1 of the Agreement. Prices shall also be modified pursuant to Sections 4.4.2 and 4.4.4

EXHIBIT 10.3

Description of OraSure Technologies, Inc.
2005 Self-Funding Management Incentive Plan

On May 17, 2005, the Board of Directors (the "Board") of OraSure Technologies, Inc. (the "Company") adopted the 2005 Self-Funding Management Incentive Plan (the "Bonus Plan"). The purpose of the Bonus Plan is to reward outstanding individual performance by management with cash bonuses. All employees, except for sales employees (who are covered by a separate commission plan) at the level of director and above, will be eligible to participate in the Bonus Plan.

Pursuant to the Bonus Plan, cash bonuses may be paid out of a cash bonus pool to be funded based on the Company's achievement of certain financial objectives regarding revenues, operating income and cash flow from operations for 2005. If the Company achieves 100% of these financial targets, the bonus pool would be funded in the amount of $1.1 million, and if the Company achieves 150% of these financial targets, the bonus pool would be funded in the amount of $1.7 million. Notwithstanding the foregoing, the total amount paid from the pool will be determined by the Board after evaluation of the Company's achievement of the foregoing financial objectives as well as strategic objectives for 2005. The Board may, in its sole discretion, approve a total payment greater than $1.7 million if it determines that the Company has achieved a breakthrough performance by substantially exceeding the financial objectives for 2005.

Payments from the bonus pool will depend on an employee's achievement of individual performance objectives. Bonus payments will be based on the target payouts set forth below, which are expressed as a percentage of base salary. The aggregate of all bonuses cannot exceed the funded amount of the bonus pool. Specific payments to individuals could exceed the following targets if the Company achieves more than 100% of its financial objectives or otherwise achieves a breakthrough performance as determined by the Board.

Title	Target Payouts
Chief Executive Officer	50%
Executive Vice President	40%
Senior Vice President	30%
Vice President	20%
Director	10%

Performance criteria for individual employees will be derived from the Company's 2005 strategic objectives concerning financial performance, strategic planning, research and development, business development, regulatory affairs and quality control, manufacturing, engineering, information systems, sales and marketing, human resources, investor relations matters and/or other objectives approved by the Board or the Compensation Committee of the Board (the "Compensation Committee"). Awards are expected to reflect a weighted average measurement of an employee's achievement of his or her individual performance objectives.

Employees must be employed by the Company as of December 31, 2005 and at the time of the bonus award in order to participate in the Bonus Plan, and awards will be adjusted on a pro rata basis to the extent any employee is employed for only a portion of the year 2005. The Chief Executive Officer will recommend individual awards for all participating employees (except for the Chief Executive Officer) for approval by the Compensation Committee based on an assessment of each individual's performance against his or her applicable performance objectives. The Compensation Committee may approve or disapprove any recommended bonus award in whole or in part in its sole discretion. The Compensation Committee shall recommend for Board approval any bonus award for the Chief Executive Officer based on an assessment of his performance against his individual performance objectives. The Board may approve or disapprove any recommended bonus award for the Chief Executive Officer in whole or in part in its sole discretion.

The Compensation Committee and the Board shall have the right in their sole discretion to reject any or all of the recommended bonus awards, even if the bonus pool has been funded and any and all applicable performance criteria have been satisfied, based on the business conditions of the Company at or immediately after the end of 2005.

Exhibit 31.1

Certification

I, Douglas A. Michels, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   c) 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
   d) 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; and
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:
   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: August 5, 2005

/s/ Douglas A. Michels

Douglas A. Michels
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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   c) 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
   d) 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; and
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:
   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: August 5, 2005

/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 June 30, 2005 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Douglas A. Michels, 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/ Douglas A. Michels

Douglas A. Michels
President and Chief Executive Officer

August 5, 2005

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 June 30, 2005 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

August 5, 2005