

ORASURE TECHNOLOGIES INC  
Form 10-Q  
May 10, 2007

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 10-Q**

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(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the quarterly period ended March 31, 2007.

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)

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**DELAWARE**  
(State or Other Jurisdiction of Incorporation or Organization)

**36-4370966**  
(IRS Employer Identification No.)

**220 East First Street, Bethlehem, Pennsylvania**  
(Address of Principal Executive Offices)

**18015**  
(Zip code)

**(610) 882-1820**

(Registrant's Telephone Number, Including Area Code)

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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 a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer  Non-accelerated filer

Indicate by checkmark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

Number of shares of Common Stock, par value \$.000001 per share, outstanding as of May 1, 2007: 46,176,062

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**PART I. FINANCIAL INFORMATION**

	<b>Page No.</b>
<b><u>Item 1. Financial Statements (unaudited)</u></b>	3
<u>Balance Sheets at March 31, 2007 and December 31, 2006</u>	3
<u>Statements of Operations for the three months ended March 31, 2007 and 2006</u>	4
<u>Statements of Cash Flows for the three months ended March 31, 2007 and 2006</u>	5
<u>Notes to Financial Statements</u>	6
<b><u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b>	13
<b><u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u></b>	25
<b><u>Item 4. Controls and Procedures</u></b>	26

**PART II. OTHER INFORMATION**

<b><u>Item 1. Legal Proceedings</u></b>	26
<b><u>Item 1A. Risk Factors</u></b>	27
<b><u>Item 6. Exhibits</u></b>	27
<b><u>Signatures</u></b>	28

## Item 1. FINANCIAL STATEMENTS

## ORASURE TECHNOLOGIES, INC.

## BALANCE SHEETS

(Unaudited)

	March 31, 2007	December 31, 2006
<b>ASSETS</b>		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 16,778,230	\$ 19,949,821
Short-term investments	69,764,099	71,051,482
Accounts receivable, net of allowance for doubtful accounts of \$244,818 and \$200,094	14,844,248	10,357,287
Inventories	6,089,147	5,534,567
Deferred income taxes	4,268,983	3,675,785
Prepaid expenses and other	1,936,016	1,989,882
Total current assets	113,680,723	112,558,824
PROPERTY AND EQUIPMENT, net	18,003,961	17,374,718
PATENTS AND PRODUCT RIGHTS, net	6,066,128	6,328,344
DEFERRED INCOME TAXES	18,275,834	19,845,789
OTHER ASSETS	117,298	457,788
	\$ 156,143,944	\$ 156,565,463
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
CURRENT LIABILITIES:		
Current portion of long-term debt	\$ 596,515	\$ 608,595
Accounts payable	4,175,736	3,311,968
Accrued expenses and other	8,722,245	12,659,149
Total current liabilities	13,494,496	16,579,712
LONG-TERM DEBT	10,007,485	10,030,541
OTHER LIABILITIES	525,262	451,235
STOCKHOLDERS EQUITY:		
Preferred stock, par value \$.000001, 25,000,000 shares authorized, none issued		
Common stock, par value \$.000001, 120,000,000 shares authorized, 46,176,062 and 45,994,752 shares issued and outstanding	46	46
Additional paid-in capital	229,327,077	228,069,433
Accumulated other comprehensive loss	(224,456)	(151,197)
Accumulated deficit	(96,985,966)	(98,414,307)
Total stockholders equity	132,116,701	129,503,975
	\$ 156,143,944	\$ 156,565,463

The accompanying notes are an integral part of these statements.



## ORASURE TECHNOLOGIES, INC.

## STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended March 31,	
	2007	2006
<b>REVENUES:</b>		
Product	\$ 19,430,185	\$ 15,128,078
Licensing and product development	678,890	89,247
	20,109,075	15,217,325
<b>COST OF PRODUCTS SOLD</b>	<b>7,584,420</b>	<b>5,617,992</b>
Gross profit	12,524,655	9,599,333
<b>OPERATING EXPENSES:</b>		
Research and development	2,919,884	1,648,766
Sales and marketing	4,770,743	4,106,565
General and administrative	4,237,351	2,957,654
	11,927,978	8,712,985
Operating income	596,677	886,348
INTEREST EXPENSE	(166,079)	(17,816)
INTEREST INCOME	1,135,347	826,635
GAIN ON SALE OF INVESTMENT	1,428,691	
FOREIGN CURRENCY LOSS	(9,348)	(18,253)
Income before income taxes	2,985,288	1,676,914
INCOME TAX PROVISION	1,498,765	777,275
NET INCOME	\$ 1,486,523	\$ 899,639
BASIC AND DILUTED EARNINGS PER SHARE	\$ 0.03	\$ 0.02
<b>SHARES USED IN COMPUTING EARNINGS PER SHARE:</b>		
BASIC	46,114,260	45,839,732
DILUTED	46,553,920	46,833,079

The accompanying notes are an integral part of these statements.

## ORASURE TECHNOLOGIES, INC.

## STATEMENTS OF CASH FLOWS

(Unaudited)

	Three Months Ended March 31,	
	2007	2006
<b>OPERATING ACTIVITIES:</b>		
Net income	\$ 1,486,523	\$ 899,639
Adjustments to reconcile net income to net cash (used in) provided by operating activities:		
Gain on sale of investment in nonaffiliated company	(1,428,691)	
Stock-based compensation	1,380,444	1,440,990
Deferred income taxes	1,086,053	658,172
Depreciation and amortization	655,700	446,811
Provision for excess and obsolete inventories	165,293	147,725
Changes in assets and liabilities:		
Accounts receivable	(4,486,961)	1,805,718
Inventories	(719,873)	(678,761)
Prepaid expenses and other	101,279	(302,353)
Accounts payable, accrued expenses, and other liabilities	751,484	(1,848,664)
Net cash (used in) provided by operating activities	(1,008,749)	2,569,277
<b>INVESTING ACTIVITIES:</b>		
Purchases of short-term investments	(26,540,067)	(17,718,483)
Proceeds from maturities and redemptions of short-term investments	27,711,438	13,425,404
Purchases of property and equipment	(898,045)	(664,756)
Payment for patents and licenses	(4,000,000)	
Proceeds from sale of investment in nonaffiliated company	1,765,944	
Net cash used in investing activities	(1,960,730)	(4,957,835)
<b>FINANCING ACTIVITIES:</b>		
Repayments of long-term debt	(35,136)	(277,423)
Proceeds from issuance of common stock	372,243	173,764
Withholding and retirement of common stock	(539,219)	(443,871)
Net cash used in financing activities	(202,112)	(547,530)
<b>EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH</b>		<b>554</b>
<b>NET DECREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(3,171,591)</b>	<b>(2,935,534)</b>
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD</b>	<b>19,949,821</b>	<b>32,826,740</b>
<b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>	<b>\$ 16,778,230</b>	<b>\$ 29,891,206</b>

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 over-the-counter or consumer retail markets in the United States, Canada, Europe and Mexico.

**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 our financial position and results of operations 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, 2006. Results of operations for the three-month period ended March 31, 2007 are not necessarily indicative of the results of operations expected for the full year.

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

*Cash and Cash Equivalents.* We consider all highly liquid investments with a purchased maturity of ninety days or less to be cash equivalents. As of March 31, 2007 and December 31, 2006, cash equivalents consisted of commercial paper.

*Short-term Investments.* We consider all short-term investments to be available-for-sale securities, in accordance with Statement of Financial Accounting Standards (SFAS) No. 115, Accounting for Certain Investments in Debt and Equity Securities. These securities are comprised of certificates of deposits, commercial paper, U.S. government and agency obligations, 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.



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The following is a summary of our available-for-sale securities at March 31, 2007 and December 31, 2006:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
<b>March 31, 2007</b>				
Certificates of deposit	\$ 800,000	\$	\$	\$ 800,000
Commercial paper	16,368,802	36,575		16,405,377
Government and agency bonds	7,838,702		(1,819)	7,836,883
Corporate bonds	44,745,853		(24,014)	44,721,839
Total available-for-sale securities	\$ 69,753,357	\$ 36,575	\$ (25,833)	\$ 69,764,099
<b>December 31, 2006</b>				
Certificates of deposit	\$ 800,000	\$	\$	\$ 800,000
Commercial paper	28,079,352	165,064		28,244,416
Government and agency bonds	3,331,455		(4,618)	3,326,837
Corporate bonds	38,713,921	2,264	(35,956)	38,680,229
Total available-for-sale securities	\$ 70,924,728	\$ 167,328	\$ (40,574)	\$ 71,051,482
<b>At March 31, 2007, maturities of investments were as follows:</b>				
Less than one year	\$ 66,250,503	\$ 36,575	\$ (24,942)	\$ 66,262,136
One to two years	3,502,854		(891)	3,501,963
Total available-for-sale securities	\$ 69,753,357	\$ 36,575	\$ (25,833)	\$ 69,764,099

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

	March 31, 2007	December 31, 2006
Raw materials	\$ 3,671,390	\$ 3,868,301
Work-in-process	456,851	533,470
Finished goods	1,960,906	1,132,796
	\$ 6,089,147	\$ 5,534,567

*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. Taxes assessed by governmental authorities, such as sales or value-added taxes, are excluded from product revenues.

*Significant Customer Concentration.* In the first quarter of 2007, Prestige Brands Holdings, Inc. accounted for 11 percent of total revenues as compared to 12 percent for the first quarter of 2006. This same customer accounted for 14 percent and 12 percent of accounts receivable as of March 31, 2007 and December 31, 2006, respectively.



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In the first quarter of 2007 and 2006, Quest Diagnostics accounted for 10 percent of total revenues. This customer accounted for 11 percent of accounts receivable as of March 31, 2007 and December 31, 2006.

In the first quarter of 2007, Abbott Laboratories accounted for 11 percent of total revenues as compared to 9 percent for the first quarter of 2006. This same customer accounted for 10 percent and 11 percent of accounts receivable as of March 31, 2007 and December 31, 2006, respectively.

Additionally, SSL International plc accounted for 10 percent of accounts receivable as of March 31, 2007 and December 31, 2006.

*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 Per Share.* We have presented basic and diluted earnings per share pursuant to SFAS No. 128, Earnings per Share. In accordance with SFAS No. 128, basic earnings per share is computed by dividing net income by the weighted average number of shares of common stock outstanding during the period. Diluted earnings per share is computed in a manner similar to basic earnings per share except that the weighted average number of shares outstanding is increased to include incremental shares from the assumed vesting or exercise of 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 per share are as follows:

	<b>Three Months</b>	
	<b>Ended March 31,</b>	
	<b>2007</b>	<b>2006</b>
Net income	\$ 1,486,523	\$ 899,639
Weighted average shares of common stock outstanding:		
Basic	46,114,260	45,839,732
Dilutive effect of stock options, warrants and restricted shares	439,660	993,347
Diluted	46,553,920	46,833,079
Earnings per share:		
Basic	\$ 0.03	\$ 0.02
Diluted	\$ 0.03	\$ 0.02

For the three-month periods ended March 31, 2007 and 2006, outstanding common stock options and unvested restricted stock, representing 2,367,708 and 322,960 shares, respectively, were excluded from the computation of diluted earnings per share, as their inclusion would have been anti-dilutive.

*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. Other comprehensive loss at March 31, 2007



and December 31, 2006 consisted of currency translation adjustments and net unrealized gains or losses on marketable securities. Comprehensive income was \$1,413,264 and \$888,241 for the three months ended March 31, 2007 and 2006, respectively.

*Recent Accounting Pronouncements.* In September 2006, the Financial Accounting Standards Board ( FASB ) issued SFAS No. 157, Fair Value Measurements. This Statement defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. We are currently assessing the impact, if any, that SFAS No. 157 will have on our financial statements.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115. SFAS No. 159 permits entities to elect to measure many financial instruments and certain other items at fair value. Unrealized gains and losses on items for which the fair value option has been elected will be recognized in earnings at each subsequent reporting date. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. We are currently assessing the impact, if any, that SFAS No. 159 will have on our financial statements.

### **3. Sale of Investment in Nonaffiliated Company**

Included in other assets at December 31, 2006 was a \$337,253 investment, representing a 7.7% ownership interest in a privately-held nonaffiliated company. We accounted for this investment using the cost method of accounting. In January, 2007, this privately-held nonaffiliated company was sold and we received \$1,765,944 for our ownership interest. Accordingly, we recorded a \$1,428,691 pre-tax gain on the sale of this investment.

### **4. Stock-Based Compensation**

We grant stock-based awards under the OraSure Technologies, Inc. 2000 Stock Award Plan (the 2000 Plan ). The 2000 Plan permits stock-based awards to employees, outside directors, and consultants or other third-party advisors. Awards which may be granted under the 2000 Plan include qualified incentive stock options, nonqualified stock options, stock appreciation rights, restricted awards, performance awards and other stock-based awards. We recognize compensation expense for stock option awards issued to employees and directors on a straight-line basis over the requisite service period of the award. To satisfy the exercise of options or to issue new restricted stock, we normally issue new shares rather than purchase shares on the open market.

The fair value of each stock option is estimated on the date of the grant using the Black-Scholes option-pricing model. The weighted average grant date fair value of stock options granted during the three months ended March 31, 2007 and 2006 was \$3.58 and \$5.06, respectively.

Total compensation cost related to stock options for the three months ended March 31, 2007 and 2006, was \$722,707 (\$539,535, net of tax) and \$921,166 (\$715,610, net of tax), respectively, of which \$61,668 and \$101,859 was capitalized into inventory during the quarters ended March 31, 2007 and 2006, respectively. The amounts recognized in cost of products sold for amounts previously capitalized were \$48,012 and \$3,086 for the three months ended March 31, 2007 and 2006, respectively.

The following table summarizes the stock option activity for the three months ended March 31, 2007:

	<b>Options</b>
Outstanding on January 1, 2007	4,788,418
Granted	434,566
Exercised	(65,905)
Forfeited	(12,476)
<b>Outstanding on March 31, 2007</b>	<b>5,144,603</b>

As of March 31, 2007, there was \$5,333,274 of unrecognized compensation expense related to unvested option awards that is expected to be recognized over a weighted average period of 1.8 years.

Net cash proceeds from the exercise of stock options were \$372,243 and \$173,764 for the three months ended March 31, 2007 and 2006, respectively. As a result of the Company's net operating loss carryforward position, no actual income tax benefit was realized from stock option exercises for these periods.

During the three-month period ended March 31, 2007, we granted 343,655 restricted shares of our common stock, with a grant date fair value of \$8.28, 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, the market value of these shares was calculated at the date of grant and is being recognized on a straight-line basis over the three-year period during which the restrictions lapse. Compensation cost of \$657,737 and \$513,050 related to these and previous grants was recognized during the three months ended March 31, 2007 and 2006, respectively.

The following table summarizes restricted stock award activity for the three months ended March 31, 2007:

	<b>Shares</b>
Issued and unvested, January 1, 2007	807,054
Granted	343,655
Vested	(180,318)
Forfeited	(4,812)
<b>Issued and unvested, March 31, 2007</b>	<b>965,579</b>

As of March 31, 2007, there was \$7,284,697 of unrecognized compensation expense related to unvested restricted stock awards that is expected to be recognized over a weighted average period of 3.3 years.

In connection with the vesting of restricted shares during the three-month periods ended March 31, 2007 and 2006, 64,913 and 42,683 shares with aggregate values of \$539,219 and \$443,871, respectively, were withheld and retired in satisfaction of minimum tax withholding obligations.

**5. Accrued Expenses**

	March 31, 2007	December 31, 2006
Royalties	\$ 1,936,516	\$ 2,813,102
Payroll and related benefits	2,208,653	2,117,630
Deferred revenue	1,722,527	1,877,546
Advertising	709,445	201,509
Professional fees	446,201	681,850
License Fees	200,000	4,200,000
Laboratory testing fees	267,488	155,996
Income taxes	323,834	5,621
Other	907,581	605,895
	\$ 8,722,245	\$ 12,659,149

Accrued royalties at March 31, 2007 and December 31, 2006 were primarily related to our OraQuick<sup>®</sup> rapid HIV testing product. Deferred revenue at March 31, 2007 and December 31, 2006 consisted primarily of customer prepayments, totaling \$1,583,627 and \$1,727,546, respectively. Advertising accruals were primarily related to our cryosurgical products. The accrual for license fees decreased at March 31, 2007, as a result of \$4.0 million in payments made during the three months ended March 31, 2007. Accrued income taxes increased as a result of the current quarter's state and federal income tax provisions.

**6. Income Taxes**

In July 2006, the Financial Accounting Standards Board ( FASB ) issued FASB Interpretation ( FIN ) No. 48, Accounting for Uncertainty in Income Taxes an Interpretation of FASB Statement No. 109, which clarifies what criteria must be met prior to recognition of the financial statement benefit of a position taken in a tax return. FIN No. 48 also provides guidance on derecognition of tax benefits, classification on the balance sheet, interest and penalties, accounting in interim periods, disclosure and transition. The Company adopted FIN No. 48 effective January 1, 2007, and pursuant to its provisions, has decided to classify interest and penalties as a component of tax expense. As a result of the implementation of FIN No. 48, the Company recognized a \$58,142 increase in liability for unrecognized tax benefits, which was accounted for as a reduction to the January 1, 2007 balance of retained earnings.

The Company had unrecognized tax benefits of approximately \$2.4 million as of January 1, 2007, of which \$2.3 million if recognized, would result in a reduction of the Company's effective tax rate. The nature and potential magnitude of significant changes in unrecognized tax benefits that is reasonably possible within the twelve months following adoption of FIN No. 48 are immaterial to the Company's financial statements. Interest and penalties are immaterial at the date of adoption. As a result of its net operating loss carryforward position, the Company is subject to audit by the Internal Revenue Service for the years ended September 30, 1991 through December 31, 2006, as well as by several states, for the years ended December 31, 2000 through 2006.

**7. Geographic Information**

Based on guidance in SFAS No. 131, Disclosures about Segments of an Enterprise and Related Information, we believe we operate within one reportable 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, based on the location of the customer (amounts in thousands):

	<b>Three months</b>	
	<b>ended March 31,</b>	
	<b>2007</b>	<b>2006</b>
United States	\$ 16,232	\$ 12,481
Europe	2,507	2,337
Other regions	1,370	399
	\$ 20,109	\$ 15,217



**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, but are not limited to: ability to market and sell products; changes in relationships, including disputes or disagreements, with strategic partners and reliance on strategic partners for the performance of critical activities under collaborative arrangements; failure of distributors or other customers to meet purchase forecasts or minimum purchase requirements for the Company's products; impact of competitors, competing products and technology changes; ability to develop, commercialize and market new products; market acceptance of oral fluid testing or other products; changes in market acceptance of products based on product performance; continued bulk purchases by customers, including governmental agencies, and the ability to fully deploy those purchases in a timely manner; ability to fund research and development and other products 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 or products required for use of our products; ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; 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; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; ability to complete consolidation or restructuring activities; 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, 2006. 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**

We operate 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 medical devices 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 larger *in vitro* diagnostic market, and are used in 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 *ADVANCE*<sup>®</sup> rapid HIV-1/2 antibody test is designed for use at the point-of-care. Our cryosurgical products are 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 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. When combined with their ease of use, non-invasive and dignified nature, and cost effectiveness, our oral fluid tests represent a very competitive alternative to the more traditional testing methods in the diagnostic space.

During the three months ended March 31, 2007, our total revenues were \$20.1 million, which represents a 32.1% increase from the same period in 2006. Our net income for the first quarter of 2007 was \$1.5 million. Cash flow from operating activities declined by \$3.6 million when compared to the same period in 2006, primarily as a result of an increase in accounts receivable balances. As of March 31, 2007, we had \$86.5 million in cash, cash equivalents and short-term investments, which is lower than the balance as of December 31, 2006 primarily as a result of \$4.0 million in payments for patents and licenses during the quarter.

Sales into the infectious disease testing market increased significantly in the first three months of 2007 due to the continued market acceptance of our OraQuick *ADVANCE*<sup>®</sup> HIV-1/2 test. This increase resulted largely from sales directly to various public health organizations, sales through Abbott Laboratories, Inc. ( Abbott ) into the hospital market and government bulk purchases by the Substance Abuse and Mental Health Services Administration ( SAMHSA ) and the Centers for Disease Control and Prevention ( CDC ).

Abbott is our exclusive OraQuick *ADVANCE*<sup>®</sup> distributor in the U.S. hospital market and is a non-exclusive distributor of this product in the U.S. physicians office marketplace. As our exclusive distributor to hospitals, Abbott sells OraQuick *ADVANCE*<sup>®</sup> to federal hospitals under the terms and conditions of our Federal Supply Schedule that is on file 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. We utilize a small internal sales force to support Abbott and work together with them to maximize the penetration of OraQuick *ADVANCE*<sup>®</sup> in the hospital market. Abbott recently announced that it will sell part of its diagnostics business, including its rights to distribute OraQuick *ADVANCE*<sup>®</sup>, to General Electric ( GE ). This transaction is expected to close later in 2007, after which we will be able to meet with executives from GE to discuss their plans for the OraQuick *ADVANCE*<sup>®</sup> product.

Competition in the market for HIV testing is intense and is expected to increase. We believe that the principal competition will come from existing laboratory-based blood tests, point-of-care rapid blood tests, laboratory-based urine assays or other oral fluid-based tests that may be developed. Our competitors include specialized biotechnology firms, as well as pharmaceutical companies with biotechnology divisions and medical diagnostic companies.

Significant competitors for our OraQuick *ADVANCE*<sup>®</sup> rapid test, such as the Ortho Diagnostics division of Johnson & Johnson, Bio-Rad Laboratories, Abbott and bioMerieux, Inc. ( BMX ), sell laboratory-based HIV-1/2 assays, and Maxim Biomedical sells an HIV-1 screening test for urine, in the United States. MedMira and Trinity Biotech each sell competing rapid HIV-1 blood tests, and Bio-Rad Laboratories and Inverness Medical/Chembio sell competing rapid HIV-1/2 blood tests in the United States. These tests compete with our OraQuick *ADVANCE*<sup>®</sup> test in hospitals and other laboratory settings. In addition, Trinity Biotech and Inverness Medical/ Chembio have received waivers under the Clinical Laboratories Improvements Act of 1988 ( CLIA ) for their rapid HIV tests and these tests compete with our OraQuick *ADVANCE*<sup>®</sup> test in the 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 HIV tests, which would provide further competition for our OraQuick *ADVANCE*<sup>®</sup> test. We believe other companies may also seek FDA approval to sell competing rapid HIV tests in the future.

Sales to the substance abuse testing market also increased during the first quarter of 2007, reflecting the growing acceptance of our Intercept<sup>®</sup> collection device and related oral fluid drug assays, as both domestic and international

corporate customers continued to adopt oral fluid based drug testing and shift away from traditional urine-based drug testing. We expect continued growth in the utilization of our Intercept<sup>®</sup> product line, primarily in the United States.

Sales to the cryosurgical systems market increased during the three-month period ended March 31, 2007. The cryosurgical systems market represents sales of Histofreezer<sup>®</sup> into both the domestic and international physicians' office markets and sales of the over-the-counter (OTC) formulation of this product to our domestic distributor, Prestige Brands Holdings, Inc. (Prestige), and our international distributors, SSL International plc (SSL) and Genomma Laboratories (Genomma). Prestige distributes our cryosurgical wart removal product under its Compound W Freeze Off<sup>®</sup> tradenames in the OTC market in the United States and Canada. SSL distributes a similar product under its Scholl's and Dr. Scholl trademarks in the OTC footcare market in several European countries. Commencing in the first quarter of 2007, Genomma began distributing a similar product under the POINTTS<sup>®</sup> tradename in Mexico. Sales of our international OTC cryosurgical products increased by 70% in the three months ended March 31, 2007, compared to the same period in 2006.

In September 2006, Prestige announced that it had acquired the Wartner<sup>®</sup> cryosurgical wart removal product line, which directly competes with the Freeze Off<sup>®</sup> product in the United States and Canadian OTC markets. Our distribution agreement with Prestige contains a covenant not to compete which precludes Prestige from acquiring, manufacturing, distributing or selling a cryosurgical product that directly competes with the Freeze Off<sup>®</sup> product. We notified Prestige that its acquisition of the Wartner product constitutes a material breach of the distribution agreement and that certain of its other actions constitute additional breaches under the agreement. We initiated the alternative dispute resolution procedures required under the agreement, which include mediation and binding arbitration. The parties' efforts to resolve this matter through mediation were not successful and arbitration pursuant to the rules of the American Arbitration Association has been commenced, pursuant to the terms of the agreement. The parties are currently engaged in discovery, and hearings in the arbitration are scheduled to occur in August. In addition, our appeal to the New York Supreme Court of the denial of our request for a preliminary injunction against Prestige remains pending. We are evaluating alternative arrangements for distributing our OTC cryosurgical product in the event a resolution with Prestige cannot be reached. As a result of this ongoing dispute, it is not possible to predict at this time the potential impact this matter may have on sales of Freeze Off<sup>®</sup> in 2007 or beyond.

In July 2004, we filed a lawsuit against 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. Schol's Freeze Away<sup>®</sup> cryosurgical wart removal product in the OTC 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<sup>®</sup> device does not infringe our patents and that one or more of our patents are either invalid or unenforceable. On November 2, 2005, a pretrial conference was held in this matter, at which the Court heard oral argument on motions for summary judgment filed by the parties. These motions remain pending. We expect a new trial schedule to be set after the Court rules on these motions.

Sales to the insurance risk assessment market continued to decline in 2007, primarily because of a reduction in the number of applications for life insurance and changes in underwriting requirements. For higher face-value policies, it appears insurance companies are more likely to use a blood test for multiple risk factors, rather than an oral-fluid test. We currently expect that our 2007 revenues in this market will decline, or at best, remain at approximately the levels attained in 2006.

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 ADVANCE<sup>®</sup> test, our OraSure<sup>®</sup> 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 our sole source providers or if third parties do not continue to sell their related products, the time required to develop replacements and obtain the required FDA approvals could disrupt our ability to sell the affected products.

bioMérieux, Inc. (BMX) currently manufactures and sells the only oral fluid HIV-1 screening test that has received FDA approval for use in detecting HIV-1 in an oral fluid specimen collected with our OraSure<sup>®</sup> collection device. BMX also supplies the HIV-1 antigen used to manufacture our oral fluid Western blot HIV-1 confirmatory test and is the exclusive world-wide distributor of that product. BMX recently notified us that they intend to discontinue

manufacturing their HIV-1 screening test during 2007. BMX also notified us that it has elected not to renew the Western blot agreements beyond December 31, 2007.

We are working closely with BMX, the FDA and CDC, our main laboratory customers and other potential suppliers to find or develop an alternative HIV-1 screening test for use with our OraSure® collection device. Under our agreement with BMX, we have the right to purchase a two-year supply of HIV-1 antigen which, when combined with our existing inventory, should enable us to continue to manufacture and supply a sufficient amount of our oral fluid Western Blot test to meet demand for the next three to four years. If, however, our customers cannot obtain an HIV-1 screening test or a confirmatory test that has been approved by the FDA for use in connection with our OraSure® collection device, these customers would likely stop purchasing our OraSure® device and our revenues would be adversely affected.

We also rely heavily on distributors to purchase and resell many of our products. For example, Prestige has exclusive distribution rights to our cryosurgical product in the OTC markets in United States and Canada. SSL has exclusive rights in the OTC footcare market in Europe, Australia and New Zealand and Genomma has similar rights in the OTC market in Mexico. In addition, Abbott has exclusive rights to distribute our OraQuick ADVANCE® test to hospitals in the U.S. We expect to enter into additional distribution agreements, for new and future products, for distribution in the U.S. and internationally. If our distributors are unable or unwilling to meet the minimum purchase commitments set forth in their agreements, substantially reduce the volume of their purchases or fail to comply with their contractual obligations, our revenues and results of operations could be adversely affected.

During the three months ended March 31, 2007, we generated 81% of our revenues in the U.S. marketplace. We are continually evaluating strategies to increase our sales penetration in markets outside the U.S. As our business in foreign countries increases, we could be exposed to other economic, political, exchange rate, regulatory and cultural risks.

### **Results of Operations**

Total revenues increased 32.1% to \$20.1 million in the first quarter of 2007 from \$15.2 million in the comparable quarter in 2006, primarily as a result of increased sales of our OraQuick ADVANCE® rapid HIV-1/2 antibody test, our substance abuse testing products and our international OTC cryosurgical products, as well as an increase in licensing and product development revenues. These increases were partially offset by a continued decline in sales in the insurance risk assessment market. Revenues derived from products sold to customers outside the U.S. were \$3.9 million and \$2.7 million, or 19% and 18% of total revenues in the first quarters of 2007 and 2006, respectively.

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

	Three Months Ended March 31,				
	Dollars		% Change	Percentage of Total Revenues	
	2007	2006		2007	2006
<b>Market</b>					
Infectious disease testing	\$ 8,932	\$ 6,142	45%	45%	40%
Substance abuse testing	3,929	3,442	14	20	23
Cryosurgical systems	5,680	4,458	27	28	29
Insurance risk assessment	889	1,086	(18)	4	7
Product revenues	19,430	15,128	28	97	99
Licensing and product development	679	89	663	3	1
Total revenues	\$ 20,109	\$ 15,217	32%	100%	100%

Sales to the infectious disease testing market increased 45% to \$8.9 million in the first quarter of 2007, primarily as a result of the increasing strength of our OraQuick *ADVANCE*<sup>®</sup> rapid HIV-1/2 antibody test. OraQuick<sup>®</sup> sales totaled \$8.2 million and \$5.2 million in the first quarters of 2007 and 2006, respectively. Sales of our OraSure<sup>®</sup> oral fluid collection device totaled \$743,000 and \$946,000 in the first quarters of 2007 and 2006, respectively.

The table below shows a breakdown of our total OraQuick<sup>®</sup> revenues (in thousands, except %) during the first quarters of 2007 and 2006.

	Three Months Ended March 31,		
	2007	2006	% Change
<b>Customers</b>			
Direct to U.S. Public Health	\$ 4,342	\$ 2,897	50%
Abbott	2,151	1,482	45
SAMHSA	329	256	29
CDC	620		N/A
International	747	561	33
Total OraQuick <sup>®</sup> revenues	\$ 8,189	\$ 5,196	58%

We believe that our OraQuick *ADVANCE*<sup>®</sup> 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 is allowing us to more fully implement a strategy to sell OraQuick<sup>®</sup> internationally. Our Notified Body recently recommended CE mark approval for our OraQuick *ADVANCE*<sup>®</sup> test. A CE mark is required to sell this product in Europe. Once final CE mark approval is received, we intend to obtain several country-specific registrations to allow us to launch the product in Europe in the second half of 2007.

In previous periods, the CDC and SAMHSA have placed bulk purchase orders of OraQuick *ADVANCE*<sup>®</sup> devices and related testing materials. We believe that federal and other governmental agencies may make future bulk purchases of OraQuick *ADVANCE*<sup>®</sup> for further distribution to the public health and other markets throughout the United States. However, failure to receive, or any delays in receiving or deploying, additional bulk orders for OraQuick *ADVANCE*<sup>®</sup> from these governmental agencies could adversely affect our financial performance.

Although sales of OraQuick *ADVANCE*<sup>®</sup> are expected to increase, such sales may negatively impact sales of our OraSure<sup>®</sup> oral fluid collection device in the infectious disease testing market. Revenues from the OraSure<sup>®</sup> collection device declined by 21% in the first quarter of 2007 when compared to the same period of 2006. Customers who now or in the future may purchase our OraSure<sup>®</sup> device for HIV-1 testing may elect instead to

purchase our OraQuick *ADVANCE*<sup>®</sup> test. It is not possible at this time, however, to estimate the timing or extent of such change in purchasing patterns or the financial impact of replacing OraSure<sup>®</sup> sales with sales of our OraQuick *ADVANCE*<sup>®</sup> test.

Sales to the substance abuse testing market increased 14% to \$3.9 million in the first quarter of 2007, primarily as a result of increased sales of our Intercept<sup>®</sup> oral fluid drug testing service in the U.S. workplace and criminal justice markets and in the direct testing market.

The table below shows a breakdown of our total Intercept<sup>®</sup> revenues (in thousands, except %) generated in each market in the first quarters of 2007 and 2006.

<b>Market</b>	<b>Three Months Ended March 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>% Change</b>
Workplace testing	\$ 1,545	\$ 1,280	21%
Criminal justice	645	534	21
International	600	557	8
Direct	202	137	47
<b>Total Intercept<sup>®</sup> revenues</b>	<b>\$ 2,992</b>	<b>\$ 2,508</b>	<b>19%</b>

We expect continued growth in Intercept<sup>®</sup> sales in 2007 as customers continue to shift from urine to oral-fluid based testing methods. However, our microplate oral fluid drug assays, which are sold for use with the Intercept<sup>®</sup> collection device, are expected to come under increasing competitive pressure in the future from home-brew assays developed internally by our laboratory customers. In addition, our oral fluid microplate assays compete with urine-based homogeneous assays that are run on fully-automated, random access analyzers. We believe our competitors are developing oral fluid tests suitable for use on these fully automated homogeneous assay systems and these assays, if and when they are developed and commercialized, could represent a significant competitive threat to our oral fluid microplate business. In order to meet this competition, we signed a letter of intent to negotiate an agreement with Roche Diagnostics to jointly develop and commercialize fully-automated homogeneous oral fluid drugs of abuse assays for use with our Intercept<sup>®</sup> device. Development of the homogeneous assays is progressing while we negotiate the terms of a final agreement with Roche.

Sales of our products in the cryosurgical systems market (which includes both the physicians office and OTC markets) increased 27% to \$5.7 million in the first quarter of 2007. This increase was primarily the result of increased sales of our domestic and international OTC cryosurgical products, offset by a slight decline in sales of Histofreezer<sup>®</sup> to the domestic physicians office market.

The table below shows a breakdown of our total cryosurgical systems revenues (in thousands, except %) generated in each market in the first quarters of 2007 and 2006.

<b>Market</b>	<b>Three Months Ended March 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>% Change</b>
Professional domestic	\$ 1,053	\$ 1,089	(3)%
Professional international	467	371	26
OTC domestic	2,150	1,819	18
OTC international	2,010	1,180	70
<b>Total cyrosurgery revenues</b>	<b>\$ 5,680</b>	<b>\$ 4,458</b>	<b>27%</b>

During the three months ended March 31, 2007, we entered into an agreement with Genomma pursuant to which Genomma will distribute on an exclusive basis our cryosurgical wart removal product in the OTC market in Mexico. Sales to Genomma under this distribution agreement were \$503,000 in the first quarter of 2007. Sales to our European distributor, SSL, increased 28% to \$1.5 million during the first quarter of 2007 compared to 2006. Despite



our pending arbitration, we had \$2.2 million in sales to Prestige during the first quarter of 2007, an increase of \$300,000 when compared to the same period of 2006.

Sales of our Histofreezer<sup>®</sup> product to physicians' offices in the U.S. market declined by 3% in the first quarter of 2007 compared to the first quarter of 2006. We anticipate that U.S. sales of Histofreezer<sup>®</sup> in this market will remain at approximately the same levels as attained in 2006. Sales of Histofreezer<sup>®</sup> in the international physicians' office market increased by 26% to \$467,000, primarily as a result of increased sales in Mexico. Sales of professional and OTC cryosurgical products in the international markets are expected to increase above 2006 levels as a result of newly-established distributor relationships for these products in Latin American countries.

We are beginning to see some evidence that sales of our OTC cryosurgical products in the United States 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<sup>®</sup> product in the professional market. However, it is not possible at this time to estimate the magnitude of the financial impact of this change.

Sales to the insurance risk assessment market decreased 18% to \$889,000 in the first quarter of 2007 from \$1.1 million in the same period in 2006, primarily because of a reduction in the number of applications for life insurance and changes in underwriting requirements. For higher face-value policies, it appears insurance companies are more likely to use a blood test for multiple risk factors, rather than an oral fluid test. We currently expect that our 2007 revenues in this market will decline, or at best, remain at approximately the levels attained in 2006.

Licensing and product development revenues increased by \$590,000 to \$679,000 during the first quarter of 2007, from \$89,000 in the comparable period in 2006. In December 2006, the Company entered into a collaboration agreement with Schering-Plough Corporation, for the development and promotion of a rapid oral fluid test for the detection of antibodies to the hepatitis C virus ( HCV ). During the three months ended March 31, 2007, the Company recognized \$652,000 in revenues associated with funded research and development under this agreement. During the remaining nine months of 2007, the Company expects to recognize an additional \$1.3 million in licensing and product development revenues pursuant to this agreement.

Prestige accounted for 11% and 12% of total revenues for the first quarter of 2007 and 2006, respectively. Quest Diagnostics accounted for 10% of total revenues for the first quarter of 2007 and 2006, respectively. In the three months ended March 31, 2007, Abbott Laboratories accounted for 11% of total revenues, compared to 9% in the same period of 2006.

Gross margin in the first quarter of 2007 was 62%, compared to 63% for the first quarter of 2006. Gross margin was negatively affected by increased product support costs, partially offset by the benefit derived from increased license and product development revenues.

Research and development expenses increased 77% to \$2.9 million in the first quarter of 2007 from \$1.6 million in the same period in 2006, primarily as a result of costs associated with the clinical development of our OraQuick *ADVANCE*<sup>®</sup> HIV-1/2 OTC test and our OraQuick<sup>®</sup> HCV test, additional costs related to research personnel hired during 2006, and expenses associated with work to obtain FDA approval of new cryosurgical offerings. Research and development expenses are expected to increase in 2007, as compared to 2006, primarily as a result of ongoing costs associated with the development of our OraQuick *ADVANCE*<sup>®</sup> HIV-1/2 OTC test and our OraQuick<sup>®</sup> HCV test, as well as product registrations in foreign countries and development of fully-automated homogeneous oral fluid drugs of abuse assays.

Sales and marketing expenses increased 16% to \$4.8 million in the first quarter of 2007 from \$4.1 million in the same period in 2006. This increase was primarily the result of increases in reimbursable distributor advertising and promotion costs, as well as commissions, and salaries, benefits and recruiting expenses associated with incremental sales personnel, offset by lower costs associated with marketing research, print ads, consulting and stock-based compensation expense. Included in advertising expense was \$508,000 and \$187,000 for 2007 and 2006, respectively, as reimbursement for certain out-of-pocket advertising and promotion expenses incurred by our distributors, Prestige and SSL, for our cryosurgical products in the domestic and international OTC markets.



General and administrative expenses increased 43% to \$4.2 million in the first quarter of 2007 from \$3.0 million in the same period in 2006. This increase was primarily attributable to increased salaries and benefits expenses associated with new personnel, increased legal expenses associated with the Prestige arbitration, increased consulting costs associated with facilities planning and the implementation of a new enterprise resource planning system, and incremental depreciation expense resulting from the purchase of the Company's Bethlehem, Pennsylvania facilities in June 2006. Offsetting these increases was a decrease in rent expense associated with the Company's Bethlehem facilities, which were leased prior to their purchase. General and administrative expenses are expected to increase in subsequent quarters of 2007, primarily due to expected increases in legal costs associated with the Schering-Plough patent infringement litigation and Prestige arbitration.

Interest expense increased to \$166,000 in the first quarter of 2007 from \$18,000 in the same period of 2006, as a result of higher outstanding debt balances during the current period, resulting from the financing of the purchase of our Bethlehem facilities in June 2006. Interest income increased to \$1.1 million in the first quarter of 2007 from \$827,000 in the same period of 2006, as a result of higher yields on our investment portfolio and larger balances available for investment.

In January, 2007, the Company sold its ownership interest in a privately-held nonaffiliated company and recorded a \$1,428,691 pre-tax gain on the sale of this investment.

During the three months ended March 31, 2007, we recorded a provision for federal and state income taxes of \$1,499,000, which represents a \$722,000 increase over the \$777,000 income tax provision recorded in the same period of 2006. The increase in our income tax provision was the result of the corresponding increase in pre-tax income, primarily resulting from the \$1.4 million gain recorded in the current quarter. Our effective tax rate was 50% and 46% during the first quarter of 2007 and 2006, respectively. Our effective tax rate reflects the impact of permanent differences, generated by items which are not deductible on the Company's income tax returns, in relation to our current year's projected pre-tax income for financial statement purposes. Primarily as a result of the expected increases in research and development expenses during 2007, our pre-tax income for the current year is projected to be less than in the prior year, thereby increasing our effective tax rate during the current period.

**Liquidity and Capital Resources**

	March 31, 2007	December 31, 2006
	(In thousands)	
Cash and cash equivalents	\$ 16,778	\$ 19,950
Short-term investments	69,764	71,051
Working capital	100,186	95,979

Our cash, cash equivalents and short-term investments decreased \$4.5 million during the first quarter of 2007 to \$86.5 million at March 31, 2007, primarily as a result of the Company's \$4.0 million payment for patents and licenses, \$1.0 million in cash flow used to fund operations, the purchase of \$898,000 of property and equipment, and \$539,000 associated with the retirement of common stock to pay minimum tax withholding obligations on restricted shares that vested during the quarter. Offsetting these uses of funds were \$1.7 million in proceeds received from the sale of an investment in a nonaffiliated company and \$372,000 in cash received from the exercise of stock options during the quarter. At March 31, 2007, the Company's working capital was \$100.2 million.

Net cash used to fund operating activities was \$1.0 million in the first quarter of 2007. Sources of operating cash during the three months ended March 31, 2007 included net income of \$1.5 million, stock-based compensation of \$1.4 million, a deferred income tax provision of \$1.1 million resulting from utilization of our net operating loss carryforwards, depreciation and amortization of \$656,000, a provision for excess and obsolete inventories of \$165,000, a decrease of \$101,000 in prepaid expenses and other assets primarily related to the amortization of prepaid insurance and real estate taxes, and an increase of \$751,000 in accrued expenses, primarily related to accruals for advertising expenses and income taxes. Offsetting these sources of cash were a \$1.4 million gain on the sale of our investment in a non-affiliated company, a \$720,000 increase in inventories primarily related to increased demand in our cryosurgical and infectious disease product lines, and a \$4.5 million increase in accounts receivable, of which \$2.3 million represents an increase in outstanding balances due from Quest, Prestige, SSL and Abbott at March 31, 2007. Accounts receivable balances have increased in the current three-month period due to the intra-quarter distribution of revenues and an overall decrease in the timeliness of remittances by customers.

Net cash used in investing activities during the first quarter of 2007 was \$2.0 million. During this three month period, we paid \$4.0 million pursuant to certain patent and license agreements and purchased \$898,000 of property and equipment. We also received \$1.7 million from the sale of our investment in a nonaffiliated company and had \$1.2 million in net redemptions of investments during the quarter ended March 31, 2007. We expect additional capital expenditures of \$6.6 million during the remaining nine months of 2007 as we purchase additional information systems equipment, upgrade certain older equipment and make improvements to our facilities.

Net cash used in financing activities was \$202,000, reflecting \$35,000 of loan principal repayments and \$539,000 for the retirement of common stock, partially offset by proceeds of \$372,000 received from the exercise of stock options.

We have in place a \$26.9 million credit facility (the "Credit Facility") with Comerica Bank, which is comprised of an \$887,000 mortgage loan, a \$3.0 million term loan, a \$15.0 million facilities expansion advance, a \$4.0 million non-revolving line of credit for the purchase of both capital equipment and software, and a \$4.0 million revolving working capital line of credit. Interest on outstanding borrowings under the non-revolving line of credit accrues at a rate, selected at our option, equal to the bank's prime rate, 180-day or 360-day LIBOR plus 2.625%, or the 4-year Treasury Note rate plus 2.30%, determined at the time of initial borrowing. Interest on outstanding borrowings under the revolving working capital line of credit accrues at a rate, selected at our option, equal to the bank's prime rate less 0.25%, or 30-day LIBOR plus 2.55%, determined at the time of initial borrowing. Interest on outstanding borrowings under the facilities expansion advance is payable monthly at either a fixed rate equal to the five-year U.S. Treasury Note rate plus 1.03% to 1.73%, or a variable rate equal to the 30, 180, or 360-day LIBOR rate plus 0.55% to 1.25%. In each case, the interest rate is determined at the date of the advance and is based upon the amount of cash and cash equivalents we invest and retain at Comerica Securities, Inc. We can also choose the fixed rate option,

without penalty, at the expiration of a previously elected LIBOR period. Principal is repayable in periodic installments, based upon the rate option that we elect, with the remaining balance of unpaid principal due on June 27, 2011.

As of March 31, 2007, we had no outstanding borrowings under the \$3.0 million term loan, the \$4.0 million non-revolving line of credit, or the \$4.0 million revolving working capital line of credit, and have the ability to borrow \$5.0 million under the facilities expansion advance at any time before June 30, 2007.

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 three facilities in Bethlehem, Pennsylvania. Borrowings under the equipment and software non-revolving line and the revolving working capital line are limited to commercially standard percentages of equipment and software purchases and accounts receivable, respectively. The Credit Facility contains certain covenants that set forth minimum requirements for our quick ratio, liquidity and tangible net worth. We were in full compliance with all covenants at March 31, 2007 and expect to remain in compliance with all covenants throughout 2007. 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.

At December 31, 2006, we had NOL carryforwards of \$53.0 million for federal income tax purposes. The Company has completed an analysis to determine the annual limitation amount applicable to utilization of the NOL carryforwards due to past ownership changes, as defined in Section 382 of the Internal Revenue Code. As a result of this study, we do not believe that the ownership change limitations would impair our ability to use our NOLs against our current forecasted taxable income.

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 and capital needs for at least the next twelve months. However, our cash requirements may vary materially from those now planned due to many factors, including, but not limited to, the scope and timing of strategic acquisitions, the cost and timing of the expansion of our manufacturing capacity, the progress of our research and development programs, the scope and results of clinical testing, the magnitude of capital expenditures, changes in existing and potential relationships with business partners, the time and cost of obtaining regulatory approvals, the costs involved in obtaining and enforcing patents, proprietary rights and any necessary licenses, the cost and timing of expansion of sales and marketing activities, the timing of market launch of new products, market acceptance of new products, competing technological and market developments and other factors.

#### **Recent Accounting Pronouncements**

In September 2006, the FASB issued Statement of Financial Accounting Standards ( SFAS ) No. 157, Fair Value Measurements. This Statement defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. We are currently assessing the impact, if any, that SFAS No. 157 will have on our financial statements.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115. SFAS No. 159 permits entities to elect to measure many financial instruments and certain other items at fair value. Unrealized gains and losses on items for which the fair value option has been elected will be recognized in earnings at each subsequent reporting date. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. We are currently assessing the impact, if any, that SFAS No. 159 will have on our financial statements.

### **Summary of Contractual Obligations**

A summary of our obligations to make future payments under contracts existing at December 31, 2006 is included in Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations, of our Annual Report on Form 10-K for the year ended December 31, 2006. As of March 31, 2007, there were no significant changes to this information.

### **Critical Accounting Policies and Estimates**

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

Our significant accounting policies are described in Note 2 to the financial statements included in our 2006 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 SAB No. 104, Revenue Recognition. This bulletin draws on existing accounting rules and provides specific guidance on revenue recognition for 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 recognize this revenue ratably 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 \$244,818 at March 31, 2007. While credit losses have been within our expectations and the allowance provided, these losses, \$16,022, (\$4,771), and \$3,541 in 2006, 2005 and 2004, respectively, can vary from period to period. Furthermore, there is no assurance that we will experience credit losses at the same rates as we have in the past. Also, at March 31, 2007, \$6.8 million, or 46% of our accounts receivable, was due from four major customers. Any significant changes in the liquidity or financial position of these customers, or others, could have a material adverse impact on the collectibility of our accounts receivable and future operating results.

*Inventories.* Our inventories are valued at the lower of cost or market, determined on a first-in, first-out basis, and include the cost of raw materials, labor and overhead. The majority of our inventories are subject to expiration dating. We continually evaluate the carrying value of our inventories and when, in the opinion of management, factors indicate that impairment has occurred, either a reserve is established against the inventories' carrying value or the inventories are completely written off. We base these decisions on the level of inventories on hand in relation to our estimated forecast of product demand, production requirements over the next twelve months and the expiration dates of raw materials and finished goods. During 2006, 2005 and 2004, we wrote-off inventory which had a cost of \$751,000, \$2.1 million and \$839,000, respectively, as a result of scrap and product expiration issues and a \$1.3 million provision for loss on our UPlink® product in 2005. 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.

*Stock-based Compensation.* Commencing January 1, 2006, we adopted SFAS No. 123 (revised 2004), Share-Based Payment, which requires us to recognize the fair value of equity-based awards as compensation expense in our statement of operations. The fair value of our stock option awards was estimated using a Black-Scholes option valuation model. This valuation model incorporates highly subjective assumptions, such as the expected stock price volatility and the estimated life of each award, in the model's computations. The fair value of awards, after considering the effect of expected forfeitures, is then amortized, generally on a straight-line basis, over the related vesting period of the award.

*Long-lived and Intangible Assets.* Our long-lived assets are comprised of property and equipment and our intangible assets primarily consist of patents and product rights. Together, these assets have a net book value of \$24.1 million, or 15.4% of our total assets, at March 31, 2007. Property and equipment, patents and product rights are depreciated or 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. At March 31, 2007, we have recorded a \$4.5 million intangible asset related to payments under a license agreement to certain patents related to the Hepatitis C Virus. Management's intent in executing this license is to provide for various alternatives for use, including uses in the international market that would not require additional research and development efforts or regulatory approvals. This \$4.5 million asset was capitalized based on management's estimate of the cash flows to be received from future product sales in these international markets. A similar analysis of estimated future cash flows will be prepared upon payment of additional license fees under this agreement, or upon changes in circumstances, to determine the appropriate accounting treatment for payments under this license agreement. 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 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 overall business strategy, significant negative industry or economic trends, shortening of product life-cycles or changes in technology. 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. In June 2005, we recorded a \$196,000 provision for loss on our UPlink® 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 March 31, 2007. Any unanticipated significant impairment in the future, however, could have a material adverse impact to our balance sheet and future operating results.

*Deferred Tax Assets.* At December 31, 2006, we had federal NOL carryforwards of \$53.0 million. The net deferred tax asset associated with these NOLs and other temporary differences was \$23.5 million at December 31, 2006. 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 or the NOLs and credit carryforwards can be utilized. We consider the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in making this assessment.

Our ability to use our NOL carryforwards to offset future federal income tax obligations could be limited by changes in the ownership of our stock. Internal Revenue Code ( IRC ) Section 382 contains provisions that limit the amount of federal NOL carryforwards that can be used in any given year in the event of specified occurrences, including significant ownership changes. The Company has completed an analysis to determine if any IRC Section 382 ownership changes have occurred that would limit the amount of NOLs that could be utilized to offset future taxable income. As a result of this analysis, the Company concluded that prior ownership changes may impose a limitation on the amount of NOLs that can be utilized in a given year. The Company does not believe, however, that this limitation will impair our future ability to utilize NOLs to offset our forecasted taxable income or to realize the related deferred tax asset.

We have begun providing for income taxes at a rate equal to our combined federal and state effective rates. 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 derivative risk to report under this Item.

A significant portion of our assets is comprised of certificates of deposit, commercial paper, U.S. government and agency obligations, and U.S. corporate bonds. All such instruments are classified as available-for-sale securities. The primary objective of our investment activities is to preserve principal while maximizing the related income without significantly increasing risk. Even so, some of the securities in which we invest may be subject to market risk. Market risk is the risk that a change in prevailing interest rates may cause the fair value of an investment to fluctuate.

As interest rates increase, the fair value of a debt instrument would be expected to decrease. Correspondingly, if interest rates decrease the fair value of a debt instrument would be expected to increase. To minimize market risk, we have the ability to hold such debt instruments to maturity, at which time the debt instrument would be redeemed at its stated or face value. We also typically invest in the shorter end of the maturity spectrum. As such, we do not believe that we have a material exposure to market risk.

At March 31, 2007, approximately \$10.5 million of the Company's long-term debt bore interest at a variable or floating rate tied to either the United States prime rate or the London Interbank Offered Rate. A one percentage point increase in these interest rates would have cost the Company approximately \$105,000 in additional interest expense.

As of March 31, 2007, we did not have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. We have operations in The Netherlands, which are subject to foreign currency fluctuations. As currency rates change, translation of revenues and expenses for these operations from euros to U.S. dollars affects year-to-year comparability of operating results. Sales denominated in a foreign currency represented approximately \$25,000 of our total revenues for the three months ended March 31, 2007. We do not expect the risk of foreign currency fluctuations to be material in the near future.

#### **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 March 31, 2007. 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.* During 2006, the Company purchased and installed a new Enterprise Resource Planning System ( ERP ), which became fully operational on January 1, 2007. An ERP is a fully-automated set of programs and databases that incorporate order processing, production planning and scheduling, purchasing, accounts receivable and inventory management and accounting. During the three months ended March 31, 2007, the Company updated certain of its internal controls over financial reporting to reflect changes to its business processes resulting from the ERP implementation. The Company is continuing to evaluate the impact of the ERP on certain of its internal controls and expects the ERP to further advance its control environment by automating manual functions and standardizing the Company's business processes. Except as described above, there was no change in the Company's internal control over financial reporting during the three months ended March 31, 2007 that was 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**

##### *Prestige Brands Dispute*

An arbitration panel has been appointed in our pending arbitration with Prestige with respect to Prestige's acquisition of the Wartne<sup>®</sup> cryosurgical product line in violation of a covenant not to compete in our agreement with Prestige. The parties are currently engaged in discovery, and hearings in the arbitration are scheduled to occur in late August,

after which the arbitration panel is expected to issue a decision in this matter. The arbitrators' decision will be final and binding on the parties and not subject to appeal.

**Item 1A. RISK FACTORS.**

There have been no material changes to the factors disclosed in Item 1A., entitled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2006.

**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.

Date: May 10, 2007

*/s/ Ronald H. Spair*

Ronald H. Spair

Chief Operating Officer and

Chief Financial Officer

*(Principal Financial Officer)*

Date: May 10, 2007

*/s/ Mark L. Kuna*

Mark L. Kuna

Senior Vice President, Finance and Controller

*(Principal Accounting Officer)*

**EXHIBIT INDEX**

**Exhibit**

- 10.1 Amendment No. 1 to Distribution Agreement, dated as of January 1, 2007, among OraSure Technologies, Inc. and SSL International plc.\*
- 10.3 Description of 2007 Management Incentive Plan is incorporated by reference to Item 5.02 to the Company's Current Report on Form 8-K filed February 8, 2007.\*\*
- 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.

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\* 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.