

ORASURE TECHNOLOGIES INC  
Form 10-Q  
May 10, 2006  
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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, 2006.

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

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**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)

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

**36-4370966**  
(IRS Employer

Identification No.)

**18015**  
(Zip code)

**(610) 882-1820**

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(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, 2006: 45,894,473

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**Table of Contents****Item 1. FINANCIAL STATEMENTS****ORASURE TECHNOLOGIES, INC.****BALANCE SHEETS****(Unaudited)**

	March 31, 2006	December 31, 2005
<b>ASSETS</b>		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 29,891,206	\$ 32,826,740
Short-term investments	49,069,951	44,793,046
Accounts receivable, net of allowance for doubtful accounts of \$288,321 and \$278,066	9,804,099	11,602,127
Inventories	4,659,101	4,128,029
Deferred income taxes	6,503,946	6,503,946
Prepaid expenses and other	1,928,766	1,553,545
Total current assets	101,857,069	101,407,433
PROPERTY AND EQUIPMENT, net	6,241,805	5,815,233
PATENTS AND PRODUCT RIGHTS, net	2,745,693	2,879,958
DEFERRED INCOME TAXES	19,546,180	20,204,352
OTHER ASSETS	367,730	440,227
	\$ 130,758,477	\$ 130,747,203
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
CURRENT LIABILITIES:		
Current portion of long-term debt	\$ 212,451	\$ 456,541
Accounts payable	2,670,681	2,546,621
Accrued expenses and other	5,843,089	7,733,941
Total current liabilities	8,726,221	10,737,103
LONG-TERM DEBT	850,688	884,021
OTHER LIABILITIES	298,559	207,037
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, 45,890,638 and 45,775,625 shares issued and outstanding	46	46
Additional paid-in capital	223,959,403	226,218,469
Deferred compensation		(3,334,792)
Accumulated other comprehensive loss	(294,223)	(282,825)
Accumulated deficit	(102,782,217)	(103,681,856)
Total stockholders equity	120,883,009	118,919,042

\$ 130,758,477      \$ 130,747,203

The accompanying notes are an integral part of these statements.

**Table of Contents****ORASURE TECHNOLOGIES, INC.****STATEMENTS OF OPERATIONS****(Unaudited)**

	<b>Three Months Ended March 31,</b>	
	<b>2006</b>	<b>2005</b>
<b>REVENUES:</b>		
Product	\$ 15,128,078	\$ 15,743,975
Licensing and product development	89,247	84,314
	15,217,325	15,828,289
<b>COST OF PRODUCTS SOLD</b>	<b>5,617,992</b>	<b>6,370,622</b>
Gross profit	9,599,333	9,457,667
<b>OPERATING EXPENSES:</b>		
Research and development	1,648,766	1,198,534
Sales and marketing	4,106,565	3,867,479
General and administrative	2,957,654	3,176,581
	8,712,985	8,242,594
Operating income	886,348	1,215,073
<b>INTEREST EXPENSE</b>	<b>(17,816)</b>	<b>(27,324)</b>
<b>INTEREST INCOME</b>	<b>826,635</b>	<b>372,481</b>
<b>FOREIGN CURRENCY GAIN (LOSS)</b>	<b>(18,253)</b>	<b>1,108</b>
Income before income taxes	1,676,914	1,561,338
<b>INCOME TAX PROVISION</b>	<b>777,275</b>	
NET INCOME	\$ 899,639	\$ 1,561,338
<b>BASIC AND DILUTED EARNINGS PER SHARE</b>	<b>\$ 0.02</b>	<b>\$ 0.03</b>
<b>SHARES USED IN COMPUTING EARNINGS PER SHARE:</b>		
<b>BASIC</b>	<b>45,839,732</b>	<b>44,644,729</b>
<b>DILUTED</b>	<b>48,066,154</b>	<b>45,045,555</b>

The accompanying notes are an integral part of these statements.

**Table of Contents****ORASURE TECHNOLOGIES, INC.****STATEMENTS OF CASH FLOWS****(Unaudited)**

	<b>Three Months Ended March 31,</b>	
	<b>2006</b>	<b>2005</b>
<b>OPERATING ACTIVITIES:</b>		
Net income	\$ 899,639	\$ 1,561,338
Adjustments to reconcile net income to net cash provided by operating activities:		
Stock-based compensation cost	1,440,990	433,422
Deferred income taxes	658,172	
Depreciation and amortization	446,811	630,514
Provision for excess and obsolete inventories	147,725	289,165
Changes in assets and liabilities:		
Accounts receivable	1,805,718	(1,668,288)
Inventories	(678,761)	(140,819)
Prepaid expenses and other assets	(302,353)	23,247
Accounts payable, accrued expenses, and other liabilities	(1,848,664)	(607,832)
<b>Net cash provided by operating activities</b>	<b>2,569,277</b>	<b>520,747</b>
<b>INVESTING ACTIVITIES:</b>		
Purchases of short-term investments	(17,718,483)	(12,937,323)
Proceeds from maturities and redemptions of short-term investments	13,425,404	17,199,281
Purchases of property and equipment	(664,756)	(152,229)
<b>Net cash provided by (used in) investing activities</b>	<b>(4,957,835)</b>	<b>4,109,729</b>
<b>FINANCING ACTIVITIES:</b>		
Repayments of long-term debt	(277,423)	(280,203)
Proceeds from issuance of common stock	173,764	38,827
Withholding and retirement of common stock	(443,871)	(19,975)
<b>Net cash used in financing activities</b>	<b>(547,530)</b>	<b>(261,351)</b>
<b>EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH</b>	<b>554</b>	<b>(8,060)</b>
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>(2,935,534)</b>	<b>4,361,065</b>
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD</b>	<b>32,826,740</b>	<b>10,121,208</b>
<b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>	<b>\$ 29,891,206</b>	<b>\$ 14,482,273</b>

The accompanying notes are an integral part of these statements.

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**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, and Europe.

**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, 2005. Results of operations for the three-month period ended March 31, 2006 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, 2006 and December 31, 2005, 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 and agency obligations, state and local government 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, 2006 and December 31, 2005:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
<b>March 31, 2006</b>				
Certificates of deposit	\$ 8,589,000	\$	\$ (335)	\$ 8,588,665
Commercial paper	2,203,380	46,620		2,250,000
Government and agency bonds	14,562,349		(49,850)	14,512,499
Corporate bonds	23,802,462		(83,675)	23,718,787
<b>Total available-for-sale securities</b>	<b>\$ 49,157,191</b>	<b>\$ 46,620</b>	<b>\$ (133,860)</b>	<b>\$ 49,069,951</b>
<b>December 31, 2005</b>				
Certificates of deposit	\$ 10,385,000	\$	\$ (464)	\$ 10,384,536
Commercial paper	1,984,999		(1,059)	1,983,940
Government and agency bonds	18,544,871		(43,851)	18,501,020
State and local government agency obligations	75,000			75,000
Corporate bonds	13,874,242	1,261	(26,953)	13,848,550
<b>Total available-for-sale securities</b>	<b>\$ 44,864,112</b>	<b>\$ 1,261</b>	<b>\$ (72,327)</b>	<b>\$ 44,793,046</b>
At March 31, 2006, maturities of investments were as follows:				
Less than one year	\$ 44,001,458	\$ 46,620	\$ (109,218)	\$ 43,938,860
1 2 years	5,155,733		(24,642)	5,131,091
<b>Total available-for-sale securities</b>	<b>\$ 49,157,191</b>	<b>\$ 46,620</b>	<b>\$ (133,860)</b>	<b>\$ 49,069,951</b>

**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, 2006	December 31, 2005
Raw materials	\$ 2,937,980	\$ 2,625,889
Work-in-process	650,184	718,804
Finished goods	1,070,937	783,336
	\$ 4,659,101	\$ 4,128,029

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

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

**Significant Customer Concentration.** In the first quarter of 2006, Prestige Brands Holdings, Inc. accounted for 12 percent of total revenues as compared to 25 percent for the same quarter of 2005. This same customer accounted for 19 percent and 15 percent of accounts receivable as of March 31, 2006 and December 31, 2005, respectively.



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In the first quarter of 2006 and 2005, Quest Diagnostics (including its wholly-owned subsidiary, LabOne, Inc.) accounted for 10 percent and 11 percent of total revenues, respectively. This customer accounted for 10 percent and 8 percent of accounts receivable as of March 31, 2006 and December 31, 2005, respectively.

Additionally, SSL International plc accounted for 13 percent and 20 percent of accounts receivable as of March 31, 2006 and December 31, 2005, respectively.

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

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

	Three Months Ended	
	March 31,	
	2006	2005
Net income	\$ 899,639	\$ 1,561,338
Weighted average shares of common stock outstanding:		
Basic	45,839,732	44,644,729
Dilutive effect of stock options, warrants and restricted shares	2,226,422	400,826
Diluted	48,066,154	45,045,555
Earnings per share:		
Basic	\$ 0.02	\$ 0.03
Diluted	\$ 0.02	\$ 0.03

For the three-month periods ended March 31, 2006 and March 31, 2005, outstanding common stock options, warrants, and unvested restricted stock, representing 322,960 and 3,306,089 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, 2006 and December 31, 2005 consisted of currency translation adjustments and net unrealized gains or losses on marketable securities.



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### **3. 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.

Under the terms of the 2000 Plan, qualified incentive stock options for shares of our common stock may be granted to eligible employees, including our officers. To date, options generally have been granted with ten-year exercise periods and an exercise price not less than the fair market value on the date of grant. Options generally vest over four years, with one quarter of the options vesting one year after grant and the remainder vesting on a monthly basis over the next three years. The 2000 Plan also provides that nonqualified options may be granted at a price not less than 75 percent of the fair market value of a share of common stock on the date of grant. The option term and vesting schedule of such awards may either be unlimited or have a specified period in which to vest and be exercised.

Prior to 2006, we accounted 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 ( APB 25 ), and related interpretations. Under APB 25, no stock-based compensation expense was recognized on stock options granted to employees or directors, as the exercise price was equal to the market price of our stock on the date of grant. We account for stock-based compensation to nonemployees using the fair value method in accordance with SFAS No. 123 (revised), Share-Based Payment ( SFAS No. 123R ), 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.

Effective January 1, 2006, we adopted SFAS No. 123R, which eliminated the ability to account for stock-based compensation under APB 25 and requires us to recognize compensation expense based on the fair value of our stock-based awards. We elected the modified prospective transition method as permitted by SFAS No. 123R. Accordingly, results from prior periods have not been restated. Under this transition method, stock-based compensation expense for the three months ended March 31, 2006 includes:

- (a) compensation expense for all stock-based awards granted prior to January 1, 2006, but not yet vested, based on the grant date fair value previously estimated in accordance with the original provisions of SFAS No. 123, Accounting for Stock- Based Compensation ( SFAS No. 123 ), and
- (b) compensation expense for all stock-based awards granted, modified or settled subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123R.

Upon the adoption of SFAS No. 123R, our deferred compensation balance of \$3,334,792 was reclassified against additional paid-in capital. Consistent with our past practice under the disclosure requirements of SFAS No. 123, we have elected to 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.

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Pursuant to the disclosure requirements of SFAS No. 123, the table below illustrates the effect on net income and earnings per share had compensation expense for our stock-based awards been determined based upon the fair value of the awards at the date of grant for the three-month period ended March 31, 2005:

	<b>Three months ended March 31,</b>	
	<b>2005</b>	
Net income:		
As reported	\$	1,561,338
Add: stock-based employee compensation expense included in net income		433,422
Deduct: total stock-based employee compensation expense determined under the fair value-based method for all awards		(1,301,018)
Pro forma	\$	693,742
Basic and diluted earnings per share:		
As reported	\$	0.03
Pro forma	\$	0.02

The fair value of each stock option was 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, 2006 and 2005, was \$5.06 and \$2.68, respectively.

	<b>Three Months Ended March 31,</b>	
	<b>March 31, 2006</b>	<b>2005</b>
<b>Black-Scholes Option Valuation Assumptions</b>		
Risk-free interest rate <sup>(1)</sup>	4.31%	3.58%
Expected dividend yield		
Expected stock price volatility <sup>(2)</sup>	56%	58%
Expected life of stock options (in years) <sup>(3)</sup>	5	4

<sup>(1)</sup> Based on the Treasury Securities constant maturity interest rate whose term is consistent with the expected life of our stock options.

<sup>(2)</sup> Expected stock price volatility is based on historical experience.

<sup>(3)</sup> Expected life of stock options is based upon historical experience.

Total compensation cost related to stock options for the three months ended March 31, 2006 and 2005, was \$921,166 (\$715,610, net of tax) and \$0, respectively, of which \$101,859 was capitalized into inventory during the quarter ended March 31, 2006.

The aggregate intrinsic value of options (the amount by which the market price of the stock on the date of exercise exceeded the market price of the stock on the date of grant) exercised during the three months ended March 31, 2006 and 2005 was \$127,127 and \$41,944, respectively.

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The following table summarizes the stock option activity for the three months ended March 31, 2006:

	Options	Weighted- Average Exercise Price Per Share	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding on January 1, 2006	4,216,785	\$ 7.08		
Granted	463,127	9.59		
Exercised	(28,337)	6.13		
Cancelled	(10,663)	9.19		
<b>Outstanding on March 31, 2006</b>	<b>4,640,912</b>	<b>\$ 7.33</b>	<b>8.19</b>	<b>\$ 13,812,050</b>
Vested or expected to be vested at March 31, 2006	4,397,874	\$ 7.33	8.19	\$ 13,269,969
<b>Exercisable on March 31, 2006</b>	<b>3,020,661</b>	<b>\$ 6.93</b>	<b>7.90</b>	<b>\$ 10,198,174</b>

As of March 31, 2006, there was \$6,395,538 of unrecognized compensation expense related to unvested option awards that is expected to be recognized over a weighted average period of 1.7 years.

Net cash proceeds from the exercise of stock options were \$173,764 and \$38,827 for the three months ended March 31, 2006 and 2005, 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, 2006, we granted 330,313 restricted shares of our common stock, with a grant date fair value of \$9.56, 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 \$513,050 and \$433,422 related to these and previous grants was recognized during the three months ended March 31, 2006 and 2005, respectively.

The following table summarizes restricted stock award activity for the three months ended March 31, 2006:

	Shares	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Issued and unvested, January 1, 2006	606,445		
Granted	330,313		
Vested	(129,359)		
Cancelled			
<b>Issued and unvested, March 31, 2006</b>	<b>807,399</b>	<b>4.11</b>	<b>\$ 1,778,268</b>
Issued and expected to vest, March 31, 2006	801,931	4.11	\$ 1,765,530

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As of March 31, 2006, there was \$5,979,534 of unrecognized compensation expense related to unvested restricted stock awards that is expected to be recognized over a weighted average period of 4.1 years.

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In connection with the vesting of restricted shares during the three-month periods ended March 31, 2006 and 2005, 42,683 and 3,052 shares with aggregate values of \$443,871 and \$19,975, respectively, were withheld and retired in satisfaction of minimum tax withholding obligations.

**4. Accrued Expenses:**

	March 31, 2006	December 31, 2005
Royalties	\$ 1,542,863	\$ 1,925,679
Payroll and related benefits	1,068,822	2,510,240
Deferred revenue	1,014,508	1,302,791
Advertising	944,925	757,906
Professional fees	364,990	487,712
Laboratory testing fees	228,216	210,604
Other	678,765	539,009
	\$ 5,843,089	\$ 7,733,941

Accrued royalties at March 31, 2006 and December 31, 2005 are primarily related to our OraQuick® rapid HIV testing product. At March 31, 2006, accrued payroll and related benefits decreased primarily as a result of the payment of annual bonuses during the first quarter. Deferred revenue at March 31, 2006 and December 31, 2005 consisted primarily of customer prepayments, totaling \$679,608 and \$1,012,891, respectively. Advertising accruals at March 31, 2006 and December 31, 2005 are primarily related to the Freeze Off product.

**5. 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):

	Three months ended	
	March 31, 2006	2005
United States	\$ 12,481	\$ 14,140
Europe	2,337	1,313
Other regions	399	375
	\$ 15,217	\$ 15,828

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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 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; 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 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 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, 2005. 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-1/2 antibody test is designed for use at the point-of-care. Our cryosurgical products are also used at the point-of care.

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

During the first quarter of 2006, our total revenues were \$15.2 million, a decrease of 4% over the comparable period in 2005, and our net income was \$900,000, representing a decrease of \$662,000 over the first quarter of 2005. Net income during 2006 includes \$819,000 pre-tax related to the expensing of stock options as well as a provision for income taxes of \$777,000. Neither expenses related to stock options nor a provision for income taxes was recorded in the comparable period in 2005. Our liquidity improved for the quarter, as we reported \$2.6 million in cash flow from operations during the first quarter of 2006 compared to \$521,000 for the first quarter of 2005, and we had \$79.0 million in cash, cash equivalents, and short-term investments as of March 31, 2006.

Sales into the infectious disease testing market during the first quarter of 2006 increased due to the continued market acceptance of our OraQuick® device. This resulted largely from sales directly to various public health organizations and sales through Abbott Laboratories into the hospital market.

In February 2005, we entered into an 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 sells 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 Centers for Disease Control and Prevention ( CDC ), the Substance Abuse and Mental Health Services Administration ( 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* 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® *ADVANCE* test. For example, the Ortho Diagnostics division of Johnson & Johnson, Bio-Rad Laboratories, Abbott, and bioMérieux Inc., each sell competing laboratory-based HIV-1 enzyme immunoassays, and Maximum Biomedical (formerly Calypte, Inc.) sells an HIV-1 screening test for urine, in the United States. In addition, MedMira and Trinity Biotech have each received FDA approval to sell competing rapid HIV-1 blood tests and Bio-Rad Laboratories received FDA approval for a rapid HIV-1/2 blood test. Under their current FDA approvals, these tests compete with our OraQuick® *ADVANCE* test in the hospital or other laboratory settings. In addition, Trinity Biotech has received CLIA (Clinical Laboratory Improvement Amendments of 1988) waiver for its rapid finger stick HIV-1 blood test, and this test competes with our OraQuick® *ADVANCE* test in markets outside of the traditional hospital and laboratory settings. In addition, ChemBio is seeking FDA approval of a rapid HIV blood test. 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® *ADVANCE* test.

Sales to the substance abuse testing market also increased during the first quarter of 2006, reflecting the growing acceptance of our Intercept® collection device and related oral fluid drug assays, as both corporate and international 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 our Intercept® drugs of abuse test. We are unable to predict at this time whether additional modifications may be required to bring our Intercept® drug testing system 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.

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Sales to the cryosurgical systems market declined during the first quarter of 2006. 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 distributor, SSL International plc (SSL). Prestige distributes Freeze Off to consumers under its Compound W trademark in the OTC market in the United States and Canada. SSL distributes the Company's cryosurgical wart removal product, under its Scholl's and Dr. Scholl trademarks, in the OTC footcare market in several European countries. The product is also expected to be made available by SSL for retail purchase in other European countries, Australia and New Zealand during 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 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 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. We expect the Court to rule on these and other motions and to set a new trial schedule in the near future.

Sales to the insurance risk assessment market continued to decline in the first quarter of 2006, primarily as a result of a reduction in the number of applications for life insurance and an increase in the average policy amount. Insurance companies are more likely to use a blood test to test for multiple risk factors rather than oral fluid for higher face value policies. Revenues from this market are expected to continue to decline or at best remain at approximately the same levels attained in 2005 unless we are successful in increasing our penetration of this market or developing new oral fluid based diagnostic tests for additional predictive health markers desired by the insurance industry.

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<sup>®</sup> ADVANCE 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 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<sup>®</sup> oral fluid collection device, as our customers are not expected to purchase OraSure<sup>®</sup> 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<sup>®</sup> collection device, which is manufactured by a third party, is either unavailable or experiences quality or performance problems, sales of our OraSure<sup>®</sup> device could be adversely affected.

## **Results of Operations**

Total revenues decreased 4% to \$15.2 million in the first quarter of 2006 from \$15.8 million in the comparable quarter in 2005, primarily as a result of lower sales of our OTC and professional cryosurgical products and a continued decline in sales in the insurance risk assessment market. These decreases were partially offset by increased sales of our OraQuick<sup>®</sup> ADVANCE rapid HIV-1/2 antibody test and our substance abuse testing products. Revenues derived from products sold to customers outside the U.S. were \$2.7 million and \$1.7 million, or 18% and 11% of total revenues in the first quarters of 2006 and 2005, respectively.

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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.

<b>Market</b>	<b>Three Months Ended March 31,</b>				
	<b>Dollars</b>		<b>%</b>	<b>Percentage of</b>	
	<b>2006</b>	<b>2005</b>	<b>Change</b>	<b>Total Revenues 2006</b>	<b>2005</b>
Infectious disease testing	\$ 6,142	\$ 5,126	20%	40%	32%
Substance abuse testing	3,442	2,925	18	23	19
Cryosurgical systems	4,458	5,578	(20)	29	35
Insurance risk assessment	1,086	2,115	(49)	7	13
<b>Product revenues</b>	<b>15,128</b>	<b>15,744</b>	<b>(4)</b>	<b>99</b>	<b>99</b>
Licensing and product development	89	84	6	1	1
<b>Total revenues</b>	<b>\$ 15,217</b>	<b>\$ 15,828</b>	<b>(4)%</b>	<b>100%</b>	<b>100%</b>

Sales to the infectious disease testing market increased 20% to \$6.1 million in the first quarter of 2006, primarily as a result of the increasing strength of our OraQuick® *ADVANCE* rapid HIV-1/2 antibody test. OraQuick® sales totaled \$5.2 million and \$4.0 million in the first quarters of 2006 and 2005, respectively. OraSure® sales totaled \$946,000 and \$1.1 million in the first quarters of 2006 and 2005, respectively.

The table below shows a breakdown of our total OraQuick® revenues (in thousands, except %) during the first quarter of 2006 and 2005.

<b>Customers</b>	<b>Three Months Ended March 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>% Change</b>
Direct to U.S. Public Health	\$ 2,897	\$ 1,579	83%
Abbott	1,482	682	117
SAMHSA	256		n/a
CDC		836	(100)
International	561	343	64
Direct to Hospitals		531	(100)
<b>Total OraQuick® revenues</b>	<b>\$ 5,196</b>	<b>\$ 3,971</b>	<b>31%</b>

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 is allowing 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 next several months, and obtain several country-specific registrations thereafter allowing us to launch the product in Europe in the second half of 2006.

In previous periods, the CDC and SAMHSA have placed bulk purchase orders of OraQuick® *ADVANCE* devices and related testing materials. We expect that federal and other governmental agencies will make future bulk purchases of OraQuick® *ADVANCE* 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* from these governmental agencies could adversely affect our financial performance.

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Although sales of OraQuick® *ADVANCE* are expected to increase, such sales may negatively impact sales of our OraSur® 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® *ADVANCE* test. It is not possible at this time, however, to estimate the timing or extent of such change in purchasing patterns or the financial impact of replacing OraSure® sales with sales of our OraQuick® *ADVANCE* test.

Sales to the substance abuse testing market increased 18% to \$3.4 million in the first quarter of 2006, primarily as a result of increased sales of our Intercept® oral fluid drug testing service in the U.S. workplace, criminal justice, and international testing markets.

The table below shows a breakdown of our total Intercept® revenues (in thousands, except %) generated in each market in the first quarter of 2006 and 2005.

<u>Market</u>	<b>Three Months Ended March 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>% Change</b>
Workplace testing	\$ 1,280	\$ 1,091	17%
Criminal justice	534	392	36
International	557	387	44
Direct	137	100	37
<b>Total Intercept® revenues</b>	<b>\$ 2,508</b>	<b>\$ 1,970</b>	<b>27%</b>

Sales of our products in the cryosurgical systems market (which includes both the physicians' office and OTC markets) decreased 20% to \$4.5 million in the first quarter of 2006. This decrease was primarily the result of lower sales of our domestic OTC cryosurgical product, called Freeze Off®, to Prestige, the owner of the Compound W® line of wart removal products. Sales of Freeze Off® to Prestige were \$1.8 million in the first quarter of 2006 compared to \$4.0 million during the first quarter of 2005. This reduction was due to the absence of an inventory buildup by Prestige that occurred during the first quarter of 2005 in anticipation of a special promotional event by one of Prestige's largest customers.

In June 2005, we entered into an agreement with SSL under which we manufacture and supply, and SSL distributes on an exclusive basis, the Company's cryosurgical wart removal product in the OTC footcare market in Europe, Australia and New Zealand. The product is manufactured and sold under SSL's Scholl and Dr. Scholl trademarks, and was made initially available for retail purchase in pharmacies and retail outlets in several European countries during the fourth quarter of 2005. Sales to SSL under the distribution agreement were \$1.2 million in the first quarter of 2006. SSL continues to build distribution networks in pharmacies and mass merchandisers throughout Europe and expects to launch the OTC product in several countries during 2006. We expect domestic and international sales of OTC cryosurgical products to our distributors to approximate \$2.8 million in the second quarter of 2006.

Sales of our Histofreezer® product to physicians' offices in the U.S. market increased slightly to \$1.1 million in the first quarter of 2006 compared to \$1.0 million in the first quarter of 2005. We anticipate that U.S. sales of Histofreezer® in the professional market will increase during the remainder of 2006, as compared to 2005. Sales of Histofreezer® in the international market decreased by 30% to \$370,000 as a result of the purchase of inventory at the end of 2005 by a large European distributor in advance of a previously announced price increase scheduled to take effect during the first quarter of 2006. Despite the decrease in the first quarter of 2006, sales of Histofreezer® in the international market are expected to increase above 2005 levels as a result of the price increase and the addition of distributors in countries where the product is currently not sold.

We are beginning to see some evidence 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 magnitude of the financial impact of this change.

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Sales to the insurance risk assessment market decreased 49% to \$1.1 million in the first quarter of 2006 from \$2.1 million in the same period in 2005. We believe this reduction is due to a continued reduction in the number of life insurance applications and an increase in the average policy amount. We currently expect that our 2006 revenues in this market will decline or at best remain at approximately the levels attained in 2005.

Licensing and product development revenues increased by 6% to \$89,000 during the first quarter of 2006, from \$84,000 in the comparable period in 2005. Licensing and product development revenues are primarily related to our collaborative Up-converting phosphor technology ( UPT ) and oral fluid research project with The University of Pennsylvania and New York University, under a grant awarded by the National Institutes of Health. The current annual phase of this grant expires in June 2006. Further revenues under this grant beyond June 2006 will depend on progress achieved in the research and future funding awarded by the National Institutes of Health, and the Company's decisions regarding the future of UPT .

Prestige accounted for 12% and 25% of total revenues for the first quarter of 2006 and 2005, respectively. Quest Diagnostics (including its wholly-owned subsidiary, LabOne, Inc.) accounted for 10% and 11% of total revenues for the first quarter of 2006 and 2005, respectively.

Gross margin in the first quarter of 2006 was 63%, compared to 60% for the first quarter of 2005. Gross margin was positively affected by a more favorable product sales mix and lower scrap expense.

Research and development expenses increased 38% to \$1.6 million in the first quarter of 2006 from \$1.2 million in the same period in 2005, primarily as a result of costs associated with the development of a rapid hepatitis C testing product as well as increased stock-compensation charges. Research and development costs are expected to increase in 2006, as compared to 2005, 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 and the expensing of stock options.

Sales and marketing expenses increased 6% to \$4.1 million in the first quarter of 2006 from \$3.9 million in the same period in 2005. This increase was primarily the result of increased travel expenses and increased stock-compensation charges, partially offset by decreased advertising expenses. Included in advertising expenses for the first quarter of 2006 and 2005 were \$187,019 and \$569,000, respectively, payable to Prestige as reimbursement for marketing expenses incurred for the Freeze Off product. Pursuant to our agreement with Prestige, we will continue to co-invest in Prestige's marketing activities for the Freeze Off product during 2006, by reimbursing Prestige for a portion of Prestige's out-of-pocket costs of advertising and promoting this product in the OTC market.

General and administrative expenses decreased 7% to \$3.0 million in the first quarter of 2006 from \$3.2 million in the same period in 2005. This decrease was primarily attributable to a decrease in legal fees associated with the Schering-Plough patent infringement litigation. This decrease was partially offset by the impact of stock option expensing in 2006. General and administrative expenses are expected to increase in 2006 versus 2005 primarily as a result of increased stock-based compensation expense and expenses related to the implementation of a new enterprise resource planning system.

Interest expense decreased to \$18,000 in the first quarter of 2006 from \$27,000 in the same period in 2005, primarily as a result of lower outstanding debt balances. Interest income increased to \$827,000 in the first quarter of 2006 from \$372,000 in the same period in 2005, as a result of higher yields on our investment portfolio.

Based on our 2005 results and our projections for future taxable income, we have begun providing for income taxes at a rate equal to our combined federal and state effective rates. As such, during the three months ended March 31, 2006, a provision for income taxes of \$777,000 was recorded, which represents a 46% effective tax rate. No provision for income taxes was recorded in the first quarter of 2005.

**Table of Contents****Liquidity and Capital Resources**

	March 31, 2006	December 31, 2005
	(In thousands)	
Cash and cash equivalents	\$ 29,891	\$32,827
Short-term investments	49,070	44,793
Working capital	93,131	90,670

Our cash, cash equivalents, and short-term investments increased \$1.3 million during the first quarter of 2006 to \$79.0 million at March 31, 2006, primarily as a result of the Company's \$2.6 million in positive cash flow from operations and \$174,000 in proceeds from the exercise of stock options during the quarter, partially offset by the purchase of \$665,000 of equipment, \$277,000 of debt repayments, and \$444,000 associated with the retirement of common stock to pay minimum tax withholding obligations on restricted shares vesting during the quarter. At March 31, 2006, the Company's working capital was \$93.1 million.

Net cash provided by operating activities was \$2.6 million in the first quarter of 2006. The \$2.6 million of cash provided by operating activities resulted from net income of \$900,000, stock-based compensation of \$1.4 million, deferred income taxes of \$658,000, depreciation and amortization of \$447,000, provisions for excess and obsolete inventories of \$148,000, and a decrease of \$1.8 million in accounts receivable, partially offset by inventory increases of \$679,000, an increase of \$302,000 in prepaid expenses and other assets, and a reduction of accounts payable and accruals of \$1.8 million.

Net cash used in investing activities during the first quarter of 2006 was \$5.0 million. We purchased \$665,000 of property and equipment and purchased a net amount of \$4.3 million of short-term investments.

Capital expenditures are anticipated to increase to \$8.2 million during 2006. We expect to incur these expenditures to purchase additional information systems equipment and to upgrade certain older equipment. In addition to these expenditures, we have exercised our option to purchase two currently leased facilities, which will require \$9.2 million of added expenditures. We are currently in the process of working with Comerica Bank to finance the purchase of these facilities.

Net cash used in financing activities was \$548,000, reflecting \$277,000 of loan principal repayments and \$444,000 for the retirement of common stock, partially offset by proceeds of \$174,000 received from the issuance of common stock.

We have in place an \$11.9 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 \$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. In April 2006, the Credit Facility was amended to extend the maturity date of our revolving working capital line of credit to June 29, 2006.

The \$887,000 mortgage loan matures in September 2012, bears interest at an annual floating rate equal to Comerica's prime rate (7.75% at March 31, 2006), and is repayable in fixed monthly principal and interest installments of \$7,426 through September 2007, at which time the interest rate and fixed monthly repayment amount will be reset for the remaining 60 monthly installments. The outstanding balance of the loan at March 31, 2006 was \$713,077.



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As of March 31, 2006, 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.

As of March 31, 2006, we also had an outstanding balance of \$129,026 under a non-revolving line of credit with Comerica Bank. This line of credit expired in 2003, however, outstanding borrowings under this line remained payable upon expiration in accordance with their original terms. The outstanding balance at March 31, 2006 consisted of four individual loans of (i) \$23,972 with a fixed annual interest rate of 5.07%, (ii) \$45,725 with a floating annual interest rate equal to Comerica's prime rate of 7.75% at March 31, 2006, (iii) \$32,158 with a floating annual interest rate equal to Comerica's prime rate of 7.75% at March 31, 2006, and (iv) \$27,171 with a floating annual interest rate equal to Comerica's prime rate of 7.75% at March 31, 2006.

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 one of our manufacturing facilities in Bethlehem, Pennsylvania. Borrowings under the revolving working capital line of credit 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 March 31, 2006 and expect to remain in compliance with all covenants during the remainder of 2006. 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 March 31, 2006, we also had a \$221,036 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%, 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 and capital needs for the foreseeable future. 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 purchase of our leased facilities in Bethlehem, Pennsylvania, and other factors.

### **Summary of Contractual Obligations**

A summary of our obligations to make future payments under contracts existing at December 31, 2005 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, 2005. As of March 31, 2006, 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,

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investments, intangible assets, accruals, income taxes, revenue recognition, stock-based compensation, 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 2005 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 \$288,321 at March 31, 2006. While credit losses have been within our expectations and the allowance provided, these losses can vary from period to period ((\$4,771), \$3,541, and \$88,659 in 2005, 2004, and 2003, respectively). Furthermore, there is no assurance that we will experience credit losses at the same rates as we have in the past. Also, at March 31, 2006, \$4.0 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

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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 2005, 2004, and 2003, we wrote-off inventory which had a cost of \$2.1 million, \$839,000, and \$540,000, respectively, as a result of scrap levels, product expiration issues and a 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.

**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 had a net book value of \$9.3 million or 7% of our total assets at March 31, 2006. 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 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 and eventual disposition of these assets. If the net book value exceeds the fair value of the impaired assets, we would incur an impairment expense equal to this difference. We currently believe the future cash flows to be received from our long-lived and intangible assets will exceed their book value and, as such, we have not recognized any impairment losses through March 31, 2006. 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, 2005, we had federal net operating loss carryforwards ( NOLs ) of \$66.6 million. The deferred tax asset associated with these NOLs and other temporary differences was \$26.7 million at December 31, 2005. 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 asset will not be realized. The ultimate realization of the deferred tax asset 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 NOLs 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 NOLs that can be used in any given year in the event of specified occurrences, including significant ownership changes. In the fourth quarter of 2005, the Company completed an analysis, with the assistance of independent tax specialists, 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 period 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.

Prior to December 31, 2005, a valuation allowance had been established for the full amount of the deferred tax asset created by these carryforwards and other items. Based on our 2005 results and our projections for future taxable income over the periods in which the deferred tax assets are deductible or the NOLs and credit carryforwards can be utilized, we believed a significant portion of the deferred tax asset was realizable at December 31, 2005. As such, we recorded the estimated net realizable value of the deferred tax asset at December 31, 2005 and have begun

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providing for income taxes at a rate equal to our combined federal and state effective rates. As we provide for income taxes, our deferred tax asset will be reduced as we utilize our NOLs. 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. Additionally, our effective tax rate is impacted by several factors which can also cause our provision for income taxes to vary significantly from period to period. These factors include, among other things, our actual annual pre-tax income, changes in our stock price and its effect on executive compensation, and the significance of permanent differences related to stock compensation.

**Stock-Based Compensation.** We grant stock options to our employees and non-employee directors as part of their compensation. The amount of stock option compensation expense incurred and to be incurred in future periods is dependent upon a number of factors, such as the number of options granted, the timing of stock option exercises and actual forfeiture rates. We estimate the fair value of all stock option awards as of the date of grant by applying the Black-Scholes option-pricing model. The application of this valuation model involves assumptions, some of which are judgmental and highly sensitive, in the determination of stock option compensation expense. These assumptions include our expected stock price volatility and the expected life of our stock options, which are based primarily on our historical experience.

**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 ). 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 for such instruments.

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

We do not currently have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. We have operations in The Netherlands which are subject to foreign currency fluctuations. As currency rates change, translation of the statement of operations for this operation from euros to U.S. dollars affects year-to-year comparability of operating results. Sales denominated in a foreign currency represented \$370,000 or 2% of our total revenues for the three months ended March 31, 2006. We do not expect the risk of foreign currency fluctuations to be material.

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**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, 2006. 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 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, 2005.

**Item 6. EXHIBITS**

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

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**SIGNATURES**

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

ORASURE TECHNOLOGIES, INC.

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

Date: May 10, 2006

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

Date: May 10, 2006

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**EXHIBIT INDEX**

**Exhibit**

- 10.1 Amendment No. 1 to Distribution Agreement, dated as of February 10, 2006, among OraSure Technologies, Inc., Medtech Holdings, Inc., Medtech Products, Inc. (as assignee of Medtech Holdings, Inc.) and Prestige Brands Holdings, Inc., as guarantor.\*
- 10.2 Letter Agreement, dated April 25, 2006, between OraSure Technologies, Inc. and Comerica Bank, is incorporated by reference to Exhibit 99 to the Company's Current Report on Form 8-K filed May 2, 2006.
- 10.3 Description of 2006 Self-Funding Management Incentive Plan is incorporated by reference to Item 1.01 to the Company's Current Report on Form 8-K filed January 30, 2006.\*\*
- 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.