

ORASURE TECHNOLOGIES INC  
Form 10-Q  
November 02, 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 September 30, 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

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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 October 31, 2007: 46,618,564

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

	SEPTEMBER 30, 2007	DECEMBER 31, 2006
<b>ASSETS</b>		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 18,949,853	\$ 19,949,821
Short-term investments	73,385,607	71,051,482
Accounts receivable, net of allowance for doubtful accounts of \$249,520 and \$200,094	12,014,370	10,357,287
Inventories	7,768,404	5,534,567
Deferred income taxes	6,429,639	3,675,785
Prepaid expenses and other	1,468,195	1,989,882
Total current assets	120,016,068	112,558,824
PROPERTY AND EQUIPMENT, net	20,218,168	17,374,718
PATENTS AND PRODUCT RIGHTS, net	5,541,690	6,328,344
DEFERRED INCOME TAXES	15,564,784	19,845,789
OTHER ASSETS	114,061	457,788
	\$ 161,454,771	\$ 156,565,463
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
CURRENT LIABILITIES:		
Current portion of long-term debt	\$ 556,469	\$ 608,595
Accounts payable	4,395,345	3,311,968
Accrued expenses and other	9,552,316	12,659,149
Total current liabilities	14,504,130	16,579,712
LONG-TERM DEBT	9,331,956	10,030,541
OTHER LIABILITIES	380,252	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, 46,435,640 and 45,994,752 shares issued and outstanding	46	46
Additional paid-in capital	233,555,894	228,069,433
Accumulated other comprehensive loss	(290,154)	(151,197)
Accumulated deficit	(96,027,353)	(98,414,307)
Total stockholders equity	137,238,433	129,503,975
	\$ 161,454,771	\$ 156,565,463

The accompanying notes are an integral part of these statements.



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

	Three Months		Nine Months	
	Ended September 30, 2007	2006	Ended September 30, 2007	2006
<b>REVENUES:</b>				
Product	\$ 20,661,204	\$ 17,508,622	\$ 60,794,834	\$ 50,124,008
Licensing and product development	754,127	130,693	2,081,940	297,046
	21,415,331	17,639,315	62,876,774	50,421,054
<b>COST OF PRODUCTS SOLD</b>	<b>8,647,522</b>	<b>6,365,346</b>	<b>24,121,646</b>	<b>18,516,174</b>
Gross profit	12,767,809	11,273,969	38,755,128	31,904,880
<b>COSTS AND EXPENSES:</b>				
Research and development	3,672,087	1,752,519	9,896,379	5,149,782
Acquired in-process technology				600,000
Sales and marketing	4,978,795	3,632,373	14,998,637	11,976,687
General and administrative	5,074,670	3,409,811	13,636,810	9,509,870
	13,725,552	8,794,703	38,531,826	27,236,339
Operating income (loss)	(957,743)	2,479,266	223,302	4,668,541
INTEREST EXPENSE	(168,490)	(182,265)	(499,302)	(224,452)
INTEREST INCOME	1,244,158	1,112,195	3,521,490	2,896,761
GAIN ON SALE OF INVESTMENT			1,428,691	
FOREIGN CURRENCY GAIN (LOSS)	9,752	(9,899)	(7,513)	(65,506)
Income before income taxes	127,677	3,399,297	4,666,668	7,275,344
INCOME TAX PROVISION	123,618	1,264,751	2,221,531	3,032,933
NET INCOME	\$ 4,059	\$ 2,134,546	\$ 2,445,137	\$ 4,242,411
<b>EARNINGS PER SHARE:</b>				
BASIC	\$	\$ 0.05	\$ 0.05	\$ 0.09
DILUTED	\$	\$ 0.05	\$ 0.05	\$ 0.09
<b>SHARES USED IN COMPUTING EARNINGS PER SHARE</b>				
BASIC	46,340,646	45,922,110	46,392,692	45,888,349
DILUTED	46,988,171	47,247,439	46,892,924	47,712,101

The accompanying notes are an integral part of these statements.



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

	Nine Months	
	Ended September 30, 2007	2006
<b>OPERATING ACTIVITIES:</b>		
Net income	\$ 2,445,137	\$ 4,242,411
Adjustments to reconcile net income to net cash provided by operating activities:		
Gain on sale of investment in nonaffiliated company	(1,428,691)	
Stock-based compensation	4,459,520	4,280,054
Deferred income taxes	1,557,785	2,617,504
Depreciation and amortization	1,996,736	1,440,409
Acquired in-process technology		600,000
Provision for excess and obsolete inventories	771,592	472,081
Changes in assets and liabilities:		
Accounts receivable	(1,657,083)	1,369,379
Inventories	(3,005,429)	(1,155,693)
Prepaid expenses and other assets	666,554	(49,717)
Accounts payable, accrued expenses, and other liabilities	1,981,186	235,093
<b>Net cash provided by operating activities</b>	<b>7,787,307</b>	<b>14,051,521</b>
<b>INVESTING ACTIVITIES:</b>		
Purchase of short-term investments	(77,787,229)	(65,900,901)
Proceeds from maturities and redemptions of short-term investments	75,283,513	38,375,046
Purchase of property and equipment	(4,280,934)	(11,552,057)
Payments for patents and licenses	(4,000,000)	(200,000)
Proceeds from sale of investment in nonaffiliated company	1,765,943	
<b>Net cash used in investing activities</b>	<b>(9,018,707)</b>	<b>(39,277,912)</b>
<b>FINANCING ACTIVITIES:</b>		
Proceeds from long-term debt		10,000,000
Repayments of long-term debt	(750,711)	(401,438)
Proceeds from issuance of common stock	1,742,999	344,304
Withholding and retirement of common stock	(760,856)	(519,117)
<b>Net cash provided by financing activities</b>	<b>231,432</b>	<b>9,423,749</b>
<b>EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH</b>		<b>5,832</b>
<b>NET DECREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(999,968)</b>	<b>(15,796,810)</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>\$ 18,949,853</b>	<b>\$ 17,029,930</b>

**SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:**

Cash paid for:



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Interest	\$	514,532	\$	169,550
Income taxes	\$	395,284	\$	294,000

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, 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 and nine-month periods ended September 30, 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 September 30, 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 income (loss).

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The following is a summary of our available-for-sale securities at September 30, 2007 and December 31, 2006:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
<b>September 30, 2007</b>				
Certificates of deposit	\$ 718,255	\$ 6,150	\$	\$ 724,405
Commercial paper	13,460,367	756	(887)	\$ 13,460,236
Government and agency bonds	7,390,272	3,791	(1,760)	\$ 7,392,303
Corporate bonds	51,859,550	16,426	(67,313)	\$ 51,808,663
Total available-for-sale securities	\$ 73,428,444	\$ 27,123	\$ (69,960)	\$ 73,385,607
<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 September 30, 2007, maturities of investments were as follows:</b>				
Less than one year	\$ 68,412,800	\$ 23,943	\$ (62,716)	\$ 68,374,027
One to two years	5,015,644	3,180	(7,244)	5,011,580
Total available-for-sale securities	\$ 73,428,444	\$ 27,123	\$ (69,960)	\$ 73,385,607

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

	September 30, 2007	December 31, 2006
Raw materials	\$ 4,185,947	\$ 3,868,301
Work-in-process	481,709	533,470
Finished goods	3,100,748	1,132,796
	\$ 7,768,404	\$ 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 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.

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Significant Customer Concentration. The Company had the following significant concentrations in revenue and accounts receivable:

	Percentage of Total Revenues			
	Three Months Ended		Nine Months Ended	
	September 30, 2007	September 30, 2006	September 30, 2007	September 30, 2006
<b>Customer</b>				
Quest Diagnostics, Incorporated	12%	15%	11%	14%
Abbott Laboratories	10	9	10	9
Prestige Brands Holdings, Inc.	11		9	8
SSL International plc	3	10	6	7

	Percentage of Accounts Receivable	
	September 30, 2007	December 31, 2006
Quest Diagnostics, Incorporated	17%	11%
Abbott Laboratories	7	11
Prestige Brands Holdings, Inc.	9	12
SSL International plc	3	10

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

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 were as follows:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2007	2006	2007	2006
Net income	\$ 4,059	\$ 2,134,546	\$ 2,445,137	\$ 4,242,411
Weighted average shares of common stock outstanding:				
Basic	46,340,646	45,922,110	46,392,692	45,888,349
Dilutive effect of stock options, warrants and restricted stock	647,525	1,325,329	500,232	1,823,752
Diluted	46,988,171	47,247,439	46,892,924	47,712,101
Earnings per share:				
Basic	\$	\$ 0.05	\$ 0.05	\$ 0.09
Diluted	\$	\$ 0.05	\$ 0.05	\$ 0.09

For the three-month periods ended September 30, 2007 and 2006, outstanding common stock options, warrants, and unvested restricted stock, representing 981,293 and 2,159,179 shares, respectively, were excluded from the



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computation of diluted earnings per share, as their inclusion would have been anti-dilutive. For the nine-month periods ended September 30, 2007 and 2006, outstanding common stock options, warrants, and unvested restricted stock, representing 2,055,454 and 1,092,909 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 income (loss) at September 30, 2007 and December 31, 2006 consisted of currency translation adjustments and net unrealized gains or losses on marketable securities. Comprehensive income (loss) was \$(1,486) and \$2,274,496 for the three months ended September 30, 2007 and 2006, respectively, and \$2,306,179 and \$4,427,441 for the nine months ended September 30, 2007 and 2006, respectively.

**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 \$1,765,943 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 each of the three-month periods ended September 30, 2007 and 2006 was \$4.69 per share. The weighted average grant date fair value of stock options granted during the nine months ended September 30, 2007 and 2006 was \$3.71 and \$4.95 per share, respectively.

Total compensation cost related to stock options for the three months ended September 30, 2007 and 2006, was \$776,836 (\$564,343, net of tax) and \$934,079 (\$711,006, net of tax), respectively, of which \$74,732 and \$62,182 was capitalized into inventory during the three months ended September 30, 2007 and 2006, respectively. The amounts recognized in cost of products sold for amounts previously capitalized were \$15,781 and \$73,413 for the three months ended September 30, 2007 and 2006, respectively. Total compensation cost related to stock options for the nine months ended September 30, 2007 and 2006 was \$2,258,446 (\$1,657,957, net of tax) and \$2,838,880 (\$2,174,710, net of tax), respectively, of which \$235,864 and \$270,191 was capitalized into inventory during the nine-month periods ended September 30, 2007 and 2006, respectively. The amounts recognized in cost of products sold for amounts previously capitalized were \$214,799 and \$148,765 for the nine-month periods ended September 30, 2007 and 2006, respectively.

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The following table summarizes the stock option activity for the nine months ended September 30, 2007:

	<b>Options</b>
Outstanding on January 1, 2007	4,788,418
Granted	509,566
Exercised	(276,894)
Forfeited	(92,390)
<b>Outstanding on September 30, 2007</b>	<b>4,928,700</b>

As of September 30, 2007, there was \$3,987,601 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 \$1,742,999 and \$344,304 for the nine months ended September 30, 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 nine-month period ended September 30, 2007, we granted 348,655 restricted shares of our common stock, with an average grant date fair value of \$8.29 per share, to certain key officers and members of management. Generally, 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 \$728,582 and \$426,771 related to these and previous grants was recognized during the three months ended September 30, 2007 and 2006, respectively. Compensation cost of \$2,133,362 and \$1,434,400 related to these and previous grants was recognized during the nine months ended September 30, 2007 and 2006, respectively.

The following table summarizes restricted stock award activity for the nine months ended September 30, 2007:

	<b>Shares</b>
Issued and unvested, January 1, 2007	807,054
Granted	348,655
Vested	(251,614)
Forfeited	(14,655)
<b>Issued and unvested, September 30, 2007</b>	<b>889,440</b>

As of September 30, 2007, there was \$5,773,306 of unrecognized compensation expense related to unvested restricted stock awards that is expected to be recognized over a weighted average period of 3.0 years.

In connection with the vesting of restricted shares during the nine-month periods ended September 30, 2007 and 2006, 87,619 and 51,616 shares with aggregate values of \$760,856 and \$519,117, respectively, were withheld and retired in satisfaction of minimum tax withholding obligations.

**5. Long-term Debt**

At September 30, 2007, we had a \$21,000,000 credit facility ( Credit Facility ) with Comerica Bank. In June 2007, we executed an amendment to our Credit Facility, pursuant to which the maturity date of our \$4,000,000 revolving working capital line of credit was extended to June 29, 2009. We also determined that we would not need to borrow \$5,000,000 in additional advances to fund the future expansion of our facilities in Bethlehem, Pennsylvania. Accordingly, we allowed this \$5,000,000 of availability under our Credit Facility to expire unused on June 30, 2007. All other terms of our Credit Facility, as previously amended, remain in effect.





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On September 28, 2007, the Company repaid its outstanding balance of \$669,000 under the mortgage loan payable included in our Credit Facility with Comerica Bank.

**6. Accrued Expenses and Other**

	September 30, 2007	December 31, 2006
Royalties	\$ 1,946,505	\$ 2,813,102
Payroll and related benefits	3,457,306	2,117,630
Deferred revenue	1,388,980	1,877,546
Advertising	115,630	201,509
Professional fees	1,394,681	681,850
Income taxes	207,539	5,621
License fees	200,000	4,200,000
Laboratory testing fees	119,957	155,996
Other	721,718	605,895
	\$ 9,552,316	\$ 12,659,149

Accrued royalties at September 30, 2007 and December 31, 2006 were primarily related to our OraQuick® rapid HIV testing product. Deferred revenue at September 30, 2007 and December 31, 2006 consisted primarily of customer prepayments, totaling \$1,257,280 and \$1,727,546, respectively. Advertising accruals at September 30, 2007 and December 31, 2006 were related to our over-the-counter cryosurgical products. Accrued license fees decreased at September 30, 2007 as a result of \$4,000,000 in payments made during the nine months ended September 30, 2007. Accrued professional fees increased at September 30, 2007 as a result of increased legal fees incurred in the current three-month period. Accrued income taxes increased as a result of the current state and federal income tax provisions.

**7. Income Taxes**

In July 2006, the 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 \$58,183 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 are 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.

**8. 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.



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The following table represents total revenues by geographic area, based on the location of the customer (amounts in thousands):

	Three Months		Nine Months	
	Ended September 30, 2007	2006	Ended September 30, 2007	2006
United States	\$ 16,806	\$ 14,136	\$ 49,682	\$ 42,120
Europe	1,654	3,053	7,042	7,089
Other regions	2,955	450	6,153	1,212
	\$ 21,415	\$ 17,639	\$ 62,877	\$ 50,421

**Table of Contents****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; 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, our Quarterly Reports on Form 10-Q 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® 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 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 first nine months of 2007, our total revenues were \$62.9 million, which represents a 25% increase from the same period in 2006. Our net income for the nine months ended September 30, 2007 was \$2.4 million, a \$1.8 million decrease from the first nine months of 2006. Net income during the first nine months of 2007 includes a pre-tax gain of \$1.4 million related to the sale of our investment in a privately-held nonaffiliated company. Cash flow from operating activities declined by \$6.3 million when compared to the same nine-month period in 2006, primarily as a result of the decrease in net income and an increase in accounts receivable and inventory balances. As of September 30, 2007, we had \$92.3 million in cash, cash equivalents and short-term investments.

Sales into the infectious disease testing market increased 24% in the first nine 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 domestic public health organizations, government bulk purchases by the Substance Abuse and Mental Health Services Administration ( SAMHSA ) and the Centers for Disease Control and Prevention ( CDC ), sales through Abbott Laboratories, Inc. ( Abbott ) into the hospital market, as well as an increase in international sales, primarily in Africa.

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. The initial term of our agreement with Abbott expires at the end of 2007. Pursuant to renewal provisions in the agreement, we have been engaged in discussions with Abbott to extend the agreement. We currently expect that our agreement with Abbott will continue in 2008.

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. Several of these companies, as well as Calypte Biomedical, which offers a rapid oral fluid HIV-1/2 test, compete with us outside of the United States. 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 U.S. Food and Drug Administration ( FDA ) approval and approvals outside the United States to sell competing rapid HIV tests in the future.

Sales to the substance abuse testing market also increased during the first nine months of 2007, reflecting the growing acceptance of our Intercept<sup>®</sup> collection device and related oral fluid drug assays, as customers continued to adopt oral

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fluid based drug testing and shift away from traditional urine-based drug testing. We expect continued growth in the utilization of our Intercept® product line, primarily in the United States.

Sales to the cryosurgical systems market increased during the nine-month period ended September 30, 2007. The cryosurgical systems market represents sales of Histofreezer® into both the domestic and international physicians' office markets and sales of the over-the-counter (OTC) formulation of this product to our domestic distributor, Prestige Brands Holdings, Inc. (Prestige), and our international distributors, SSL International plc (SSL) and Genomma Laboratories (Genomma). Prestige has distributed our cryosurgical wart removal product under its Compound W Freeze Off® tradename 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 2007, Genomma began distributing a similar product under the POINTTS tradename in Mexico. Sales of our international OTC cryosurgical products increased by 120% in the nine months ended September 30, 2007, compared to the same period in 2006.

In September 2006, Prestige announced that it had acquired the Wartner® cryosurgical wart removal product line, which directly competes with the Freeze Off® 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® 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 included 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 commenced, pursuant to the terms of the agreement. On October 22, 2007, we received a decision from the arbitration panel concluding that Prestige's acquisition of Wartner® breached the non-compete provision and that we are entitled to an award of our legal fees and share of arbitrators' costs. All counterclaims asserted by Prestige were rejected. The panel also found that our distribution agreement with Prestige will terminate on December 31, 2007 and we are not entitled to receive other compensatory damages.

Sales to Prestige for the nine months ended September 30, 2007 were \$5.6 million. Since the arbitration panel found that our distribution agreement with Prestige will terminate on December 31, 2007, we have been evaluating alternative product and distribution options for the United States OTC cryosurgical market.

Sales to the insurance risk assessment market declined by 7% during the first nine months of 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® test, our OraSure® oral fluid collection device and our oral fluid Western blot HIV-1 confirmatory product. If we are unable to obtain necessary components or materials from 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.

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® 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. Earlier this year, BMX 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 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

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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 and 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 nine months ended September 30, 2007, we generated 79% 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****Three months ended September 30, 2007 compared to September 30, 2006**

Total revenues increased 21% to \$21.4 million in the third quarter of 2007 from \$17.6 million in the comparable quarter of 2006, primarily as a result of increased sales of our OTC cryosurgery products and our infectious disease testing products. Revenues derived from products sold to customers outside the U.S. were \$4.6 million and \$3.5 million, or 22% and 20% of total revenues, in the third 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.

<u>Market</u>	Three Months Ended September 30,				
	Dollars			Percentage of Total Revenues	
	2007	2006	% Change	2007	2006
Infectious disease testing	\$ 8,233	\$ 7,536	9%	38%	42%
Substance abuse testing	4,070	4,213	(3)	19	24
Cryosurgical systems	6,738	4,025	67	31	23
Insurance risk assessment	1,620	1,734	(7)	8	10
Product revenues	20,661	17,508	18	96	99
Licensing and product development	754	131	476	4	1
Total revenues	\$ 21,415	\$ 17,639	21%	100%	100%

**Infectious Disease Testing Market**

Sales to the infectious disease testing market totaled \$8.2 million in the third quarter of 2007, an increase of 9% over the comparable period of 2006. OraQuick® sales increased to \$7.5 million in the third quarter of 2007, from \$6.6 million in the same quarter of 2006, primarily as a result of a 31% increase in sales to the hospital market through our distributor, Abbott, and a 17% increase in sales to the U.S. public health market. In addition, international sales of OraQuick® increased by 116% in the three months ended September 30, 2007 when compared to 2006. OraSure® sales totaled \$702,000 and \$906,000 in the third quarters of 2007 and 2006, respectively.





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

	Three Months Ended September 30,		
	2007	2006	% Change
<b>Customers</b>			
Direct to U.S. Public Health	\$ 4,492	\$ 3,837	17%
Abbott	2,159	1,651	31
SAMHSA	5		N/A
CDC	25	748	(97)
International	850	394	116
<b>Total OraQuick® revenues</b>	<b>\$ 7,531</b>	<b>\$ 6,630</b>	<b>14%</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 have received final CE mark approval for our OraQuick *ADVANCE*® test, thereby enabling us to sell this product in Europe. Several sites in Europe are currently conducting investigational studies with our OraQuick *ADVANCE*® test in support of our obtaining several country-specific registrations to allow us to launch the product in Europe. We are also aggressively pursuing distributors in the European Union.

In previous periods, the CDC and SAMHSA have placed bulk purchase orders for OraQuick *ADVANCE*® devices and related testing materials. In September 2007, the CDC awarded \$35 million in additional funding to expand HIV testing and prevention programs in populations disproportionately affected by HIV, primarily African Americans. These funds were allocated to targeted state and public health agencies, for utilization over the next 12 months. We expect part of this funding to be used to purchase rapid HIV tests, including our OraQuick *ADVANCE*® test.

Although sales of OraQuick *ADVANCE*® are expected to increase, such sales may negatively impact sales of our OraSure® oral fluid collection device in the infectious disease testing market. Revenues from the OraSure® collection device in the third quarter of 2007 were down \$204,000 compared to those recorded in the same period of 2006. 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.

**Substance Abuse Testing Market**

Sales to the substance abuse testing market decreased 3% to \$4.1 million in the third quarter of 2007, primarily as a result of a decline in sales of our Q.E.D.® rapid oral fluid alcohol test.

The table below shows a breakdown of our total Intercept® revenues (in thousands, except %) generated in each market in the third quarter of 2007 and 2006.

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	Three Months Ended September 30,		
	2007	2006	% Change
<b>Market</b>			
Workplace testing	\$ 1,804	\$ 1,679	7%
Criminal justice	613	640	(4)
International	482	599	(20)
Direct	273	175	56
Total Intercept® revenues	\$ 3,172	\$ 3,093	3%

We expect continued growth in Intercept® 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® 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 are developing and intend to commercialize fully-automated homogeneous oral fluid drugs of abuse assays with Roche Diagnostics for use with our Intercept® device.

**Cryosurgical Systems Market**

Sales of our products in the cryosurgical systems market (which includes both the physicians office and OTC markets) were \$6.7 million in the third quarter of 2007, a 67% increase compared to the same period in 2006. This increase was a result of increased sales of both our international and domestic OTC cryosurgical products, partially offset by lower sales of our Histofreezer® product in the U.S. professional market.

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

	Three Months Ended September 30,		
	2007	2006	% Change
<b>Market</b>			
Professional domestic	\$ 1,028	\$ 1,755	(41)%
Professional international	574	576	0
OTC domestic	2,453		N/A
OTC international	2,683	1,694	58
Total cryosurgical systems revenues	\$ 6,738	\$ 4,025	67%

Early in 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 new distribution agreement were \$2.1 million in the third quarter of 2007. Sales to our European distributor, SSL, decreased to \$0.6 million during the third quarter of 2007 as compared to \$1.7 million in the same period of 2006, as SSL managed its inventory levels in anticipation of launching an enhanced product and labeling configuration. During the three months ended September 30, 2007, we recorded \$2.5 million in sales to Prestige. We had no sales to Prestige during the three months ended September 30, 2006. In October 2007, we shipped approximately \$650,000 of product to Prestige. As a result of the recent arbitration decision and termination of our distribution agreement with Prestige at the end of 2007, we do not expect any further revenues from Prestige in the future. We are currently evaluating alternative product and distribution options for our cryosurgical product in the U.S. OTC market.

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Sales of our Histofreezer<sup>®</sup> product to physicians' offices in the U.S. market decreased 41% during the third quarter of 2007 compared to the same period in 2006 as a result of increased competition and price sensitivity. We anticipate that U.S. sales of Histofreezer<sup>®</sup> for 2007 will be slightly less than the levels attained in 2006. Sales of Histofreezer<sup>®</sup> in the European physicians' office market were consistent between periods. 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 in European and Latin American countries.

### **Insurance Risk Assessment Market**

Sales to the insurance risk assessment market decreased 7% to \$1.6 million in the third quarter of 2007 from \$1.7 million in the same period in 2006. Because of a reduction in the number of applications for life insurance coverage and changes in underwriting requirements, we 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**

Licensing and product development revenues increased to \$754,000 during the third quarter of 2007, from \$131,000 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 September 30, 2007, the Company recognized \$727,000 in revenues associated with funded research and development under this agreement. We do not expect to recognize any additional licensing and product development revenues pursuant to this agreement.

### **Significant Customer Concentration**

Quest Laboratories accounted for 12% and 15% of total revenues for the third quarter of 2007 and 2006, respectively. Abbott accounted for 10% and 9% of total revenues for the third quarter of 2007 and 2006, respectively. Prestige accounted for 11% and 0% of total revenues for the three-month periods ended September 30, 2007 and 2006, respectively. SSL accounted for 3% and 10% of total revenues for the third quarter of 2007 and 2006, respectively.

### **Gross Margin**

Gross margin in the third quarter of 2007 was 60%, down from 64% in the same quarter of 2006. This decrease is primarily attributed to a \$420,000 increase in scrap expense, higher product support costs and a less favorable product mix during the current three-month period, compared to 2006.

### **Operating Expenses**

Research and development expenses increased 106% to \$3.7 million in the third quarter of 2007 from \$1.8 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 the latter half of 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 37% to \$5.0 million in the third quarter of 2007 from \$3.6 million in the same period in 2006. This increase was primarily the result of increased staffing and related charges such as travel, recruiting and relocation expenses.

General and administrative expenses increased 49% to \$5.1 million in the third quarter of 2007 from \$3.4 million in the same period in 2006. This increase was primarily attributable to increased legal expenses associated with the Prestige proceedings and increased salaries and benefits expenses associated with new personnel.

**Table of Contents****Other Income/Expense**

Interest expense decreased to \$168,000 in the third quarter of 2007 from \$182,000 in the same period of 2006, as a result of lower outstanding debt balances during the current period. Interest income increased to \$1.2 million in the third quarter of 2007 from \$1.1 million in the same period of 2006, as a result of higher yields on our investment portfolio and larger balances available for investment.

**Income Taxes**

During the three months ended September 30, 2007, we recorded a provision for federal and state income taxes of \$124,000, which represents a \$1.1 million decrease from the \$1.3 million income tax provision recorded in the same period of 2006. The decrease in our income tax provision in the current period was the result of the corresponding decrease in pre-tax income, primarily resulting from the incremental expenses discussed above.

**Nine months ended September 30, 2007 compared to September 30, 2006**

Total revenues increased 25% to \$62.9 million for the first nine months of 2007 from \$50.4 million in the comparable period in 2006, primarily as a result of increased sales in the infectious disease, substance abuse and cryosurgical systems markets, offset by a decrease in revenues in the insurance risk assessment market. Revenues derived from products sold to customers outside the U.S. were \$13.2 million and \$8.3 million, or 21% and 16% of total revenues, during the first nine months 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.

<b>Market</b>	<b>Nine Months Ended September 30,</b>				
	<b>Dollars</b>			<b>Percentage of Total Revenues</b>	
	<b>2007</b>	<b>2006</b>	<b>% Change</b>	<b>2007</b>	<b>2006</b>
Infectious disease testing	\$ 26,350	\$ 21,239	24%	42%	42%
Substance abuse testing	12,396	11,694	6	20	23
Cryosurgical systems	18,190	13,063	39	29	26
Insurance risk assessment	3,859	4,128	(7)	6	8
Product revenues	60,795	50,124	21	97	99
Licensing and product development	2,082	297	601	3	1
Total revenues	\$ 62,877	\$ 50,421	25%	100%	100%

**Infectious Disease Testing Market**

Sales to the infectious disease testing market increased 24% to \$26.4 million in the first nine months 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 \$24.0 million and \$18.5 million in the first nine months of 2007 and 2006, respectively. Sales of OraQuick<sup>®</sup> to the public health market and to the hospital market through our distributor, Abbott, increased by 33% and 17%, respectively, during the first nine months of 2007 compared to 2006. In addition, international sales of OraQuick<sup>®</sup> increased by 78% in the nine months ended September 30, 2007 when compared to 2006, and shipments of OraQuick<sup>®</sup> under bulk purchase orders from the CDC and SAMHSA increased to \$1.5 million during the first nine months of 2007, from \$1.3 million in the same period of 2006. OraSure<sup>®</sup> sales totaled \$2.4 million and \$2.8 million in the first nine months of 2007 and 2006, respectively.



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The table below shows a breakdown of our total OraQuick® revenues (in thousands, except %) during the first nine months of 2007 and 2006.

	Nine Months Ended September 30,		
	2007	2006	% Change
<b>Customers</b>			
Direct to U.S. Public Health	\$ 14,339	\$ 10,794	33%
Abbott	6,087	5,224	17
SAMHSA	339	256	32
CDC	1,125	1,009	11
International	2,110	1,185	78
<b>Total OraQuick® revenues</b>	<b>\$ 24,000</b>	<b>\$ 18,468</b>	<b>30%</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 have received final CE mark approval for our OraQuick *ADVANCE*® test, thereby enabling us to sell this product in Europe. Several sites in Europe are currently conducting investigational studies with our OraQuick *ADVANCE*® test in support of our obtaining several country-specific registrations to allow us to launch the product in Europe. We are also aggressively pursuing distributors in the European Union.

In previous periods, the CDC and SAMHSA have placed bulk purchase orders for OraQuick *ADVANCE*® devices and related testing materials. In September 2007, the CDC awarded \$35 million in additional funding to expand HIV testing and prevention programs in populations disproportionately affected by HIV, primarily African Americans. These funds were allocated to targeted state and public health agencies, for utilization over the next 12 months. We expect part of this funding to be used to purchase rapid HIV tests, including our OraQuick *ADVANCE*® test.

Although sales of OraQuick *ADVANCE*® are expected to increase, such sales may negatively impact sales of our OraSure® oral fluid collection device in the infectious disease testing market. Revenues from the OraSure® collection device in the nine month period ended September 30, 2007 were \$2.4 million, as compared to \$2.8 million in the same period of 2006. 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.

**Substance Abuse Testing Market**

Sales to the substance abuse testing market increased 6% to \$12.4 million in the first nine months of 2007, primarily as a result of increased domestic sales of our Intercept® oral fluid drug testing service.

The table below shows a breakdown of our total Intercept® revenues (in thousands, except %) generated in each market in the first nine months of 2007 and 2006:

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<u>Market</u>	Nine Months Ended September 30,		
	2007	2006	% Change
Workplace testing	\$ 5,288	\$ 4,675	13%
Criminal justice	1,881	1,428	32
International	1,598	1,615	(1)
Direct	739	528	40
Total Intercept® revenues	\$ 9,506	\$ 8,246	15%

We expect continued growth in Intercept® 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® 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 are developing and intend to commercialize fully-automated homogeneous oral fluid drugs of abuse assays with Roche Diagnostics for use with our Intercept® device.

**Cryosurgical Systems Market**

Sales of our products in the cryosurgical systems market (which includes both the physicians office and OTC markets) were \$18.2 million in the first nine months of 2007, a 39% increase compared to the same period in 2006. This increase was primarily the result of increased sales of our international and domestic OTC cryosurgical products, partially offset by lower sales of our Histofreezer® product in the U.S. professional market.

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

<u>Market</u>	Nine Months Ended September 30,		
	2007	2006	% Change
Professional domestic	\$ 3,441	\$ 4,156	(17)%
Professional international	1,551	1,496	4
OTC domestic	5,587	3,956	41
OTC international	7,611	3,455	120
Total cryosurgical systems revenues	\$ 18,190	\$ 13,063	39%

Early in 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 new distribution agreement were \$3.8 million for the first nine months of 2007. Sales to our European distributor, SSL, increased to \$3.8 million during the first nine months of 2007 as compared to \$3.5 million in the same period of 2006. We had \$5.6 million in sales to Prestige during the nine months ended September 30, 2007, a \$1.6 million increase when compared to the \$4.0 million recorded in the same period of 2006. In October 2007, we shipped approximately \$650,000 of product to Prestige. As a result of the recent arbitration decision and termination of our distribution agreement with Prestige at the end of 2007, we do not expect any further revenues from Prestige in the





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future. We are currently evaluating alternative product and distribution options for our cryosurgical product in the U.S. OTC market.

Sales of our Histofreezer<sup>®</sup> product to physicians' offices in the U.S. market during the first nine months of 2007 decreased by 17% compared to those recorded in the same period in 2006, as a result of increased competition and price sensitivity. We anticipate that U.S. sales of Histofreezer<sup>®</sup> for 2007 will remain at approximately the same levels as attained in 2006. Sales of Histofreezer<sup>®</sup> in the international physicians' office market increased by 4% to \$1.6 million during the nine month period ended September 30, 2007. 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 European and Latin American countries.

### **Insurance Risk Assessment Market**

Sales to the insurance risk assessment market decreased 7% to \$3.9 million in the first nine months of 2007 from \$4.1 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**

Licensing and product development revenues increased to \$2.1 million during the first nine months of 2007, from \$297,000 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 HCV. During the nine months ended September 30, 2007, the Company recognized \$2.0 million in revenues associated with funded research and development under this agreement. We do not expect to recognize any additional licensing and product development revenues pursuant to this agreement.

### **Significant Customer Concentration**

Quest Laboratories accounted for 11% and 14% of total revenues for the nine-month periods ended September 30, 2007 and 2006, respectively. Abbott accounted for 10% and 9% of total revenues for the nine-month periods ended September 30, 2007 and 2006, respectively.

### **Gross Margin**

Gross margin in the first nine months of 2007 was 62%, a decrease from 63% in the same period of 2006. The decrease in gross margins was attributed primarily to the \$1.1 million in scrap expense incurred during the current nine-month period, as compared to the \$484,000 incurred in the same period of 2006.

### **Operating Expenses**

Research and development expenses increased 92% to \$9.9 million in the first nine months of 2007 from \$5.1 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 latter half of 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.

A charge of \$600,000 for acquired in-process technology was recorded in the second quarter of 2006 related to the exercise of an option to expand the scope of our HIV-2 patent license to cover products other than our OraQuick *ADVANCE*<sup>®</sup> test.

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Sales and marketing expenses increased 25% to \$15.0 million in the nine-month period ended September 30, 2007 from \$12.0 million in the same period in 2006. This increase was primarily the result of higher salaries and commissions, incremental salaries, benefits, recruiting and relocation expenses associated with additional sales personnel, increases in reimbursable distributor advertising and promotion costs, and increased travel and consulting expenses. Partially offsetting those increases were decreases in expenses for print advertising, public relations and marketing research.

General and administrative expenses increased 43% to \$13.6 million in the first nine months of 2007 from \$9.5 million in the same period in 2006. This increase was primarily attributable to increased legal expenses associated with the Prestige proceedings, increased compensation and benefits expenses associated with new personnel, 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.

**Other Income/Expense**

Interest expense increased to \$499,000 in the nine-month period ended September 30, 2007 from \$224,000 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 \$3.5 million in the nine months ended September 30, 2007 from \$2.9 million in the same period of 2006, as a result of higher yields on our investment portfolio and higher outstanding investment balances.

In January 2007, the Company sold its ownership interest in a privately-held nonaffiliated company and recorded a \$1.4 million pre-tax gain on the sale of this investment.

**Income Taxes**

During the nine months ended September 30, 2007, we recorded a provision for federal and state income taxes of \$2.2 million, which represents an \$800,000 decrease from the \$3.0 million income tax provision recorded in the same period of 2006. The decrease in our income tax provision in the current period was the result of the corresponding decrease in pre-tax income, primarily resulting from the incremental expenses discussed above. Our effective tax rate was 48% and 42% during the nine-month periods ended September 30, 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, spread ratably over the year, and our current year's projected pre-tax income for financial statement purposes.

**Liquidity and Capital Resources**

	September 30, 2007	December 31, 2006
Cash and cash equivalents	\$ 18,950	\$ 19,950
Short-term investments	73,386	71,051
Working capital	105,512	95,979

Our cash, cash equivalents, and short-term investments increased \$1.3 million during the first nine months of 2007 to \$92.3 million at September 30, 2007, primarily as a result of \$7.8 million in positive cash flow from operations, \$1.8 million in proceeds received from the sale of an investment in a nonaffiliated company and \$1.7 million in cash received from the exercise of stock options during the current nine-month period. Offsetting these sources of cash were the Company's \$4.0 million payment for patents and licenses, the purchase of \$4.3 million of property and equipment, \$751,000 in repayments of long-term debt, and \$761,000 associated with the retirement of common stock to pay

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minimum tax withholding obligations on restricted shares that vested during the current period. At September 30, 2007, the Company's working capital was \$105.5 million.

Net cash provided by operating activities was \$7.8 million in the first nine months of 2007. Sources of operating cash during this period included net income of \$2.4 million, stock-based compensation of \$4.5 million, a deferred income tax provision of \$1.6 million resulting from utilization of our net operating loss carryforwards, depreciation and amortization of \$2.0 million, a provision for excess and obsolete inventories of \$772,000, a \$667,000 decrease in prepaid expenses and other assets primarily related to the amortization of prepaid insurance and real estate taxes, and a \$2.0 million increase in accounts payable and accrued expenses, primarily related to accruals for current period purchases, profit sharing, 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 \$3.0 million increase in inventories primarily related to increased demand in our cryosurgical and infectious disease product lines, and a \$1.7 million increase in accounts receivable at September 30, 2007. Overall accounts receivable balances have increased in the current nine-month period due to higher revenues.

Net cash used in investing activities during the first nine months of 2007 was \$9.0 million. During this nine-month period, we paid \$4.0 million pursuant to a certain patent and license agreement, purchased \$4.3 million of property and equipment, and invested \$2.5 million in short-term investments. We also received \$1.8 million from the sale of our investment in a nonaffiliated company. We expect capital expenditures for the full year to be approximately \$5.0 million as we purchase additional manufacturing equipment, upgrade certain older equipment and make improvements to our facilities.

Net cash provided by financing activities was \$231,000, reflecting \$751,000 of loan principal repayments and the early pay off of one of the Company's mortgage loans and \$761,000 for the retirement of common stock, offset by proceeds of \$1.7 million received from the exercise of stock options.

We have in place a \$21.0 million credit facility with Comerica Bank (the Credit Facility), which is comprised of a \$3.0 million term loan, a \$10.0 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 September 30, 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. On June 28, 2007, we executed an amendment to our Credit Facility, pursuant to which the maturity date of our \$4,000,000 revolving working capital line of credit was extended to June 29, 2009. We also determined that we would not need to borrow the \$5,000,000 in additional advances to fund future expansion of our facilities in Bethlehem, Pennsylvania. Accordingly, we allowed this \$5,000,000 in availability under our Credit Facility to expire, unused on June 30, 2007. All other terms of our Credit Facility, as previously amended, remain in effect.

On September 28, 2007, the Company repaid its outstanding balance of approximately \$669,000 under the original \$887,000 mortgage loan payable to Comerica Bank.

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

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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 September 30, 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.

As of December 31, 2006, we had net operating loss ( NOL ) carryforwards of \$53.0 million for federal income tax purposes. The net deferred tax asset associated with these NOLs and other temporary differences was \$23.5 million and \$22.0 million at December 31, 2006 and September 30, 2007, respectively. 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. We have 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, we concluded that prior ownership changes may impose a limitation on the amount of NOLs that can be utilized in a given year. We do 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.

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, and other factors.

**Table of Contents****Summary of Contractual Obligations**

The following sets forth our approximate aggregate obligations at September 30, 2007 for future payments under contracts and other contingent commitments, for 2007 and beyond:

Contractual Obligations	Total	Payments due by December 31,					
		2007	2008	2009	2010	2011	Thereafter
Long-term debt <sup>1</sup>	\$ 9,888,425	\$ 514,010	\$ 556,751	\$ 557,897	\$ 509,762	\$ 7,750,005	\$
Operating leases <sup>2</sup>	167,508	79,884	76,211	11,413			
Employment contracts <sup>3</sup>	3,975,975	1,580,550	1,487,100	683,925	224,400		
Purchase obligations <sup>4</sup>	12,546,877	11,294,861	1,252,016				
Minimum commitments under contracts <sup>5</sup>	5,291,667	\$	\$ 500,000	\$ 500,000	\$ 500,000	\$ 500,000	\$ 3,291,667
Total contractual obligations	\$ 31,870,452	\$ 13,469,305	\$ 3,872,078	\$ 1,753,235	\$ 1,234,162	\$ 8,250,005	\$ 3,291,667

<sup>1</sup> Represents principal repayments required under notes payable to our lenders.

<sup>2</sup> Represents payments required under our operating leases.

<sup>3</sup> Represents salary payments payable under the terms of employment agreements executed by us with certain officers and employees.

<sup>4</sup> Represents payments required by non-cancelable purchase orders related to inventory, capital expenditures and other goods or services.

<sup>5</sup> Represents payments required pursuant to a certain research, licensing and royalty agreement executed by the Company. This agreement is cancelable within a specified number of days of communication by the Company to terminate such agreement. Additional payments up to \$5.5 million may be required for the achievement of specific development and/or commercial milestones, pursuant to one of the licensing agreements.

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**Table of Contents****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. A more detailed review of our critical accounting policies is contained in our 2006 Annual Report on Form 10-K filed with the Securities and Exchange Commission. During the first three quarters of 2007, there have been no material changes in our critical accounting policies.

**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 September 30, 2007, approximately \$9.8 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 \$97,500 in additional interest expense.

As of September 30, 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 \$268,000 of our total revenues for the nine months ended September 30, 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 September 30, 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

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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 September 30, 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 improve 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 September 30, 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**

#### **Schering-Plough Patent Infringement Litigation**

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

In June 2007, the District Court issued a decision denying each party's motions for summary judgment. In reaching this decision, the Court eliminated several legal defenses raised by Schering-Plough.

A status conference in this lawsuit was held in early September and the trial was scheduled by the Court to commence on December 10, 2007. In late September 2007, the Court also issued a decision denying Schering-Plough's request that the Court reconsider a portion of its June 13 decision dealing with one of the three patents asserted in this case, i.e. No. 4,865,028.

#### **Prestige Brands Dispute**

Prestige, through an affiliate, is the exclusive distributor of our cryosurgical wart removal product in the OTC market in the United States and Canada. Prestige distributes this product under its Compound W Freeze Off® trade name. In September 2006, Prestige announced that it had acquired the Wartner® cryosurgical wart removal product line, which directly competes with the Freeze Off® product in the OTC market.

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® 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. As a result, an arbitration was commenced pursuant to the alternative dispute resolution provisions of the agreement. During the arbitration, Prestige asserted various counterclaims against us.

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On October 22, 2007, we received a decision in the arbitration concluding, among other things, that (1) the acquisition of Wartner® by Prestige was a breach of the distribution agreement, (2) we are entitled to an award of our legal fees and our share of the compensation paid to the arbitrators, (3) all of Prestige's counterclaims are rejected, (4) our request for specific performance of the agreement is denied and we are not entitled to additional compensatory damages, and (5) the distribution agreement will terminate on December 31, 2007. The arbitration decision is final and binding and not subject to direct appeal by either party. In order to obtain recovery of legal fees, we are required to submit proof of the incurrence of such fees for approval by the arbitrators. Prestige is likely to contest our claim.

**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.



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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.

Date: November 2, 2007

*/s/ Ronald H. Spair*  
Ronald H. Spair  
Chief Operating Officer and Chief Financial Officer  
(Principal Financial Officer)

Date: November 2, 2007

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

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**EXHIBIT INDEX**

**Exhibit**

- 10.1 Fifth Amendment to Loan and Security Agreement, dated as of June 28, 2007, between OraSure Technologies, Inc. and Comerica Bank, is incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K filed July 5, 2007.
- 10.2 Letter Agreement, dated September 24, 2007, between OraSure Technologies, Inc. and SSL International plc, is incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K filed September 28, 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.