ORASURE TECHNOLOGIES INC
Form 10-Q
November 02, 2007
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# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 10-Q

**(Mark One)**

**x 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**

# ORASURE TECHNOLOGIES, INC.

**(Exact Name of Registrant as Specified in Its Charter)**

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

**(610) 882-1820**

**(Registrant s Telephone Number, Including Area Code)**

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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 x 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 x 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 x

Number of shares of Common Stock, par value $.000001 per share, outstanding as of October 31, 2007: 46,618,564

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**PART I. FINANCIAL INFORMATION**

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**Item 1. FINANCIAL STATEMENTS**

**ORASURE TECHNOLOGIES, INC.**

**BALANCE SHEETS**

**(Unaudited)**

| | SEPTEMBER 30, 2007 | DECEMBER 31, 2006 |
|---|---|---|
| **ASSETS** | | |
| 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 |
| **LIABILITIES AND STOCKHOLDERS EQUITY** | | |
| 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.

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**ORASURE TECHNOLOGIES, INC.**

**STATEMENTS OF OPERATIONS**

**(Unaudited)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2007 | 2006 | 2007 | 2006 |
| REVENUES: | | | | |
| 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 |
| COST OF PRODUCTS SOLD | 8,647,522 | 6,365,346 | 24,121,646 | 18,516,174 |
| Gross profit | 12,767,809 | 11,273,969 | 38,755,128 | 31,904,880 |
| COSTS AND EXPENSES: | | | | |
| 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 |
| EARNINGS PER SHARE: | | | | |
| BASIC | $ | $ 0.05 | $ 0.05 | $ 0.09 |
| DILUTED | $ | $ 0.05 | $ 0.05 | $ 0.09 |
| SHARES USED IN COMPUTING EARNINGS PER SHARE | | | | |
| 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.

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**ORASURE TECHNOLOGIES, INC.**

**STATEMENTS OF CASH FLOWS**

**(Unaudited)**

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2007** | **2006** |
| OPERATING ACTIVITIES: | | |
| 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 |
| Net cash provided by operating activities | 7,787,307 | 14,051,521 |
| INVESTING ACTIVITIES: | | |
| 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 | |
| Net cash used in investing activities | (9,018,707) | (39,277,912) |
| FINANCING ACTIVITIES: | | |
| 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) |
| Net cash provided by financing activities | 231,432 | 9,423,749 |
| EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH | | 5,832 |
| NET DECREASE IN CASH AND CASH EQUIVALENTS | (999,968) | (15,796,810) |
| CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD | 19,949,821 | 32,826,740 |
| CASH AND CASH EQUIVALENTS, END OF PERIOD | $ 18,949,853 | $ 17,029,930 |
| SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION: | | |
| Cash paid for: | | |

| | | | | |
|---|---|---|---|---|
| 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 |
|---|---|---|---|---|
| **September 30, 2007** | | | | |
| 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 |
| **December 31, 2006** | | | | |
| 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 |
| **At September 30, 2007, maturities of investments were as follows:** | | | | |
| 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, | | September 30, | |
| | 2007 | 2006 | 2007 | 2006 |
| **Customer** | | | | |
| 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 September 30, | | Nine Months Ended 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:

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

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:

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

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 Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2007 | 2006 | 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 |

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**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*® 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*® 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*® 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*® 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*® 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*® 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*® 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*® 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® 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.

| | Three Months Ended September 30, | | | | |
|---|---|---|---|---|---|
| | Dollars | | | Percentage of Total Revenues | |
| | 2007 | 2006 | % Change | 2007 | 2006 |
| **Market** | | | | | |
| 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 |