

ORASURE TECHNOLOGIES INC
Form 10-Q
May 07, 2008
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 31, 2008.

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)

Edgar Filing: ORASURE TECHNOLOGIES INC - Form 10-Q

DELAWARE
(State or Other Jurisdiction of
Incorporation or Organization)

36-4370966
(IRS Employer
Identification No.)

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

18015
(Zip code)

(610) 882-1820

(Registrant's Telephone Number, Including Area Code)

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

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company
Indicate by checkmark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

Number of shares of Common Stock, par value \$.000001 per share, outstanding as of May 2, 2008: 46,846,982

Table of Contents

| PART I. FINANCIAL INFORMATION | | Page No. |
|---|--|-----------------|
| <u>Item 1. Financial Statements (unaudited)</u> | | 3 |
| <u>Balance Sheets at March 31, 2008 and December 31, 2007</u> | | 3 |
| <u>Statements of Operations for the three months ended March 31, 2008 and 2007</u> | | 4 |
| <u>Statements of Cash Flows for the three months ended March 31, 2008 and 2007</u> | | 5 |
| <u>Notes to Financial Statements</u> | | 6 |
| <u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u> | | 13 |
| <u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u> | | 22 |
| <u>Item 4. Controls and Procedures</u> | | 22 |
| <u>PART II. OTHER INFORMATION</u> | | |
| <u>Item 1. Legal Proceedings</u> | | 22 |
| <u>Item 1A Risk Factors.</u> | | 23 |
| <u>Item 6. Exhibits</u> | | 23 |
| <u>Signatures</u> | | 24 |

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

| | MARCH 31, 2008 | DECEMBER 31, 2007 |
|---|----------------|-------------------|
| ASSETS | | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | \$ 12,516,849 | \$ 32,229,697 |
| Short-term investments | 77,878,638 | 63,336,408 |
| Accounts receivable, net of allowance for doubtful account of \$86,294 and \$186,468 | 13,728,720 | 11,296,355 |
| Inventories | 9,929,487 | 9,409,743 |
| Deferred income taxes | 2,200,344 | 5,060,974 |
| Prepaid expenses and other | 2,433,110 | 2,455,534 |
| Total current assets | 118,687,148 | 123,788,711 |
| PROPERTY AND EQUIPMENT, net | 21,171,942 | 20,911,157 |
| PATENTS AND PRODUCT RIGHTS, net | 5,017,252 | 5,279,471 |
| DEFERRED INCOME TAXES | 19,328,441 | 17,265,591 |
| OTHER ASSETS | 96,001 | 107,586 |
| | \$ 164,300,784 | \$ 167,352,516 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| CURRENT LIABILITIES: | | |
| Current portion of long-term debt | \$ 557,036 | \$ 556,751 |
| Accounts payable | 3,653,921 | 5,615,998 |
| Accrued expenses and other | 8,440,597 | 11,995,710 |
| Total current liabilities | 12,651,554 | 18,168,459 |
| LONG-TERM DEBT | 8,719,971 | 8,817,669 |
| OTHER LIABILITIES | 69,504 | 311,799 |
| STOCKHOLDERS' EQUITY | | |
| Preferred stock, par value \$.000001, 25,000,000 shares authorized, none issued | | |
| Common stock, par value \$.000001, 120,000,000 shares authorized, 46,846,982 and 46,644,046 shares issued and outstanding | 47 | 47 |
| Additional paid-in capital | 237,011,531 | 236,293,489 |
| Accumulated other comprehensive loss | (153,509) | (238,896) |
| Accumulated deficit | (93,998,314) | (96,000,051) |
| Total stockholders' equity | 142,859,755 | 140,054,589 |
| | \$ 164,300,784 | \$ 167,352,516 |

The accompanying notes are an integral part of these statements.

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

| | Three Months Ended March 31, | |
|--|---|---------------------|
| | 2008 | 2007 |
| REVENUES: | | |
| Product | \$ 17,635,611 | \$ 19,430,185 |
| Licensing and product development | 453,208 | 678,890 |
| | 18,088,819 | 20,109,075 |
| COST OF PRODUCTS SOLD | 7,445,851 | 7,584,420 |
| Gross profit | 10,642,968 | 12,524,655 |
| COSTS AND EXPENSES: | | |
| Research and development | 4,597,631 | 2,919,884 |
| Sales and marketing | 5,215,989 | 4,770,743 |
| General and administrative | 3,840,781 | 4,237,351 |
| | 13,654,401 | 11,927,978 |
| Operating income (loss) | (3,011,433) | 596,677 |
| INTEREST EXPENSE | (83,126) | (166,079) |
| INTEREST INCOME | 1,017,805 | 1,135,347 |
| OTHER INCOME | 4,883,714 | 1,428,691 |
| FOREIGN CURRENCY LOSS | (73,000) | (9,348) |
| Income before income taxes | 2,733,960 | 2,985,288 |
| INCOME TAX PROVISION | 732,223 | 1,498,765 |
| NET INCOME | \$ 2,001,737 | \$ 1,486,523 |
| EARNINGS PER SHARE: | | |
| BASIC | \$ 0.04 | \$ 0.03 |
| DILUTED | \$ 0.04 | \$ 0.03 |
| SHARES USED IN COMPUTING EARNINGS PER SHARE | | |
| BASIC | 46,783,527 | 46,114,260 |
| DILUTED | 47,267,643 | 46,553,920 |

The accompanying notes are an integral part of these statements.

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

| | Three Months Ended March 31, | |
|---|-------------------------------------|----------------------|
| | 2008 | 2007 |
| OPERATING ACTIVITIES: | | |
| Net income | \$ 2,001,737 | \$ 1,486,523 |
| Adjustments to reconcile net income to net cash used in operating activities: | | |
| Gain on sale of investment in nonaffiliated company | | (1,428,691) |
| Stock-based compensation | 1,385,668 | 1,380,444 |
| Deferred income taxes | 745,885 | 1,086,053 |
| Depreciation and amortization | 690,693 | 655,700 |
| Provision for excess and obsolete inventories | 370,332 | 165,293 |
| Changes in assets and liabilities: | | |
| Accounts receivable | (2,433,811) | (4,486,961) |
| Inventories | (890,076) | (719,873) |
| Prepaid expenses and other assets | 34,009 | 101,279 |
| Accounts payable, accrued expenses, and other liabilities | (5,613,823) | 751,484 |
| Net cash used in operating activities | (3,709,386) | (1,008,749) |
| INVESTING ACTIVITIES: | | |
| Purchase of short-term investments | (36,608,135) | (26,540,067) |
| Proceeds from maturities and redemptions of short-term investments | 22,204,837 | 27,711,438 |
| Purchase of property and equipment | (755,312) | (898,045) |
| Payments of patents and licenses | | (4,000,000) |
| Proceeds from sale of investment in nonaffiliated company | | 1,765,944 |
| Net cash used in investing activities | (15,158,610) | (1,960,730) |
| FINANCING ACTIVITIES: | | |
| Repayments of long-term debt | (97,413) | (35,136) |
| Proceeds from issuance of common stock | 92,517 | 372,243 |
| Withholding and retirement of common stock | (839,956) | (539,219) |
| Net cash used in financing activities | (844,852) | (202,112) |
| NET DECREASE IN CASH AND CASH EQUIVALENTS | (19,712,848) | (3,171,591) |
| CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD | 32,229,697 | 19,949,821 |
| CASH AND CASH EQUIVALENTS, END OF PERIOD | \$ 12,516,849 | \$ 16,778,230 |
| SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION: | | |
| Cash paid for: | | |
| Interest | \$ 125,302 | \$ 169,718 |
| Income taxes | \$ 371,284 | \$ 94,500 |

The accompanying notes are an integral part of these statements.

Table of Contents

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 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, 2007. Results of operations for the three-month period ended March 31, 2008 are not necessarily indicative of the results of operations expected for the full year.

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

Cash and Cash Equivalents. We consider all highly liquid investments with a purchased maturity of ninety days or less to be cash equivalents. As of March 31, 2008 and December 31, 2007, cash equivalents consisted of commercial paper, U.S. government obligations, corporate bonds, and certificates of deposit.

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).

Table of Contents

The following is a summary of our available-for-sale securities at March 31, 2008 and December 31, 2007:

| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|--|-------------------|------------------------------|-------------------------------|---------------|
| March 31, 2008 | | | | |
| Certificates of deposit | \$ 4,222,915 | \$ 17,123 | \$ | \$ 4,240,038 |
| Commercial paper | 20,026,530 | 16,565 | (1,275) | \$ 20,041,820 |
| Government and agency bonds | 10,602,812 | 49,713 | (3,949) | \$ 10,648,576 |
| Corporate bonds | 42,902,330 | 97,939 | (52,065) | \$ 42,948,204 |
| Total available-for-sale securities | \$ 77,754,587 | \$ 181,340 | \$ (57,289) | \$ 77,878,638 |
| December 31, 2007 | | | | |
| Certificates of deposit | \$ 2,721,321 | \$ 3,759 | \$ (6,925) | \$ 2,718,155 |
| Commercial paper | 4,383,327 | 1,158 | (92) | \$ 4,384,393 |
| Government and agency bonds | 5,541,885 | 15,681 | | \$ 5,557,566 |
| Corporate bonds | 50,704,757 | 24,104 | (52,567) | \$ 50,676,294 |
| Total available-for-sale securities | \$ 63,351,290 | \$ 44,702 | \$ (59,584) | \$ 63,336,408 |
| At March 31, 2008, maturities of our available-for-sale securities were as follows: | | | | |
| Less than one year | \$ 73,490,513 | \$ 168,272 | \$ (30,408) | \$ 73,628,377 |
| One to two years | 4,264,074 | 13,068 | (26,881) | 4,250,261 |
| Total available-for-sale securities | \$ 77,754,587 | \$ 181,340 | \$ (57,289) | \$ 77,878,638 |

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

| | March 31, 2008 | December 31, 2007 |
|-----------------|-------------------|----------------------|
| Raw materials | \$ 5,748,210 | \$ 4,924,139 |
| Work in process | 611,753 | 386,535 |
| Finished goods | 3,569,524 | 4,099,069 |
| | \$ 9,929,487 | \$ 9,409,743 |

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 recorded net of allowances for any discounts or rebates. We do not grant price protection or product return rights to our customers, except for warranty returns. Historically, returns arising from warranty issues have been infrequent and immaterial. Accordingly, we expense warranty returns as incurred.

Royalty income from the grant of license rights is recognized during the period in which the revenue is earned and the amount is determinable from the licensee. We may also receive consideration from the settlement of patent infringement litigation where there was no prior patent license agreement. We record the consideration related to the settlement of such patent infringement litigation as other income.

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

Table of Contents

is recognized as the related work is performed and costs are incurred. We record shipping and handling charges billed to our customers as product revenue and the related expense as cost of products sold. Taxes assessed by governmental authorities, such as sales or value-added taxes, are excluded from product revenues.

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

| Customer | Percentage of Total Revenues Three Months Ended March 31, | |
|---------------------------------|--|------|
| | 2008 | 2007 |
| Quest Diagnostics, Incorporated | 9% | 10% |
| Abbott Laboratories | 11 | 11 |
| Prestige Brands Holdings, Inc. | | 11 |

| | Percentage of Accounts Receivable | |
|---------------------------------|-----------------------------------|-------------------|
| | March 31, 2008 | December 31, 2007 |
| Quest Diagnostics, Incorporated | 8% | 11% |
| SSL International plc | 19 | 13 |

As a result of the decision in the arbitration proceedings with respect to Prestige's acquisition of the competing Wartner cryosurgical product line, our distribution agreement with Prestige terminated on December 31, 2007.

Research and Development. Research and development expenses consist of expenses incurred in performing research and development activities including salaries and benefits, facilities expenses, overhead expenses, clinical trial and related clinical manufacturing expenses, contract services and other outside expenses. Research and development costs are charged to expense as incurred. Clinical trial expenses include expenses associated with contract research organizations, or CROs. The invoicing from CROs for services can precede the services provided or can lag several months. Invoices paid prior to service being provided are recorded as a prepaid expense and expensed appropriately as services are provided. We accrue the cost of services rendered in connection with CRO activities based on purchase order estimates provided by the CRO. Differences between actual and estimated clinical trial expenses recorded are generally not material and are adjusted for in the period in which they become known.

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.

Table of Contents

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

| | Three Months Ended March 31, | |
|---|---------------------------------|--------------|
| | 2008 | 2007 |
| Net income | \$ 2,001,737 | \$ 1,486,523 |
| Weighted average shares of common stock outstanding: | | |
| Basic | 46,783,527 | 46,114,260 |
| Dilutive effect of stock options, warrants and restricted stock | 484,116 | 439,660 |
| Diluted | 47,267,643 | 46,553,920 |
| Earnings per share: | | |
| Basic | \$ 0.04 | \$ 0.03 |
| Diluted | \$ 0.04 | \$ 0.03 |

For the three-month periods ended March 31, 2008 and 2007, outstanding common stock options and unvested restricted stock, representing 3,199,598 and 2,367,708 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 March 31, 2008 and December 31, 2007 consisted of currency translation adjustments and net unrealized gains or losses on marketable securities. Comprehensive income was \$2,087,124 and \$1,413,264 for the three months ended March 31, 2008 and 2007, respectively.

Recent Accounting Pronouncements. In September 2006, the Financial Accounting Standards Board (FASB) issued SFAS No. 157, Fair Value Measurements. This Statement defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. On February 8, 2008, the FASB issued Staff Position 157-2, Effective Date of FASB 157 (FSP 157-2), which deferred the provisions of SFAS No. 157 to annual periods beginning after November 15, 2008 for non-financial assets and liabilities. Non-financial assets include fair value measurements associated with business acquisitions and impairment testing of tangible and intangible assets. See additional disclosures in Note 7, Fair Value of Financial Instruments, regarding the impact of the adoption of SFAS No. 157.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115. SFAS No. 159 permits entities to elect to measure many financial instruments and certain other items at fair value. Unrealized gains and losses on items for which the fair value option has been elected will be recognized in earnings at each subsequent reporting date. SFAS No. 159 is effective in the first quarter of fiscal year 2008. We have elected not to apply the fair value option to any of our financial instruments.

3. Stock-Based Compensation

We grant stock-based awards under the OraSure Technologies, Inc. 2000 Stock Award Plan, as amended and restated (the 2000 Plan). The 2000 Plan permits stock-based awards to employees, outside directors, and

Table of Contents

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

The fair value of each stock option is estimated on the date of the grant using the Black-Scholes option-pricing model. The weighted average grant date fair value of stock options granted during the three months ended March 31, 2008 and 2007 was \$3.14 and \$3.58, respectively.

Total compensation cost related to stock options for the three months ended March 31, 2008 and 2007 was \$544,414 (\$441,267, net of tax) and \$722,707 (\$539,535, net of tax), respectively, of which \$23,234 and \$83,353 was capitalized into inventory during the quarters ended March 31, 2008 and 2007, respectively. The amounts recognized in cost of products sold for amounts previously capitalized were \$56,672 and \$80,824 for the three months ended March 31, 2008 and 2007, respectively.

The following table summarizes the stock option activity for the three months ended March 31, 2008:

| | Options |
|-----------------------------------|----------------|
| Outstanding on January 1, 2008 | 4,726,541 |
| Granted | 465,629 |
| Exercised | (14,786) |
| Forfeited | (8,582) |
| Outstanding on March 31, 2008 | 5,168,802 |

As of March 31, 2008, there was \$4,128,316 of unrecognized compensation expense related to unvested option awards that is expected to be recognized over a weighted average period of 1.8 years.

Net cash proceeds from the exercise of stock options were \$92,517 and \$372,243 for the three months ended March 31, 2008 and 2007, 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.

As mentioned above, the 2000 Plan permits us to grant restricted shares of our common stock to eligible employees, including officers. Generally, these shares are nontransferable and are subject to three-year vesting requirements or forfeiture, as determined by the Compensation Committee of our Board of Directors. The market value of these shares at the date of grant is recognized on a straight-line basis over the period during which the restrictions lapse. During the three months ended March 31, 2008, we granted 388,565 restricted shares of our common stock, with a grant date fair value of \$8.06, to certain key officers and members of management. Compensation cost of \$841,254 and \$657,737 related to restricted shares was recognized during the three months ended March 31, 2008 and 2007, respectively.

Table of Contents

The following table summarizes restricted stock award activity for the three months ended March 31, 2008:

| | Shares |
|--------------------------------------|-----------|
| Issued and unvested, January 1, 2008 | 882,961 |
| Granted | 388,565 |
| Vested | (290,278) |
| Forfeited | |
| Issued and unvested, March 31, 2008 | 981,248 |

As of March 31, 2008, there was \$7,318,614 of unrecognized compensation expense related to unvested restricted stock awards that is expected to be recognized over a weighted average period of 2.9 years.

In connection with the vesting of restricted shares during the three-months ended March 31, 2008 and 2007, 102,128 and 64,913 shares with aggregate values of \$839,956 and \$539,219, respectively, were withheld and retired in satisfaction of minimum tax withholding obligations.

4. Accrued Expenses

| | March 31, 2008 | December 31, 2007 |
|------------------------------|-------------------|----------------------|
| Payroll and related benefits | \$ 2,344,796 | \$ 3,771,489 |
| Deferred revenue | 1,979,592 | 2,841,640 |
| Royalties | 1,963,154 | 2,485,869 |
| Advertising | 497,764 | 288,020 |
| Professional fees | 304,444 | 1,371,850 |
| Other | 1,350,847 | 1,236,842 |
| | \$ 8,440,597 | \$ 11,995,710 |

Deferred revenue at March 31, 2008 and December 31, 2007 included customer prepayments of \$1,844,699 and \$2,726,440, respectively.

5. Other Income

On January 11, 2008, we entered into a settlement and license agreement with Schering-Plough Healthcare Products, Inc. (Schering) to resolve our patent infringement litigation against Schering. Under the terms of the agreement, Schering was required to make a payment of \$4.9 million to us. This payment was received during the first quarter of 2008 and recorded in other income.

In January 2007, our shares in a privately-held nonaffiliated company were sold and we received \$1,765,943 for our ownership interest. Accordingly, during the first quarter of 2007, we recorded a \$1,428,691 pre-tax gain on the sale of this investment in other income.

6. 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 our revenues outside the United States are export sales, and we do not have significant operating assets outside the United States.

Table of Contents

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

| | Three Months Ended March 31, | |
|---------------|---|-------------|
| | 2008 | 2007 |
| United States | \$ 14,142 | \$ 16,232 |
| Europe | 2,437 | 2,507 |
| Other regions | 1,510 | 1,370 |
| | \$ 18,089 | \$ 20,109 |

7. Fair Value of Financial Instruments

We adopted SFAS No. 157 effective January 1, 2008 for financial assets and liabilities measured on a recurring basis. SFAS No. 157 applies to all financial assets and financial liabilities that are being measured and reported on a fair value basis. Upon adoption of SFAS No. 157, there was no impact to our consolidated financial statements. The statement requires fair value measurements be classified and disclosed in one of the following three categories:

- Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;
- Level 2: Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability;
- Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

All our available for sale securities included in Note 2 were classified and measured as Level 1 instruments.

8. Recent Litigation

On April 22, 2008, a complaint was filed against us in the United States District Court for the District of New Jersey by Inverness Medical Innovations, Inc., Inverness Medical Switzerland GmbH and Church & Dwight Co., Inc., alleging that we infringed U.S. Patent No. 6,485,982. The complaint specifically refers to our OraQuick *ADVANCE*[®] Rapid HIV-1/2 Antibody Test. The complaint seeks injunctive relief, damages and an award of attorneys' fees. We believe that none of our products, including the OraQuick *ADVANCE* HIV test, infringe the patent asserted in this lawsuit or any other party's intellectual property rights. We also believe that the patent asserted in this matter is invalid or unenforceable, and we intend to defend this lawsuit vigorously. We are unable at this time to determine the impact, if any, that this lawsuit may have on our financial statements.

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/loss per share, net income, 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; inventory levels at distributors and other customers; 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 and legal requirements; history of losses and ability to achieve sustained profitability; volatility of our stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including changes in international funding sources; loss or impairment of sources of capital or investments; ability to meet financial covenants in agreements with financial institutions; ability to retain qualified personnel; exposure to patent infringement, product liability and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; ability to complete consolidation or restructuring activities; ability to identify, complete and realize the full benefits of potential acquisitions; and general political, business and economic conditions. These and other factors that could cause the forward-looking statements to be materially different are described in greater detail in our filings with the Securities and Exchange Commission, including our registration statements and our Annual Report on Form 10-K for the year ended December 31, 2007. 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 *in vitro* diagnostic business. Our business principally involves the development, manufacture, marketing and sale of oral fluid diagnostic products and specimen collection devices using our proprietary oral fluid technologies, as well as other diagnostic products including immunoassays and other *in vitro* diagnostic tests that are used on other specimen types, and other medical devices used for the removal of warts and other benign skin lesions by cryosurgery, or freezing. Our diagnostic products include tests which are performed on a rapid basis at the point of care and tests which are processed in a laboratory. 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 has been sold in the over-the-counter (OTC) or consumer retail market in the United States, Canada, Europe, Mexico and Australia.

Table of Contents

In vitro diagnostic testing is the process of analyzing oral fluid, blood, urine and other bodily fluids or tissue for the presence of specific substances or markers for infectious diseases, drugs of abuse or other conditions. 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. *In vitro* diagnostic tests are performed outside the body, in contrast to *in vivo* tests, which are performed directly on or within the body. When combined with their ease of use, non-invasive and dignified nature, and cost effectiveness, our oral fluid tests represent a very competitive alternative to the more traditional testing methods in the diagnostic space.

During the three months ended March 31, 2008, our total revenues were \$18.1 million, which represents a 10% decrease from the same period in 2007. Our net income for the first quarter of 2008 was \$2.0 million, compared to \$1.5 million for the first quarter of 2007. Cash flow used in operating activities was \$3.7 million primarily as a result of increases in accounts receivable and inventories coupled with a decrease in accrued expenses. As of March 31, 2008, we had \$90.4 million in cash, cash equivalents and short-term investments, a \$5.2 million decrease from December 31, 2007.

Sales into the infectious disease testing market increased in the first quarter of 2008 as a result of increased demand for our OraQuick *ADVANCE*[®] HIV-1/2 test. This increase resulted largely from increased sales directly to various public health organizations, which reflects continued growth of our base business and incremental sales resulting from the testing initiatives funded by the Centers for Disease Control and Prevention (CDC) and directed to the populations disproportionately affected by HIV/AIDS.

We have an agreement for the distribution of OraQuick *ADVANCE*[®] with Abbott Laboratories (Abbott), which was renewed for 2008. Under this agreement, Abbott is our exclusive distributor in the U.S. hospital market and a non-exclusive distributor in the U.S. physicians' office marketplace. As our exclusive distributor to hospitals, Abbott sells OraQuick *ADVANCE*[®] to federal hospitals under the terms and conditions of our Federal Supply Schedule that is 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, the Substance Abuse and Mental Health Services Administration (SAMHSA) and other government agencies. We utilize a small internal sales force to support Abbott and work together with them to maximize the penetration of OraQuick *ADVANCE*[®] in the hospital market.

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.

Sales of our cryosurgical products decreased during the first quarter of 2008 compared to 2007 as a result of the termination of the distribution agreement for our domestic OTC product, as well as a decrease in sales of our OTC product internationally. The cryosurgical systems market represents sales of Histofreezer[®] into both the domestic and international physicians' office markets and sales of the OTC formulation of this product through international distributors. Prestige Brands Holdings, Inc. (Prestige) previously distributed our cryosurgical wart removal product under its Compound W Freeze Off[®] tradenames in the OTC market in the United States and Canada. Our distribution agreement with Prestige terminated on December 31, 2007. As a result, we are currently evaluating alternative strategies for the OTC distribution of this product in the United States and Canada. However, it is not possible to predict at this time what the terms of such an arrangement might be or if such an arrangement will be successful.

SSL International plc (SSL) distributes our cryosurgical product under its Scholl's and Dr. Scholl trademarks in the OTC market in several European countries, Australia and New Zealand. Genomma Labs (Genomma) also distributes a similar product to the OTC market in Mexico and has rights to Argentina, Brazil, various other Latin American countries and South Africa. Overall, our international OTC cryosurgical sales decreased 22% in 2008 compared to the prior year due to the purchasing patterns and inventory levels maintained by these distributors.

Table of Contents

Sales to the substance abuse testing market decreased during the first quarter of 2008, due primarily to economic conditions in the United States and reduced international public sector funding. Our workplace testing business has been impacted by the decline in employment rates in some of the markets that buy our Intercept® collection device and related assays. The international decrease in public sector funding in the international market has slowed the implementation of criminal justice testing. We expect renewed growth in the utilization of our Intercept® product line as employment conditions in the U.S. recover, international criminal justice funding is increased and customers continue to adopt oral fluid-based drug testing and shift away from traditional urine-based drug testing.

Sales to the insurance risk assessment market increased during the three months ended March 31, 2008, largely due to decreased sales in the first three months of 2007 due to the timing of purchases by our laboratory distributors in the latter part of 2006 and early 2007.

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 Food and Drug Administration (FDA) approvals could disrupt our ability to sell the affected products.

In past years, bioMerieux, Inc. (BMX) manufactured and sold the only oral fluid HIV-1 screening test that had received FDA approval for use in detecting HIV-1 in an oral fluid specimen collected with our OraSure® collection device. BMX also supplied the HIV-1 antigen used to manufacture our oral fluid Western blot HIV-1 confirmatory test and was the exclusive world-wide distributor of that product. BMX discontinued manufacturing their HIV-1 EIA screening test during 2007. As a result, we intend to seek FDA approval of an alternative HIV-1 EIA screening test for use with our OraSure® collection device. BMX also elected not to renew our Western blot agreements beyond December 31, 2007, and we are now selling the Western blot test directly to our laboratory customers.

We also rely heavily on distributors to purchase and resell many of our products. For example, Abbott has exclusive rights to distribute our OraQuick *ADVANCE*® HIV test to hospitals in the U.S. Similarly, SSL has exclusive rights to distribute our wart removal product in the OTC market in Europe, Australia and New Zealand. We also granted Genomma exclusive rights to distribute our wart removal product in the OTC market in Mexico, and in January 2008, we granted them similar rights in Argentina, Brazil, various other Latin American countries and South Africa.

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 or otherwise substantially reduce the volume of their purchases, our revenues and results of operations could be adversely affected.

During the three months ended March 31, 2008, we generated 78% of our revenues in the U.S. marketplace. We are continually evaluating strategies to increase our sales penetration in markets outside the U.S. As our business in foreign countries increases, we could be exposed to other economic, political, exchange rate, regulatory and cultural risks.

Results of Operations

Total revenues decreased 10% to \$18.1 million in the first quarter of 2008 from \$20.1 million in the comparable quarter in 2007. Increased sales of our OraQuick *ADVANCE*® rapid HIV-1/2 antibody test, professional cryosurgical product and insurance risk assessment testing products were offset by decreased sales of our OTC cryosurgical product and our substance abuse testing products. Revenues derived from products sold to customers outside the U.S. were \$3.9 million in the first quarters of 2008 and 2007, or 22% and 19% of total revenues, respectively.

Table of Contents

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.

| Market | Three Months Ended March 31, | | | Percentage of Total | |
|-----------------------------------|------------------------------|-----------|--------|---------------------|------|
| | Dollars | | % | Revenues | |
| | 2008 | 2007 | Change | 2008 | 2007 |
| Infectious disease testing | \$ 9,480 | \$ 8,932 | 6% | 52% | 45% |
| Substance abuse testing | 3,277 | 3,929 | (17) | 18 | 20 |
| Cryosurgical systems | 3,336 | 5,680 | (41) | 18 | 28 |
| Insurance risk assessment | 1,538 | 889 | 73 | 9 | 4 |
| Product revenues | 17,631 | 19,430 | (9) | 97 | 97 |
| Licensing and product development | 458 | 679 | (33) | 3 | 3 |
| Total revenues | \$ 18,089 | \$ 20,109 | (10)% | 100% | 100% |

Sales to the infectious disease testing market increased 6% to \$9.5 million in the first quarter of 2008, primarily as a result of the increasing demand for our OraQuick *ADVANCE*[®] rapid HIV-1/2 antibody test. OraQuick[®] sales totaled \$8.9 million and \$8.2 million in the first quarters of 2008 and 2007, respectively. Sales of our OraSure[®] oral fluid collection device totaled \$627,000 and \$743,000 in the first quarters of 2008 and 2007, respectively.

The table below shows a breakdown of our total OraQuick[®] revenues (in thousands, except %) during the first quarters of 2008 and 2007.

| Customers | Three Months Ended March 31, | | |
|--------------------------------------|------------------------------|----------|----------|
| | 2008 | 2007 | % Change |
| Direct to U.S. Public Health | \$ 6,282 | \$ 4,342 | 45% |
| Abbott | 1,925 | 2,151 | (11) |
| SAMHSA | | 329 | (100) |
| CDC | | 620 | (100) |
| International | 646 | 747 | (14) |
| Total OraQuick [®] revenues | \$ 8,853 | \$ 8,189 | 8% |

During the first quarter of 2008, OraQuick[®] revenue derived from direct sales to the U.S. public health market increased by 45% as compared to the same period of 2007. This increase is the result of continued growth in usage of the OraQuick *ADVANCE*[®] rapid HIV-1/2 antibody test in public health settings, including city-wide testing programs. In September 2007, the CDC awarded incremental 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 during 2008. Sales relating to city-wide testing initiatives increased 96% to \$589,000 during the first quarter of 2008, compared to \$300,000 in 2007.

For the three months ended March 31, 2008, sales to our hospital distributor, Abbott, decreased 11% to \$1.9 million, as compared to \$2.2 million in 2007. This decrease was largely the result of Abbott's ordering patterns, as well as increased competition in the hospital market.

Table of Contents

In previous periods, the CDC and SAMHSA placed bulk purchases orders for OraQuick *ADVANCE*[®] devices and related testing materials directly with the Company. It is not likely that comparable-sized bulk purchase orders from these governmental entities or others will be received in the future.

We believe that our OraQuick *ADVANCE*[®] device, which is FDA-approved for detecting antibodies to both HIV-1 and HIV-2 in oral fluid, finger-stick and venous whole blood, and plasma samples, and has received a waiver under the Clinical Laboratory Improvements Amendment of 1988 (CLIA) for use with all sample types except plasma, provides a significant competitive advantage, thereby enabling us to fully implement a strategy for selling OraQuick[®] internationally. We have received final CE mark approval for our OraQuick *ADVANCE*[®] test, thereby enabling us to sell this product in Europe. We have established distribution channels in several European countries and are pursuing other distributors elsewhere in the European Union.

International sales of our OraQuick[®] HIV test decreased 14% to \$646,000 in the three months ended March 31, 2008 compared to \$747,000 in 2007. The primary reason for the decrease was a 25% decrease in sales to Africa as a funding source for a large customer changed and the new source is requiring the purchase of a competing blood test that is less expensive than our oral fluid OraQuick[®] test.

We have continued to see evidence that sales of OraQuick *ADVANCE*[®] are negatively impacting sales of our OraSure[®] oral fluid collection device in the infectious disease testing market in the U.S. During the first quarter of 2008, our sales of OraSure[®] declined \$116,000. Some customers who have purchased our OraSure[®] device for laboratory HIV-1 testing in the past are now electing instead to purchase our OraQuick *ADVANCE*[®] test. It is not possible at this time to estimate the extent of such change in purchasing patterns or the future financial impact of replacing OraSure[®] sales with sales of our OraQuick *ADVANCE*[®] test.

Sales to the substance abuse testing market decreased 17% to \$3.3 million in the first quarter of 2008 from \$3.9 million in the first quarter of 2007, as sales of our Intercept[®] device for workplace testing were impacted by a continued decrease in employment rates domestically and a decrease in funding internationally. The international market experienced a decrease in public sector funding which has slowed the implementation of criminal justice testing.

The table below shows a breakdown of our total Intercept[®] revenues (in thousands, except %) generated in each market in the first quarters of 2008 and 2007.

| Market | Three Months Ended March 31, | | |
|---|------------------------------|-----------------|--------------|
| | 2008 | 2007 | % Change |
| Workplace testing | \$ 1,016 | \$ 1,545 | (34)% |
| Criminal justice | 619 | 645 | (4) |
| International | 525 | 600 | (13) |
| Direct | 271 | 202 | 34 |
| Total Intercept[®] revenues | \$ 2,431 | \$ 2,992 | (19)% |

We expect renewed growth in Intercept[®] sales as employment conditions in the U.S. recover, international criminal justice funding is increased and customers continue to shift from urine-based 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 jointly developing and intend to commercialize fully-automated homogeneous oral fluid drugs of abuse assays with Roche Diagnostics for use with our Intercept[®] device.

Table of Contents

Sales of our products in the cryosurgical systems market (which includes both the physicians' office and OTC markets) decreased 41% to \$3.3 million in the first quarter of 2008 from \$5.7 million in the same period of the prior year. This decrease was primarily the result of the absence of U.S. OTC cryosurgical product sales as a result of the termination of our distribution relationship for this product at the end of 2007, coupled with a decrease in international OTC cryosurgical products sales related to the variability of distributor purchases.

The table below shows a breakdown of our total cryosurgical systems revenues (in thousands, except %) generated in each market in the first quarters of 2008 and 2007.

| Market | Three Months Ended March 31, | | |
|--|------------------------------|-----------------|--------------|
| | 2008 | 2007 | % Change |
| Professional domestic | \$ 1,034 | \$ 1,053 | (2)% |
| Professional international | 737 | 467 | 58 |
| OTC domestic | | 2,150 | (100) |
| OTC international | 1,565 | 2,010 | (22) |
| Total cryosurgical systems revenues | \$ 3,336 | \$ 5,680 | (41)% |

Our domestic OTC cryosurgical product, called Freeze Off[®], was distributed in the United States and Canada by Prestige, owner of the Compound W[®] line of wart removal products. Our distribution agreement with Prestige terminated on December 31, 2007. Sales to Prestige were \$2.2 million during the first quarter of 2007. We are currently evaluating alternative arrangements for the OTC distribution of our product in the United States and Canada. However, it is not possible to predict at this time what the terms of such an arrangement might be or if such an arrangement will be successful.

We have an agreement with SSL under which we manufacture and supply, and SSL distributes on an exclusive basis, the Company's cryosurgical wart removal product in the OTC market in Europe, Australia and New Zealand. The product is manufactured and sold under SSL's Scholl and Dr. Scholl trademarks. Sales to SSL under the distribution agreement were \$1.2 million and \$1.5 million in the first quarters of 2008 and 2007, respectively. SSL continues to build distribution networks in pharmacies and mass merchandisers throughout Europe and expects to launch the OTC product in additional countries during 2008.

Early in 2007, we entered into an agreement with Genomma pursuant to which Genomma distributes on an exclusive basis our cryosurgical wart removal product in the OTC market in Mexico. Sales to Genomma under this distribution agreement were \$401,000 and \$503,000 in the first quarters of 2008 and 2007, respectively. Recently, we renewed our Mexico agreement and additional rights were given to Genomma in Argentina, Brazil, various other Latin American countries, and South Africa. In the Mexican OTC market, Genomma recently reduced their purchase forecast as a result of an unexpected return of product to them by a number of retail outlets in the latter part of the first quarter of 2008 due to overstocking of inventory during the winter months. We are working closely with Genomma to drive greater uptake of our product in the retail channel in Mexico and to generate new orders through sales in other Latin and South American countries. We believe these markets have potential for our cryosurgery product, but the full realization will be delayed.

Sales to the insurance risk assessment market increased 73% to \$1.5 million in the first quarter of 2008 compared to \$889,000 in 2007. This increase was primarily due to lower sales in the first three months of 2007 caused by the timing of purchases by laboratory distributors in the latter part of 2006 and early 2007.

During the first quarter of 2008, licensing and product development revenues decreased by \$221,000 from \$679,000 during 2007. First quarter 2008 licensing revenue included a payment from Schering-Plough Healthcare Products, Inc. (Schering-Plough) pursuant to our license and settlement agreement entered into in January 2008. We expect to continue to receive royalty revenues from Schering-Plough throughout the remainder of 2008.

Table of Contents

In December 2006, we entered into a collaboration agreement with Schering-Plough Corporation (SPC), for the development and promotion of a rapid oral fluid test for the detection of antibodies to HCV. During the three months ended March 31, 2007, the Company recognized \$652,000 in revenues associated with funded research and development under this agreement. We do not expect to recognize any additional licensing and product development revenues pursuant to this agreement. However, in early 2008, we entered into a new collaboration agreement with SPC for the development and promotion of our rapid oral fluid HCV test on a worldwide basis. Under the terms of the new agreement, we will retain the rights to market and sell the HCV test throughout the world, and SPC will reimburse us for certain development and regulatory costs based on the achievement of certain milestones. SPC will also provide promotional support for the product in international markets. Revenues from this agreement are not expected to be material in 2008.

Gross margin in the first quarter of 2008 was 59%, compared to 62% for the first quarter of 2007. Gross margin was negatively affected by several factors, including an unfavorable product mix versus the year ago period, increased scrap and spoilage expense, and higher unabsorbed overhead.

Research and development expenses increased 58% to \$4.6 million in the first quarter of 2008 from \$2.9 million in the same period in 2007, primarily as a result of costs associated with the clinical development of our OraQuick[®] HIV OTC and OraQuick[®] HCV tests. Research and development costs are expected to increase in 2008, primarily due to clinical trial work associated with the development of our OraQuick[®] HIV OTC test and our OraQuick[®] HCV test, as well as costs expected to be incurred for the qualification of a new HIV microplate assay for use with our OraSure[®] oral fluid collection device.

Sales and marketing expenses increased 9% to \$5.2 million in the first quarter of 2008 from \$4.8 million in the same period in 2007. This increase was primarily the result of increases in salaries, benefits and recruiting expenses associated with incremental sales personnel, increases in marketing expenses, partially offset by lower costs associated with reimbursable distributor advertising and promotional costs.

General and administrative expenses decreased 10% to \$3.8 million in the first quarter of 2008 from \$4.2 million in the same period in 2007. This decrease was primarily attributable to decreased legal costs as a result of the conclusion of the Prestige and Schering-Plough legal proceedings, lower consulting fees and a decrease in certain other corporate taxes, partially offset by an increase in staffing costs.

Interest expense decreased to \$83,000 in 2008 from \$166,000 in 2007, as a result of lower outstanding debt balances, a decreased interest rate, and an increase in capitalized interest related to construction in progress. Interest income decreased to \$1.0 million in 2008 from \$1.1 million in 2007, as a result of lower yields on our investment portfolio.

As a result of our license and settlement agreement entered into with Schering-Plough to resolve our patent infringement litigation, we received a payment of \$4.9 million during the first quarter of 2008, which was recorded as other income.

In January 2007, we sold our ownership interest in a privately-held nonaffiliated company and recorded a \$1.4 million pre-tax gain on the sale of this investment which was also included in other income during the quarter ended March 31, 2007.

We purchase some of our cryosurgical products from, or utilize the services of, vendors located in The Netherlands. As a result of the decline in the exchange rate between the United States dollar and the Euro, we recorded a \$73,000 and \$9,300 loss on foreign currency transactions for the three months ended March 31, 2008 and 2007, respectively.

During the three months ended March 31, 2008 and 2007, we recorded provisions for federal and state income taxes of \$0.7 million and \$1.5 million, respectively, which reflect a 27% and 50% effective tax rate in each period, respectively. The estimated annual effective rate for the quarter ended March 31, 2008 reflects a projected loss for the fiscal year, offset by the impact of permanent differences generated by items which are not deductible on our income tax returns.

Table of Contents**Liquidity and Capital Resources**

| | March 31, 2008 | December 31, 2007 |
|---------------------------|-------------------|----------------------|
| | (In thousands) | |
| Cash and cash equivalents | \$ 12,517 | \$ 32,230 |
| Short-term investments | 77,879 | 63,336 |
| Working capital | 106,036 | 105,620 |

Our cash, cash equivalents and short-term investments decreased \$5.2 million during the first quarter of 2008 to \$90.4 million at March 31, 2008, primarily as a result of \$3.7 million in cash flow used to fund operations, the purchase of \$755,000 of property and equipment, repayments of \$97,000 on long-term debt and \$840,000 associated with the repurchase and retirement of common stock to pay minimum tax withholding obligations on restricted shares that vested during the quarter. Offsetting these uses of funds was \$92,000 in cash received from the exercise of stock options during the quarter.

Net cash used to fund operating activities was \$3.7 million in the first quarter of 2008. Sources of operating cash during the three months ended March 31, 2008 included net income of \$2.0 million, stock-based compensation of \$1.4 million, a deferred income tax provision of \$746,000 resulting from utilization of our net operating loss carryforwards, depreciation and amortization of \$691,000, a provision for excess and obsolete inventories of \$370,000, and a decrease of \$34,000 in prepaid expenses and other assets. Offsetting these sources of cash were a \$890,000 increase in inventories primarily related to increased demand in our cryosurgical and infectious disease product lines, and a \$2.4 million increase in accounts receivable, of which \$1.5 million represents an increase in outstanding balances due from SSL and Genomma at March 31, 2008. Accounts receivable balances have increased in the current three-month period primarily due to the intra-quarter distribution of revenues. Accounts payable decreased \$1.9 million and accrued expenses decreased \$3.7 million largely due to payments on our year-end royalty, legal, and other accruals.

Net cash used in investing activities during the first quarter of 2008 was \$15.2 million. During this three month period, we purchased \$755,000 of property and equipment. We also had net purchases of short-term investments of \$14.4 million during the quarter ended March 31, 2008. We expect additional capital expenditures of \$3.1 million during the remaining nine months of 2008 as we purchase additional information systems equipment, upgrade certain older equipment and make improvements to our facilities.

Net cash used in financing activities was \$845,000, reflecting \$97,000 of loan principal repayments and \$840,000 for the repurchase and retirement of common stock, partially offset by proceeds of \$92,000 received from the exercise of stock options.

We have in place a \$14 million credit facility (the "Credit Facility") with Comerica Bank ("Comerica") which is comprised of a \$10 million facilities advance and a \$4 million revolving working capital line of credit. At our option, interest on the facilities 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 plus 0.55% to 1.25%. 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. Interest on any advances under the revolving working capital line of credit is payable at either the U.S. prime rate less 0.25% or 30-day LIBOR plus 2.55%, in each case determined at the time of funding.

In January 2008, we elected to fix the interest rate on the facilities advance at 4.15% until its maturity in June 2011, with principal and interest payable on a monthly basis.

Table of Contents

As of March 31, 2008, we had \$9.3 million in outstanding borrowings under the facilities advance and no outstanding borrowings under the \$4 million revolving working capital line of credit.

All borrowings under the Credit Facility are collateralized by a first priority security interest in all of our assets, including present and future accounts receivable, chattel paper, contracts and contract rights, equipment and accessories, general intangibles, investments, instruments, inventories and a mortgage on our three facilities in Bethlehem, Pennsylvania. Borrowings under the revolving working capital line of credit are limited to commercially standard percentages of accounts receivable. The Credit Facility contains certain covenants that set forth minimum requirements for our quick ratio, liquidity and tangible net worth. We were in full compliance with all covenants at March 31, 2008. The Credit Facility also restricts our ability to pay dividends, to make certain investments, to incur additional indebtedness, to sell or otherwise dispose of a substantial portion of assets, and to merge or consolidate operations with an unaffiliated entity, without the consent of Comerica.

At December 31, 2007, we had NOL carryforwards of \$45.5 million for federal income tax purposes. During the fourth quarter of 2005, the Company retained independent tax specialists to perform an ownership change study and analysis to determine the annual limitation amount applicable to utilization of the NOL carryforwards due to past ownership changes, as defined in Section 382 of the Internal Revenue Code. We continue to review ownership changes on a quarterly basis. We do not believe that the ownership change limitations would impair our ability to use our NOLs against our forecasted taxable income.

The combination of our current cash and short-term investments, anticipated 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.

Summary of Contractual Obligations

A summary of our obligations to make future payments under contracts existing at December 31, 2007 is included in Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations, of our Annual Report on Form 10-K for the year ended December 31, 2007. As of March 31, 2008, there were no significant changes to this information.

Critical Accounting Policies and Estimates

Management's Discussion and Analysis of Financial Condition and Results of Operations discusses our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires that we make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. On an on-going basis, we evaluate our judgments and estimates, including those related to bad debts, inventories, investments, intangible assets, income taxes, revenue recognition, restructuring costs, contingencies and litigation. We base our judgments and estimates on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. A more detailed review of our critical accounting policies is contained in our 2007 Annual Report on Form 10-K filed with the Securities and Exchange Commission. During the first quarter of 2008, there have been no material changes in our critical accounting policies.

Table of Contents

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We do not hold any amounts of derivative financial instruments or derivative commodity instruments and, accordingly, we have no material derivative risk to report under this Item.

A significant portion of our assets is comprised of certificates of deposit, commercial paper, U.S. government and agency obligations, and U.S. corporate bonds. All such instruments are classified as available-for-sale securities. The primary objective of our investment activities is to preserve principal while maximizing the related income without significantly increasing risk. Even so, some of the securities in which we invest may be subject to market risk. Market risk is the risk that a change in prevailing interest rates may cause the fair value of an investment to fluctuate. As interest rates increase, the fair value of a debt instrument would be expected to decrease. Correspondingly, if interest rates decrease the fair value of a debt instrument would be expected to increase. To minimize market risk, we have the ability to hold such debt instruments to maturity, at which time the debt instrument would be redeemed at its stated or face value. We also typically invest in the shorter end of the maturity spectrum. As such, we do not believe that we have a material exposure to market risk.

At March 31, 2008, we had approximately \$9.3 million of outstanding debt. In January 2008 we elected to fix the interest rate at 4.15% until the debt's maturity in June 2011. As a result, we have no exposure to interest rate changes.

As of March 31, 2008, 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 \$15,000 of our total revenues for the quarter ended March 31, 2008. We do not expect the risk of foreign currency fluctuations to be material in the near future.

Item 4. CONTROLS AND PROCEDURES.

(a) Evaluation of Disclosure Controls and Procedures. The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) as of March 31, 2008. Based on that evaluation, the Company's management, including such officers, concluded that the Company's disclosure controls and procedures were adequate and effective as of March 31, 2008 to ensure that information required to be disclosed by the Company in the reports that we file or submit under the Securities Exchange Act of 1934 is accumulated and communicated to the Company's management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure and is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission.

(b) Changes in Internal Control Over Financial Reporting. There was no change in the Company's internal control over financial reporting that occurred during the three months ended March 31, 2008 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

On April 22, 2008, a complaint was filed against the Company in the United States District Court for the District of New Jersey by Inverness Medical Innovations, Inc., Inverness Medical Switzerland GmbH and Church & Dwight Co., Inc., alleging that the Company infringes U.S. Patent No. 6,485,982. The complaint specifically refers to the Company's OraQuick *ADVANCE* Rapid HIV-1/2 Antibody Test. The complaint seeks injunctive relief, damages and an award of attorneys' fees. We believe that none of our products, including the OraQuick *ADVANCE* HIV test, infringe the patent asserted in this lawsuit or any other party's intellectual property rights. We also believe that the patent asserted in this matter is invalid or unenforceable, and we intend to defend this lawsuit vigorously.

Table of Contents

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, 2007.

Item 6. EXHIBITS

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

Table of Contents

SIGNATURES

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

ORASURE TECHNOLOGIES, INC.

Date: May 7, 2008

/s/ Ronald H. Spair
Ronald H. Spair
Chief Operating Officer and Chief Financial Officer

(Principal Financial Officer)

Date: May 7, 2008

/s/ Mark L. Kuna
Mark L. Kuna
Senior Vice President, Finance and Controller

(Principal Accounting Officer)

Table of Contents

EXHIBIT INDEX

Exhibit

- 10.1 Description of OraSure Technologies, Inc. 2008 Self-Funding Management Incentive Plan is incorporated by reference to Item 5.02 to the Company's Current Report on Form 8-K filed February 25, 2008.*
- 10.2 Description of OraSure Technologies, Inc. 2008 Stock Award Guidelines is incorporated by reference to Item 5.02 to the Company's Current Report on Form 8-K filed February 25, 2008.*
- 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.

* Management contract or compensatory plan or arrangement.