ORASURE TECHNOLOGIES INC
Form 10-Q
August 05, 2011
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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 June 30, 2011.

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)

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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x 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 the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨	Accelerated filer x
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 x

Number of shares of Common Stock, par value $.000001 per share, outstanding as of August 2, 2011: 47,016,428

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PART I. FINANCIAL INFORMATION

PART II. OTHER INFORMATION

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Item 1. FINANCIAL STATEMENTS

ORASURE TECHNOLOGIES, INC.

BALANCE SHEETS

(Unaudited)

	JUNE 30, 2011	DECEMBER 31, 2010
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 75,399,491	$ 73,843,402
Short-term investments		1,895,000
Accounts receivable, net of allowance for doubtful accounts of $132,539 and $105,954	11,744,080	12,471,249
Inventories	8,146,605	7,345,594
Prepaid expenses	1,718,705	1,930,108
Total current assets	97,008,881	97,485,353
PROPERTY AND EQUIPMENT, net	19,478,446	19,610,583
PATENTS AND PRODUCT RIGHTS, net	4,434,919	4,806,919
OTHER ASSETS	333,456	617,238
	$ 121,255,702	$ 122,520,093
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	$ 7,541,680	$ 7,791,680
Accounts payable	3,723,978	2,898,846
Accrued expenses and other	8,788,184	8,986,879
Total current liabilities	20,053,842	19,677,405
COMMITMENTS AND CONTINGENCIES (Note 6)		
STOCKHOLDERS EQUITY		
Preferred stock, par value $.000001, 25,000,000 shares authorized, none issued		
Common stock, par value $.000001, 120,000,000 shares authorized, 46,951,200 and 46,225,622 shares issued and outstanding	47	46
Additional paid-in capital	245,057,576	241,663,337
Accumulated other comprehensive loss	(233,829)	(235,264)
Accumulated deficit	(143,621,934)	(138,585,431)
Total stockholders equity	101,201,860	102,842,688
	$ 121,255,702	$ 122,520,093

See accompanying notes to the financial statements.

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ORASURE TECHNOLOGIES, INC.

STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
REVENUES:				
Product	$ 18,699,285	$ 17,703,803	$ 35,749,397	$ 34,276,557
Licensing and product development	364,275	1,514,033	727,891	2,886,803
	19,063,560	19,217,836	36,477,288	37,163,360
COST OF PRODUCTS SOLD	6,802,596	7,040,201	12,949,493	13,581,663
Gross profit	12,260,964	12,177,635	23,527,795	23,581,697
OPERATING EXPENSES:				
Research and development	5,142,987	3,028,658	9,563,227	6,135,433
Sales and marketing	5,351,841	5,610,352	10,283,717	11,304,696
General and administrative	4,125,516	4,073,941	8,593,127	8,852,584
	14,620,344	12,712,951	28,440,071	26,292,713
Operating loss	(2,359,380)	(535,316)	(4,912,276)	(2,711,016)
INTEREST EXPENSE	(79,556)	(77,955)	(157,743)	(153,750)
INTEREST INCOME	18,475	48,702	57,420	90,818
FOREIGN CURRENCY GAIN (LOSS)	(10,196)	14,237	(18,374)	28,926
OTHER EXPENSE	(7,743)	(2,474)	(5,530)	(3,158)
Loss before income taxes	(2,438,400)	(552,806)	(5,036,503)	(2,748,180)
INCOME TAXES				
NET LOSS	$ (2,438,400)	$ (552,806)	$ (5,036,503)	$ (2,748,180)
LOSS PER SHARE:				
BASIC AND DILUTED	$ (0.05)	$ (0.01)	$ (0.11)	$ (0.06)
SHARES USED IN COMPUTING LOSS PER SHARE				
BASIC AND DILUTED	46,814,379	46,201,638	46,666,895	46,157,097

See accompanying notes to the financial statements.

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ORASURE TECHNOLOGIES, INC.

STATEMENTS OF CASH FLOWS

(Unaudited)

	Six Months Ended June 30, 2011	2010
OPERATING ACTIVITIES:		
Net loss	$ (5,036,503)	$ (2,748,180)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,930,692	1,696,618
Depreciation and amortization	1,683,955	1,330,672
Changes in assets and liabilities:		
Accounts receivable	728,401	671,602
Inventories	(801,011)	(36,949)
Prepaid expenses and other assets	495,185	579,636
Accounts payable	825,335	(366,677)
Accrued expenses and other liabilities	(199,351)	(4,206,401)
Net cash used in operating activities	(373,297)	(3,079,679)
INVESTING ACTIVITIES:		
Proceeds from maturities and redemptions of short-term investments	1,895,000	2,741,000
Purchases of property and equipment	(1,179,818)	(1,112,611)
Net cash provided by investing activities	715,182	1,628,389
FINANCING ACTIVITIES:		
Repayments of long-term debt	(250,000)	(259,760)
Proceeds from exercise of stock options	2,312,023	5,455
Repurchase of common stock	(847,819)	(677,221)
Net cash provided by (used in) financing activities	1,214,204	(931,526)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	1,556,089	(2,382,816)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	73,843,402	74,933,630
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 75,399,491	$ 72,550,814
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid (received) for:		
Interest	$ 105,719	$ 171,825
Income taxes	$ 25,000	$ (585,893)

See accompanying notes to the financial statements.

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ORASURE TECHNOLOGIES, INC.

Notes to the Financial Statements

(Unaudited)

1. The Company

We develop, manufacture and market oral fluid diagnostic products and specimen collection devices using our proprietary oral fluid technologies, as well as other diagnostic products, including immunoassays and *in vitro* diagnostic tests that are used on other specimen types. We also manufacture and sell medical devices used for the removal of benign skin lesions by cryosurgery, or freezing. Our diagnostic products include tests that are performed on a rapid basis at the point of care and tests that 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 or consumer retail markets in North America, Europe, Central and South America and Australia.

The economic downturn, including disruptions in the capital and credit markets, may continue indefinitely and intensify, and could adversely affect our results of operations, cash flows and financial condition or those of our customers and suppliers. These circumstances could adversely affect our access to liquidity needed to conduct or expand our business or conduct future acquisitions or make other discretionary investments. They may also adversely impact the capital needs of our customers and suppliers, which, in turn, could adversely affect their ability to purchase our products or supply us with necessary equipment, raw materials or components. This could adversely affect our results of operations, cash flows and financial condition. The recent weak business climate could cause longer sales cycles and slower growth, and could expose us to increased business or credit risk in dealing with customers or suppliers adversely affected by economic conditions. Our ability to collect accounts receivable may be delayed or precluded if our customers are unable to pay their obligations.

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 our Annual Report on Form 10-K for the fiscal year ended December 31, 2010. Results of operations for the three and six months ended June 30, 2011 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 about future events. These estimates and underlying assumptions affect the amounts of assets and liabilities reported, disclosures about contingent assets and liabilities, and reported amounts of revenues and expenses. Such estimates include the valuation of accounts receivable, inventories and intangible assets, as well as assumptions related to contingencies, accruals and indemnifications, among others. These estimates and assumptions are based on management s best estimates and judgment. Management evaluates its estimates and assumptions on an ongoing basis, using historical experience and other factors, which management believes to be reasonable under the circumstances, including the current economic environment. We adjust such estimates and assumptions when facts and circumstances dictate. Illiquid credit markets, volatile equity, foreign currency, and energy markets, and declines in consumer spending have combined to increase the uncertainty inherent in such estimates and assumptions. Since future events and their effects cannot be determined with precision, actual results could differ significantly from these estimates. Changes in these estimates resulting from continuing changes in the economic environment will be reflected in the financial statements in those future periods.

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 June 30, 2011 and December 31, 2010, cash equivalents consisted of money market accounts.

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Short-term Investments. We consider all short-term investments to be available-for-sale securities. These securities are comprised of certificates of deposits 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, if any, reported in stockholders equity as a component of accumulated other comprehensive loss.

Our available-for-sale securities as of December 31, 2010 consisted of certificates of deposits with amortized cost and fair value of $1,895,000. These certificates of deposits matured during the second quarter of 2011.

Fair Value of Financial Instruments. As of June 30, 2011, the carrying values of cash and cash equivalents, accounts receivable, accounts payable and accrued expenses approximate their respective fair values based on their short-term nature. In addition, we believe the carrying value of our debt instrument, which does not have a readily ascertainable market value, approximates fair value, given that the interest rate on outstanding borrowings approximates current market rates and it has a short-term maturity date.

Fair value measurements of all financial assets and liabilities that are being measured and reported on a fair value basis are required to 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; and

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 were classified and measured as Level 1 instruments as of December 31, 2010.

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:

	June 30, 2011	December 31, 2010
Raw materials	$ 4,537,032	$ 4,453,560
Work in process	740,226	258,335
Finished goods	2,869,347	2,633,699
	$ 8,146,605	$ 7,345,594

Property and Equipment. Property and equipment are stated at cost. Additions or improvements are capitalized, while repairs and maintenance are charged to expense. Depreciation and amortization are provided using the straight-line method over the estimated useful lives of the related assets. Buildings are depreciated over twenty to forty years, while computer equipment, machinery and equipment, and furniture and fixtures are depreciated over three to ten years. Building improvements are amortized over their estimated useful lives. When assets are sold or otherwise disposed of, the related property amounts are relieved from the accounts, and any gain or loss is recorded in the statement of operations. Accumulated depreciation of property and equipment as of June 30, 2011 and December 31, 2010 was $20,883,285 and $20,204,317, respectively.

Patents and Product Rights. Patents and product rights consist of costs associated with the acquisition of patents, licenses and product distribution rights. Patents and product rights are amortized using the straight-line method over their estimated useful lives of three to ten years. Accumulated amortization of patents and product rights as of June 30, 2011 and December 31, 2010 was $6,013,701 and $5,641,701, respectively.

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Impairment of Long-Lived Assets. If indicators of impairment exist, we assess the recoverability of the affected long-lived assets, which include property and equipment and patents and product rights, by determining whether the carrying value of such assets can be recovered through the sum of the undiscounted future cash flows from the use and eventual disposition of the assets. If impairment is indicated, we measure the amount of such impairment by comparing the carrying value of the assets to the fair value of these assets, which is generally determined based on the present value of the expected future cash flows associated with the use of the assets.

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 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. We had no significant concentrations (greater than 10%) in revenues for either the three or six months ended June 30, 2011 and 2010. As of June 30, 2011 and December 31, 2010, one of our customers, Quest Diagnostics, Incorporated, accounted for 11% and 10% of our accounts receivable balances, respectively.

Research and Development. Research and development expenses consist of costs 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 can precede the services provided or can lag the service period by several months. Invoices paid prior to service being provided are recorded as a prepaid expense and then expensed appropriately as services are provided. We accrue the cost of services rendered but unbilled by CROs based on purchase order estimates provided by the CROs. 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.

Loss Per Share. Basic and diluted loss per share is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during the period. Diluted loss per share is generally computed assuming the exercise or vesting of all dilutive securities such as common stock options and unvested restricted stock. Common stock options and unvested restricted stock totaling 6,813,649 and 6,694,066 shares were outstanding as of June 30, 2011 and 2010, respectively. As a result of our net losses for the three and six months ended June 30, 2011 and 2010, these shares were excluded from the respective periods computation of diluted loss per share, as their inclusion would have been anti-dilutive. Had we reported a profit for the three and six months ended June 30, 2011, outstanding common stock options and unvested restricted stock, representing 1,531,179 and 2,588,024 equivalent shares, respectively, would have been excluded from the computation of diluted earnings per share, as their inclusion would have been anti-dilutive. Had we reported a profit for the three and six months ended June 30, 2010, outstanding common stock options and unvested restricted stock, representing 4,578,979 and 4,718,770 equivalent shares, respectively, would have been excluded from the computation of diluted earnings per share, as their inclusion would have been anti-dilutive.

Other Comprehensive Loss. We classify items of other comprehensive loss by their nature and disclose the accumulated balance of other comprehensive loss separately from accumulated deficit and additional paid-in capital in the stockholders equity section of our balance sheet. Accumulated other comprehensive loss as of June 30, 2011 and December 31, 2010 consisted of currency translation adjustments. Comprehensive loss was $2,436,696 and $554,841 for the three months ended June 30, 2011 and 2010, respectively, and $5,035,068 and $2,749,878 for the six months ended June 30, 2011 and 2010, respectively.

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3. Stock-Based Compensation

We grant stock-based awards under the OraSure Technologies, Inc. Stock Award Plan, as amended and restated (the Plan). The Plan permits stock-based awards to employees, outside directors and consultants or other third-party advisors. Awards which may be granted under the 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 June 30, 2011 and 2010 was $3.51 and $2.77 per share, respectively. The weighted average grant date fair value of stock options granted during the six months ended June 30, 2011 and 2010 was $2.86 and $2.27 per share, respectively.

Total compensation cost related to stock options for the three months ended June 30, 2011 and 2010 was $342,814 and $200,377, respectively, of which $17,242 and $12,967 was capitalized into inventory during the quarters ended June 30, 2011 and 2010, respectively. The amounts recognized in cost of products sold for amounts previously capitalized were $15,266 and $12,042 for the three months ended June 30, 2011 and 2010, respectively.

Total compensation cost related to stock options for the six months ended June 30, 2011 and 2010 was $684,762 and $475,619, respectively, of which $24,270 and $26,774 was capitalized into inventory during the six months ended June 30, 2011 and 2010, respectively. The amounts recognized in cost of products sold for amounts previously capitalized were $24,946 and $31,988 for the six months ended June 30, 2011 and 2010, respectively.

The following table summarizes the stock option activity for the six months ended June 30, 2011:

	Options
Outstanding on January 1, 2011	5,503,533
Granted	973,225
Exercised	(455,045)
Forfeited	(113,720)
Outstanding on June 30, 2011	5,907,993

As of June 30, 2011, there was $3,927,138 of unrecognized compensation expense related to unvested option awards that is expected to be recognized over a weighted average period of 2.1 years.

Net cash proceeds from the exercise of stock options were $2,312,023 and $5,455 for the six months ended June 30, 2011 and 2010, respectively. As a result of the Company s net operating loss carryforward position, no actual income tax benefit was realized from the stock option exercises during these periods.

As mentioned above, the Plan also permits us to grant restricted shares of our common stock to eligible employees, including officers and outside directors. Generally, these shares are nontransferable until vested and are subject to vesting requirements and/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 six months ended June 30, 2011, we granted 525,880 restricted shares of our common stock, with a weighted average grant date fair value of $6.61 per share, to certain key officers, members of management and outside directors. Compensation cost of $615,325 and $604,869 related to restricted shares was recognized during the three months ended June 30, 2011 and 2010, respectively. Compensation cost of $1,245,929 and $1,221,000 related to restricted shares was recognized during the six months ended June 30, 2011 and 2010, respectively.

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The following table summarizes restricted stock award activity for the six months ended June 30, 2011:

	Shares
Issued and unvested, January 1, 2011	792,156
Granted	525,880
Vested	(397,380)
Forfeited	(15,000)
Issued and unvested, June 30, 2011	905,656

As of June 30, 2011, there was $4,351,192 of unrecognized compensation expense related to unvested restricted stock awards that is expected to be recognized over a weighted average period of 2.2 years. In connection with the vesting of restricted shares, during the six months ended June 30, 2011 and 2010, 126,847 and 128,625 shares, respectively, with aggregate values of $847,819 and $677,221, respectively, were withheld and retired in satisfaction of minimum tax withholding obligations.

4. Accrued Expenses

	June 30, 2011	December 31, 2010
Payroll and related benefits	$ 3,382,115	$ 4,343,350
Royalties	1,970,320	1,985,799
Deferred revenue	1,645,564	896,531
Professional fees	720,354	213,308
Clinical research obligations	20,000	400,860
Other	1,049,831	1,147,031
	$ 8,788,184	$ 8,986,879

Deferred revenue at June 30, 2011 and December 31, 2010 included customer prepayments of $1,594,464 and $851,031, respectively.

5. Long-term Debt

As of June 30, 2011, we had in place a $10,000,000 credit facility (the Credit Facility) with Comerica Bank (Comerica). Pursuant to the terms of the Credit Facility, principal and interest fixed at 4.15% per annum were payable monthly through June 27, 2011. An amendment to the Credit Facility was executed with Comerica on June 24, 2011, extending the current terms of the Credit Facility and its maturity date to September 27, 2011. As of June 30, 2011, we had no available borrowings under this Credit Facility. We are evaluating possible options to address the upcoming expiration of the Credit Facility, including refinancing with a new credit facility or other borrowings.

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. The Credit Facility contains certain covenants that set forth minimum requirements for our quick ratio, liquidity, and tangible net worth. We were in compliance with all covenants as of June 30, 2011. 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.

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6. Commitments and Contingencies

From time-to-time, we are involved in certain legal actions arising in the ordinary course of business. In management s opinion, based upon the advice of counsel, the outcomes of such actions are not expected to have a material adverse effect on our future financial position or results of operations.

7. Geographic Information

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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
United States	$ 16,341	$ 16,457	$ 30,579	$ 31,325
Europe	1,293	1,852	3,279	3,194
Other regions	1,430	909	2,619	2,644
	$ 19,064	$ 19,218	$ 36,477	$ 37,163

8. Subsequent Event

On July 25, 2011, we announced that we will acquire DNA Genotek Inc. (DNAG), a privately-held provider of oral fluid sample collection, stabilization and preparation products for molecular diagnostic applications. Pursuant to the terms of a definitive Support Agreement, we will acquire all of the outstanding capital stock of DNAG for approximately $53,000,000 in cash, subject to certain working capital, debt and escrow adjustments. The transaction is expected to be completed in the third quarter of 2011. DNAG is based in Ottawa, Canada and will operate as a wholly-owned subsidiary of our company.

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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/loss per share, net income (loss), expenses, cash flow or other financial performance or developments, clinical trial or development activities, 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, whether through an internal, direct sales force or third parties; ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements; 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; changes in relationships, including disputes or disagreements, with strategic partners or other parties 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 replacing distributors and success of direct sales efforts; inventory levels at distributors and other customers; ability to identify, complete, integrate, and realize the full benefits of potential future acquisitions, including the Company s acquisition of DNA Genotek; impact of competitors, competing products and technology changes; impact of the economic downturn, high unemployment and poor credit conditions; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; 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, extended shelf life or other factors; 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; history of losses and ability to achieve sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; 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 the impact of changes in international funding sources and testing algorithms; loss or impairment of sources of capital; ability to meet financial covenants in agreements with financial institutions; ability to refinance outstanding debt under expiring credit facilities on acceptable terms or at all; ability to retain qualified personnel; exposure to 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; and general political, business and economic conditions. These and other factors are discussed more fully in our Securities and Exchange Commission (SEC) filings, including our registration statements, Annual Report on Form 10-K for the year ended December 31, 2010, Quarterly Reports on Form 10-Q, and other filings with the SEC. Although forward-looking statements help to provide information about future prospects, readers should keep in mind that forward-looking statements 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

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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 *in vitro* diagnostic tests that are used on other specimen types. We also manufacture and sell medical devices used for the removal of 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 is sold in the over-the-counter (OTC) or consumer retail market in North America, Europe, Central and South America, and Australia.

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. When combined with their ease of use, non-invasive nature, and cost effectiveness, our oral fluid tests represent a very competitive alternative to the more traditional testing methods in the diagnostic space.

We rely heavily on distributors to purchase and resell many of our products. For example, Genomma Labs (Genomma) has exclusive rights to our wart removal product in the OTC market in Mexico, Argentina, Brazil and various other Central and South American countries and Reckitt Benckiser (formerly SSL International plc) has similar rights to our wart removal product in the OTC footcare market in Europe, Australia and New Zealand. We have contracted with several distributors to sell our OraQuick *ADVANCE*® HIV-1/2 test to the U.S. physician office market and our Intercept® and OraSure® product lines are sold by several laboratory distributors. We use distributors to sell our Histofreezer® product into the domestic and international physician office markets and we are engaging distributors to sell our OraQuick® rapid HCV test in Europe. We expect to enter into additional distribution agreements for existing and future products 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.

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*® HIV-1/2 test, our OraQuick® HCV 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 these sole sources, the time required to develop replacements and obtain the required U.S. Food and Drug Administration (FDA) approvals could disrupt our ability to sell the affected products.

Current Financial Results

During the six months ended June 30, 2011, our total revenues were $36.5 million compared to $37.2 million in the six months ended June 30, 2010. Product revenues during the six months ended June 30, 2011 increased 4% when compared to the first half of 2010, which was offset by lower licensing and product development revenues. The reduction in licensing and product development revenues primarily resulted from the absence of $2.0 million in milestone payments received under the terms of our collaboration agreement with Merck & Co., Inc. (Merck) during the first half of 2010 for the development and promotion of our OraQuick® rapid HCV test in Europe. Our net loss for the six months ended June 30, 2011 was $5.0 million, or $0.11 per share, compared to a net loss of $2.7 million, or $0.06 per share, for the six months ended June 30, 2010.

Cash used in operating activities for the six months ended June 30, 2011 was approximately $373,000, compared to the $3.1 million used in operating activities for the six months ended June 30, 2010. As of June 30, 2011, we had $75.4 million in cash, cash equivalents and short-term investments, compared to $75.7 million at December 31, 2010.

Recent Developments

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Acquisition of DNA Genotek Inc.

On July 25, 2011, we announced that we will acquire DNA Genotek Inc. (DNAG), a privately-held provider of oral fluid sample collection, stabilization and preparation products for molecular diagnostic applications. Pursuant to the terms of a definitive Support Agreement, we will acquire all of the outstanding capital stock of DNAG for approximately $53,000,000 in cash, subject to certain working capital, debt and escrow adjustments. The transaction is expected to close in the third quarter of 2011, subject to customary closing conditions. DNAG is based in Ottawa, Canada and will operate as a wholly-owned subsidiary of our Company.

OraQuick® HCV Test

In March 2011, we submitted to the FDA an application for waiver under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) for our OraQuick® HCV test for use with venous and fingerstick whole blood specimens. This application remains pending and we are in active dialogue with the FDA regarding our submission. We have received a request for additional data from the FDA, which will require us to design and perform a relatively small study. While the study should last only about a week, there are set-up and close-out activities that will require until the fourth quarter of 2011 to complete. We intend to provide the requested data to the FDA as quickly as possible to facilitate the prompt completion of the agency s review of our application.

OraQuick® HIV OTC Test

We are conducting the final phase of clinical testing for an OraQuick® HIV OTC test. In this study individuals conduct unsupervised self-testing using the investigational OTC version of our OraQuick *ADVANCE*® HIV test with an oral fluid collection. One of the study objectives specified by the FDA was to identify at least 100 HIV infected, but undiagnosed individuals. In order to meet this requirement, we expected to enroll and test approximately 4,000 to 5,000 participants in our study. This trial is progressing, and we remain on track to complete this study during the third quarter of 2011.

In planning for our FDA submission, we have decided to split our filing into three separate parts or modules, the filing of which will be spaced to allow the FDA sufficient review time between modules. The first module, which we expect to file later in August 2011, will contain data from all studies performed prior to the final phase that is currently under way. The second module will contain information about our manufacturing and Customer Care Call Center. The final module will contain the results of the unobserved clinical trial and is expected to be filed near the end of this year.

Substance Abuse Testing

In the first quarter of 2011, the FDA issued 510(k) clearances for use of high throughput oral fluid assays for PCP, opiates, cocaine and methamphetamines with our Intercept® oral fluid collection device. These were the first such clearances resulting from our collaboration with Roche Diagnostics. In the second quarter of 2011, the FDA issued an additional 510(k) clearance for an amphetamines assay. We expect to begin selling a panel of 510(k) cleared assays together with our Intercept® device during the fourth quarter of this year. Clinical work on an assay for marijuana (THC) is continuing, and is expected to be completed in late 2011 or the first quarter of 2012.

Competitive and Economic Outlook

Competition in the market for HIV testing is intense and is expected to increase. We believe that our principal competition will come from existing point-of-care rapid blood tests, laboratory-based blood tests, and urine assays or other oral fluid-based tests that may be developed. Our competitors include medical diagnostic companies and specialized biotechnology firms, as well as pharmaceutical companies with biotechnology divisions. Competing rapid blood tests are often sold at a lower price than we charge for our OraQuick® HIV test. This competition can result in lost sales and degradation of the price we can charge for our product (and the resulting profit margin).

Our OraQuick® HCV test is available in Europe and competes against laboratory-based HCV blood tests. Significant sales in Europe have not yet materialized principally because of differences in European healthcare systems

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compared to our U.S. systems. Unlike the U.S., adoption of rapid point-of-care diagnostics is not widespread in Europe because laboratory testing is entrenched and healthcare systems are structured around centralized testing models. We intend to continue working to build awareness and acceptance of our OraQuick® HCV test in European and other international markets. In non-U.S. countries outside of Europe, we expect the OraQuick® HCV product to compete against other rapid HCV blood tests and laboratory-based tests.

Two factors are likely to impact domestic sales of our OraQuick® HCV test. First, since our test is currently classified by the FDA as moderately complex, we can only sell it to laboratories certified or accredited as meeting the quality and training requirements under CLIA. However, with a CLIA waiver, we would be able to sell our test to many other customers that perform CLIA waived tests, such as outreach clinics, community-based organizations and physician offices. Thus, a CLIA waiver will be required for us to deploy the test extensively in both the public health and hospital markets and to enable penetration, with the assistance of our collaborator, Merck, into the physician office market. Second, we believe the recent FDA approval of two new therapeutic treatments for HCV, both of which are more effective than previously available treatments, will help drive more widespread awareness and testing for HCV, including with our OraQuick® rapid test.

In the substance abuse testing market, we expect competition for our products to intensify. Other companies have developed, and will continue to develop, competing oral fluid drug testing products. In particular, there are at least two competitors that sell high-throughput fully automated oral fluid drug testing products in unregulated settings in the United States. In addition, we believe that at least one of these competitors has recently received 510(k) clearance of its product and that this 510(k) cleared product will be offered by one of our laboratory distributors. These new products will compete against both our Intercept® products and the high-throughput assays we intend to commercialize jointly with Roche Diagnostics.

Finally, current economic conditions, including disruptions in the capital and credit markets, may continue for the foreseeable future and intensify, and has adversely affected and could continue to adversely affect our financial performance and condition or those of our customers and suppliers. These circumstances could adversely affect our access to liquidity needed to conduct or expand our business or conduct future acquisitions or make other discretionary investments. Many of our customers rely on public funding provided by state and local governments, and this funding has been and may continue to be reduced or deferred as a result of current economic conditions. These circumstances may adversely impact our customers and suppliers, which, in turn, could adversely affect their ability to purchase our products or supply us with necessary equipment, raw materials or components. In addition, demand for our products may also be adversely affected by current economic conditions.

Results of Operations

Three months ended June 30, 2011 compared to June 30, 2010

Total revenues decreased to $19.1 million in the second quarter of 2011 from $19.2 million in the comparable quarter of 2010. Product revenues during the three months ended June 30, 2011 increased 6% when compared to the second quarter of 2010. Increased sales of our infectious disease and substance abuse testing products were partially offset by lower sales of our cryosurgical systems and insurance risk assessment products. In addition, the higher product revenues were offset by a $1.2 million reduction in licensing and product development revenues during the second quarter.

Revenues derived from products sold to customers outside the U.S. were $2.7 million and $2.8 million, or 14% of total revenues, in the second quarters of 2011 and 2010. Because the majority of our international sales are denominated in U.S. dollars, the impact of fluctuating foreign currency exchange rates was not material to our operating results.

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

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	Three Months Ended June 30,				
	Dollars			Percentage of Total Revenues	
Market	2011	2010	% Change	2011	2010
Infectious disease testing	$ 11,284	$ 9,974	13%	59%	52%
Substance abuse testing	3,185	3,052	4	17	16
Cryosurgical systems	2,802	3,120	(10)	15	16
Insurance risk assessment	1,429	1,558	(8)	7	8
Product revenues	18,700	17,704	6	98	92
Licensing and product development	364	1,514	(76)	2	8
Total revenues	$ 19,064	$ 19,218	(1)%	100%	100%

Infectious Disease Testing Market

Sales to the infectious disease testing market increased 13% to $11.3 million in the second quarter of 2011. OraQuick® sales totaled $11.0 million and $9.6 million in the second quarters of 2011 and 2010, respectively.

The table below shows a breakdown of our total OraQuick® revenues (dollars in thousands) during the second quarters of 2011 and 2010.

	Three Months Ended June 30,		
Market	2011	2010	% Change
Domestic	$ 10,168	$ 9,248	10%
International	858	317	171
Total OraQuick® revenues	$ 11,026	$ 9,565	15%

During the three months ended June 30, 2011, sales of OraQuick® in the U.S. market increased by 10%, or $920,000, when compared to the same period of 2010. The increase in OraQuick® sales was largely the result of new or expanded HIV-testing programs implemented in the U.S., as well as variability of customer ordering patterns. International sales of our OraQuick® HIV test increased 171% to $858,000 for the three months ended June 30, 2011 from $317,000 for the three months ended June 30, 2010. This increase reflects higher product sales in Asia, Africa, Latin America and Europe, as certain private and government customers were able to fund purchases.

Sales of our OraSure® oral fluid collection device decreased 37% from $409,000 in the second quarter of 2010 to $258,000 in the second quarter of 2011. Some customers who have purchased our OraSure® device for laboratory HIV-1 testing in the past are now electing to purchase our OraQuick *ADVANCE*® test. We believe this is the result of customers recognizing the benefits of rapid HIV testing, especially with oral fluid.

Substance Abuse Testing Market

Substance abuse testing revenues increased 4% from $3.1 million in the second quarter of 2010 to $3.2 million in the second quarter of 2011 as a result of increased domestic sales of our Intercept® drug testing system.

The table below shows a breakdown of our total Intercept® revenues (dollars in thousands) generated in each market during the second quarters of 2011 and 2010.

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Market	Three Months Ended June 30, 2011	2010	% Change
Domestic	$ 2,083	$ 1,949	7%
International	514	443	16
Total Intercept® revenues	$ 2,597	$ 2,392	9%

Domestic Intercept® revenues increased 7% from $1.9 million in the second quarter of 2010 to $2.1 million in the second quarter of 2011. This increase is largely the result of growth in the workplace market segment as hiring conditions have slowly begun to improve and we have seen the results of focused sales and marketing efforts.

International Intercept® revenues increased 16% from $443,000 in the second quarter of 2010 to $514,000 in the second quarter of 2011 as result of variability in customer ordering patterns.

Pursuant to a development agreement with Roche Diagnostics, homogenous fully-automated oral fluid drugs of abuse assays have been developed for use with our Intercept® collection device. The FDA recently has issued 510(k) clearance of high throughput assays for PCP, opiates, cocaine, methamphetamines, and amphetamines. The assays use Roche s technology and will run on various automated analyzers to allow oral fluid samples to be processed with the same efficiency currently achieved with urine-based drug tests. We have also entered into a commercialization agreement with Roche pursuant to which a drug testing system comprised of our Intercept® device and the newly developed homogenous assays will be marketed and sold on a worldwide basis. At least two competitors have developed oral fluid tests suitable for use on fully automated homogeneous assay systems and one competitor has received FDA 510(k) clearance of its products. We believe one of our laboratory distributors will begin offering this 510(k) cleared product line later this year and will reduce purchases of our Intercept® system. These new products represent a significant competitive threat to our Intercept® device and oral fluid microplate business and the assays being developed with Roche.

Cryosurgical Systems Market

Sales in the cryosurgical systems market (which includes both the physicians office and OTC markets) decreased 10% to $2.8 million in the second quarter of 2011, compared to $3.1 million in the same period of the prior year.

The table below shows a breakdown of our total cryosurgical systems revenues (dollars in thousands) generated in each market during the second quarters of 2011 and 2010.

Market	Three Months Ended June 30, 2011	2010	% Change
Professional domestic	$ 1,713	$ 1,575	9%
Professional international	247	270	(9)
Over-the-counter	842	1,275	(34)
Total cryosurgical systems revenues	$ 2,802	$ 3,120	(10)%

Domestic physicians office sales increased 9% or $138,000 for the second quarter of 2011 as compared to the second quarter of 2010, as a result of increased penetration in the cryosurgical market resulting from the continued efforts of our manufacturers sales representatives and improved focus by our distributors. In early 2010, we signed agreements with two manufacturers sales representative organizations to support sales of our Histofreezer® product in the U.S. Under these arrangements, over 40 additional sales representatives have been working with our physicians office distributors throughout the United States. Furthermore, during the second quarter of 2011, we

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received orders from certain customers that have worked through their previously purchased inventory of less expensive international product that was diverted into the domestic professional market in 2009 and part of 2010.

During the three months ended June 30, 2011, sales of Histofreezer® in the international market decreased 9% as compared to the second quarter of 2010. This decrease was largely the result of lower sales in Asia and Australia, partially offset by increased sales in the European market.

Sales of our cryosurgical OTC products during the second quarter of 2011 decreased 34% primarily due to variability in ordering patterns of our European OTC distributor, Reckitt Benckiser (formerly, SSL International). Sales to Reckitt Benckiser decreased $578,000 during the second quarter of 2011 compared to the second quarter of 2010. This decrease was partially offset by a 39% increase in sales to our Latin American distributor, Genomma.

The terms of our distribution contract with Reckitt Benckiser, which was subject to an annual renewal at the end of 2010, has been extended through July 2011. We are currently in negotiations to extend this contract further.

Insurance Risk Assessment Market

Sales to the insurance risk assessment market decreased 8% to $1.4 million in the second quarter of 2011 from $1.6 million in the second quarter of 2010 as a result of variability in the timing of orders and general softness in the life insurance market.

Licensing and Product Development

Licensing and product development revenues decreased 76% to $364,000 during the second quarter of 2011 from $1.5 million during the second quarter of 2010. During the second quarter of 2010, we received a $1.0 million milestone payment as a result of our achievement of certain commercial objectives pursuant to our collaboration agreement with Merck for the development and promotion of our OraQuick® rapid HCV test in Europe. No such payment was received in the same period of 2011. The remaining licensing revenues for these periods represent royalties received on domestic outsales of Merck s OTC cryosurgical wart removal product, pursuant to our license and settlement agreement executed in January 2008.

Gross Margin

Gross margin in the second quarter of 2011 was 64% compared to 63% for the second quarter of 2010. Gross margin in the second quarter of 2010 benefitted from the $1.0 million HCV milestone payment described above. Margin in the second quarter of 2011 benefited from lower direct labor costs and improved absorption of overhead costs as a result of staffing optimization and a change to automated manufacturing during 2011. These changes accounted for 3.2% of margin for the second quarter of 2011. This improvement more than offset the negative margin impact associated with the absence of the HCV milestone revenues in 2011.

Operating Expenses

Research and development expenses increased 70% from $3.0 million in the second quarter of 2010 to $5.1 million in the same period in 2011, primarily as a result of higher clinical trial costs related to the development of our OraQuick® HIV OTC test.

Sales and marketing expenses decreased 5% to $5.4 million in the second quarter of 2011 from $5.6 million in the second quarter of 2010, as a result of lower consulting costs, partially offset by higher staffing costs.

General and administrative expenses remained flat at $4.1 million for the second quarters of 2011 and 2010.

Income Taxes

In 2008, we established a full valuation allowance against our total net deferred tax asset. Management has continued to evaluate whether the full valuation is still appropriate. As of June 30, 2011 and 2010, we concluded that the full

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valuation allowance remained appropriate since the facts and circumstances necessitating the allowance had not changed. As a result, no income tax benefit was recorded in the second quarters of 2011 or 2010.

Six months ended June 30, 2011 compared to June 30, 2010

Total revenues decreased to $36.5 million in the first half of 2011 from $37.2 million in the comparable period of 2010. Product revenues during the six months ended June 30, 2011 increased 4% when compared to product revenues in the first half of 2010. Increased sales of our infectious disease and substance abuse testing products were partially offset by lower sales of our cryosurgical systems and insurance risk assessment products. In addition, higher product revenues were offset by a $2.2 million reduction in licensing and product development revenues during the first half of 2011 as compared to 2010.

Revenues derived from products sold to customers outside the U.S. were $5.9 million and $5.8 million, or 16% of total revenues, in the first six months of 2011 and 2010. Because the majority of our international sales are denominated in U.S. dollars, the impact of fluctuating foreign currency exchange rates was not material to our operating results.

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

	Six Months Ended June 30,				
	Dollars			Percentage of Total Revenues	
Market	2011	2010	% Change	2011	2010
Infectious disease testing	$ 21,246	$ 19,454	9%	58%	52%
Substance abuse testing	6,246	5,766	8	17	16
Cryosurgical systems	5,512	6,114	(10)	15	16
Insurance risk assessment	2,745	2,942	(7)	8	8
Product revenues	35,749	34,276	4	98	92
Licensing and product development	728	2,887	(75)	2	8
Total revenues	$ 36,477	$ 37,163	(2)%	100%	100%

Infectious Disease Testing Market

Sales to the infectious disease testing market increased 9% to $21.2 million in the first half of 2011. OraQuick® sales totaled $20.7 million and $18.6 million in the first six months of 2011 and 2010, respectively.

The table below shows a breakdown of our total OraQuick® revenues (dollars in thousands) during the first six months of 2011 and 2010.

	Six Months Ended June 30,		
Market	2011	2010	% Change
Domestic	$ 19,069	$ 17,979	6%
International	1,604	655	145
Total OraQuick® revenues	$ 20,673	$ 18,634	11%

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During the six months ended June 30, 2011, sales of OraQuick® in the U.S. market increased by 6%, or $1.1 million, when compared to the same period of 2010. The increase in domestic OraQuick® sales was largely the result of new or expanded HIV testing programs implemented in the U.S. as well as variability in customer ordering patterns. International sales of our OraQuick® HIV test increased 145% to $1.6 million for the six months ended June 30, 2011 from $655,000 for the six months ended June 30, 2010. This increase reflects higher product sales in Asia, Africa, Latin America, and Europe, as certain private and government customers were able to fund purchases.

Sales of our OraSure® oral fluid collection device decreased 30% from $820,000 in the first half of 2010 to $573,000 in the first half of 2011. Some customers who have purchased our OraSure® device for laboratory HIV-1 testing in the past are now electing to purchase our OraQuick *ADVANCE*® test. We believe this is the result of customers recognizing the benefits of rapid HIV testing, especially with oral fluid.

Substance Abuse Testing Market

Substance abuse testing revenues increased 8% from $5.8 million in the first half of 2010 to $6.2 million in the first half of 2011 as a result of increased domestic sales of our Intercept® drug testing system.

The table below shows a breakdown of our total Intercept® revenues (dollars in thousands) generated in each market during the first six months of 2011 and 2010.

	Six Months Ended June 30,		
Market	**2011**	**2010**	**% Change**
Domestic	$ 3,962	$ 3,477	14%
International	1,035	960	8
Total Intercept® revenues	$ 4,997	$ 4,437	13%

Domestic Intercept® revenues increased 14% from $3.5 million in the first half of 2010 to $4.0 million in the first half of 2011. This increase is largely the result of variability in the ordering patterns of one of our larger laboratory drug testing customers and growth achieved within the workplace market segment as hiring conditions have slowly begun to improve.

International Intercept® revenues for the first half of 2011 and 2010 increased from $960,000 in the first half of 2010 to $1.0 million in the first half of 2011, as result of variability in customer ordering patterns.

Pursuant to a development agreement with Roche Diagnostics, homogenous fully-automated oral fluid drugs of abuse assays have been developed for use with our Intercept® collection device. The FDA recently has issued 510(k) clearance for high throughput assays for PCP, opiates, cocaine, methamphetamines, and amphetamines. The assays use Roche s technology and will run on various automated analyzers to allow oral fluid samples to be processed with the same efficiency currently achieved with urine-based drug tests. We have also entered into a commercialization agreement with Roche pursuant to which a drug testing system comprised of our Intercept® device and the newly developed homogenous assays will be marketed and sold on a worldwide basis. At least two competitors have developed oral fluid tests suitable for use on fully automated homogeneous assay systems and one competitor has received 510(k) clearance of its products. We believe one of our laboratory distributors will begin offering this 510(k) cleared product line later this year and will reduce purchases of our Intercept® system. These new products represent a significant competitive threat to our Intercept® device and oral fluid microplate business and the assays being developed with Roche.

Cryosurgical Systems Market

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Sales in the cryosurgical systems market (which includes both the physicians office and OTC markets) decreased 10% to $5.5 million in the first six months of 2011, compared to $6.1 million in the same period of the prior year.

The table below shows a breakdown of our total cryosurgical systems revenues (dollars in thousands) generated in each market during the first six months of 2011 and 2010.

	Six Months Ended June 30,		
Market	**2011**	**2010**	**% Change**
Professional domestic	$ 3,055	$ 2,787	10%
Professional international	587	539	9
Over-the-counter	1,870	2,788	(33)
Total cryosurgical systems revenues	$ 5,512	$ 6,114	(10)%

Domestic physicians office sales increased 10% or $268,000 for the first six months of 2011 as compared to the first six months of 2010, as a result of increased penetration in the cryosurgical market resulting from the continued efforts of our manufacturers sales representatives and improved focus on our products by our distribution partners. In early 2010, we signed agreements with two manufacturers sales representative organizations to support sales of our Histofreezer® product in the U.S. Under these arrangements, over 40 additional sales representatives have been working with our physicians office distributors throughout the United States.

During the six months ended June 30, 2011, sales of Histofreezer® in the international market increased 9% as compared to the first six months of 2010. This increase was largely experienced in the European market as a result of increased pricing and improved economic conditions in some local markets.

Sales of our cryosurgical OTC products during the first half of 2011 decreased 33% primarily due to the decline in sales to both our Latin America OTC distributor, Genomma, and our European OTC distributor, Reckitt Benckiser (formerly, SSL International).

In the first half of 2010, Genomma had purchases totaling $1.4 million compared to $422,000 in the first half of 2011. In late 2010, the Mexican government placed limitations on the advertising Genomma could use for our product. In addition, during the first quarter of 2011, Genomma informed us of some changes required by the Brazilian government to our package insert, which have since been made. Both events negatively impacted sales of our product during 2011. When compared to the first six months of 2010, sales to Genomma during the same period of 2011 were also lower as a result of an initial order fulfilled in the first quarter of 2010 for the commercial launch of our product in Brazil during that same period.

Sales to our European OTC distributor Reckitt Benckiser decreased $122,000 during the first half of 2011 compared to the first half of 2010, largely due to variability in ordering patterns. The terms of our distribution contract with Reckitt Benckiser, which was subject to an annual renewal at the end of 2010, has been extended through July 2011. We are currently in negotiations to extend this contract.

Insurance Risk Assessment Market

Sales to the insurance risk assessment market decreased 7% to $2.7 million in the first six months of 2011 from $2.9 million in the first six months of 2010 as a result of variability in the timing of orders and general softness in the life insurance market.

Licensing and Product Development

Licensing and product development revenues decreased 75% to $728,000 during the first half of 2011 from $2.9 million during the first half of 2010. During the first six months of 2010, we received $2.0 million in milestone

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payments as a result of our achievement of certain regulatory and commercial objectives pursuant to our collaboration agreement with Merck for the development and promotion of our OraQuick® rapid HCV test in Europe. The remaining licensing revenues for these periods represent royalties received on domestic outsales of Merck s OTC cryosurgical wart removal product, pursuant to our license and settlement agreement executed in January 2008.

Gross Margin

Gross margin in the six months ended June 30, 2011 was 64% compared to 63% for the six months ended June 30, 2010. Gross margin in the first half of 2010 benefitted from the $2.0 million in HCV milestone payments described above. Margin in the first half of 2011 benefited from lower direct labor costs and improved absorption of overhead costs as a result of staffing optimization and a change to automated manufacturing during 2011. These changes accounted for 2.8% of margin for the first half of 2011. This improvement more than offset the negative margin impact associated with the absence of the HCV milestone revenues in 2011.

Operating Expenses

Research and development expenses increased 56% from $6.1 million in the first six months of 2010 to $9.6 million in the same period in 2011, primarily as a result of higher clinical trial costs related to the development of our OraQuick® HIV OTC test. This increase was partially offset by lower clinical trial costs related to our OraQuick® HCV test.

Sales and marketing expenses decreased 9% to $10.3 million in the first six months of 2011 from $11.3 million in the first six months of 2010, as a result of lower consulting, recruiting and market research costs, partially offset by an increase in staffing costs.

General and administrative expenses decreased 3% to $8.6 million in the first six months of 2011 from $8.9 million in the same period in 2010. This decrease was primarily attributable to lower consulting and staffing expenses, partially offset by an increase in legal expenses.

Income Taxes

In 2008, we established a full valuation allowance against our total net deferred tax asset. Management has continued to evaluate whether the full valuation is still appropriate. As of June 30, 2011 and 2010, we concluded that the full valuation allowance remained appropriate since the facts and circumstances necessitating the allowance had not changed. As a result, no income tax benefit was recorded in the first six months of 2011 or 2010.

Liquidity and Capital Resources

	June 30, 2011	December 31, 2010
	(In thousands)	
Cash and cash equivalents	$ 75,399	$ 73,843
Short-term investments		1,895
Working capital	76,955	77,808

Our cash, cash equivalents and short-term investments decreased $339,000 from $75.7 million at December 31, 2010 to $75.4 million at June 30, 2011. Our working capital declined slightly from $77.8 million at December 31, 2010 compared to $77.0 million at June 30, 2011.

During the first six months of 2011, we used $373,000 in cash to finance our operating activities. Cash used in operating activities resulted from funding our net loss of $5.0 million, partially offset by non-cash stock-based

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compensation expense of $1.9 million and depreciation and amortization of $1.7 million. Also contributing to the cash used in operating activities were an $801,000 increase in inventory largely due to stocking of our OraQuick® HIV and HCV tests and a $199,000 decrease in accrued expenses and other liabilities. Offsetting these uses of cash were a $728,000 decrease in accounts receivable, a $495,000 decrease in prepaid expenses and other assets, and an $825,000 increase in accounts payable.

Net cash provided by investing activities of $715,000 during the first six months of 2011 resulted from the maturity of $1.9 million of certificates of deposit, partially offset by purchases of property and equipment of $1.2 million.

Net cash provided by financing activities was $1.2 million for the six months ended June 30, 2011, primarily as a result of $2.3 million in proceeds received from the exercise of stock options, partially offset by $250,000 in loan principal repayments and $848,000 used for the repurchase of common stock related to the vesting of restricted shares.

As of June 30, 2011, we had in place a $10,000,000 credit facility (the Credit Facility) with Comerica Bank (Comerica). Pursuant to the terms of the Credit Facility, principal, and interest fixed at 4.15% per annum, were payable monthly through June 27, 2011. An amendment to the Credit Facility was executed with Comerica on June 24, 2011, extending the current terms of the Credit Facility and its maturity date to September 27, 2011. As of June 30, 2011, we had no available borrowings under this Credit Facility. We are evaluating possible options to address the upcoming expiration of the Credit Facility, including refinancing with a new credit facility or other borrowings.

All borrowings from Comerica 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. The Comerica agreement 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 as of June 30, 2011. The agreement 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.

The combination of our current cash and cash equivalents is expected to be sufficient to fund our operating and capital needs through at least the next twelve months, including funding the expected $53 million purchase price of DNA Genotek Inc. Our cash requirements, however, may vary materially from those now planned due to many factors, including, but not limited to, the scope and timing of future 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 cost of any future litigation, the magnitude of capital expenditures, changes in existing and potential relationships with business partners, the time and cost of obtaining regulatory approvals, the costs involved in obtaining and enforcing patents, proprietary rights and any necessary licenses, the cost and timing of expansion of sales and marketing activities, the timing of market launch of new products, market acceptance of new products, competing technological and market developments, the impact of the ongoing economic downturn and other factors.

Summary of Contractual Obligations

A summary of our obligations to make future payments under contracts existing at December 31, 2010 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, 2010. As of June 30, 2011, there were no significant changes to this information, including the absence of any off-balance sheet arrangements. For a summary of our obligations to make future payments to DNAG under that certain Support Agreement, dated July 25, 2011, see Note 8 to the financial statements included herein.

Critical Accounting Policies and Estimates

This 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

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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 and realization of the related deferred tax assets, 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 2010 Annual Report on Form 10-K filed with the SEC. During the first six months of 2011, there were no material changes in our critical accounting policies.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

The majority of our assets are comprised of cash and cash equivalents and as a result we have little exposure to market risks associated with available-for-sale securities.

In January 2008, we elected to fix the interest rate on our long-term debt at 4.15% until the debt s maturity, as amended, in September 2011. As a result, we have no exposure to interest rate changes.

As of June 30, 2011, we did not have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. We have operations in Europe and Africa, which are subject to foreign currency fluctuations. Sales denominated in a foreign currency were immaterial as a percentage of our total revenues for the six months ended June 30, 2011. We do not expect the risk of foreign currency fluctuations to be material to us in the near future.

On July 25, 2011, we announced that we entered into a definitive Support Agreement to acquire all of the outstanding capital stock of DNA Genotek Inc. The purchase price set forth in the Support Agreement is 50,000,000 Canadian dollars, or approximately US$53,000,000 at the July 25, 2011 exchange rate. Given this purchase price is payable in Canadian dollars, fluctuations in the exchange rate of the U.S. and Canadian dollar could have a material impact on the final U.S. dollar equivalent paid for this acquisition. For example, a one percent decline in the current exchange rate between the U.S. and Canadian dollar would increase the cash paid for this acquisition by approximately $521,000. We are closely monitoring this exchange rate risk and we are evaluating strategies to mitigate it, if necessary.

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, 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 June 30, 2011. 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 June 30, 2011 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 was 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 was recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC.

(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 June 30, 2011 that has materially affected, or is reasonably likely to materially affect, the Company s internal control over financial reporting.

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PART II. OTHER INFORMATION

Item 1A. RISK FACTORS

Except as noted below, 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, 2010:

There are risks associated with our recent entry into a definitive agreement to acquire DNA Genotek Inc.

On July 25, 2011, we entered into a definitive Support Agreement to acquire all of the outstanding capital stock of DNAG, a leading provider of oral fluid sample collection, stabilization and preparation products for molecular diagnostic applications. There are risks associated with our having entered into this agreement.

We cannot assure you that all conditions to the proposed acquisition will be completed and the proposed acquisition consummated. The proposed acquisition is subject to the satisfaction of customary closing conditions. In the event that the proposed acquisition is not completed, we may be subject to risks, including the costs related to the proposed acquisition, such as legal, accounting, and advisory fees, which must be paid even if the acquisition is not completed. If the proposed acquisition is not completed, the market price of our Common Stock could decline.

We and DNAG entered into the Support Agreement with the expectation that the acquisition will result in benefits to both companies. Because of difficulties associated with combining or managing geographically distant operations, we may not achieve successful integration of DNAG in a timely manner, or at all, and we may not realize the benefits of the acquisition to the extent, or in the timeframe, anticipated. It is possible that the integration process could result in the loss of key employees, diversion of each company s management s attention, the disruption or interruption of, or the loss of momentum in, each company s ongoing business or inconsistencies in standards, controls, procedures and policies, any of which could adversely affect either company s ability to maintain relationships with licensors, collaborators, partners, suppliers and employees or our ability to achieve the anticipated benefits of the acquisition, or could reduce our earnings or otherwise adversely affect the business and financial results of the combined company and, as a result, adversely affect the market price of our Common Stock.

We may incur costs integrating DNAG s business operations, technology, development programs, products and personnel with those of OraSure s. These costs are difficult to estimate, may be higher than expected, and may harm the financial results of the combined company. We have incurred substantial direct transaction costs associated with the proposed acquisition and we expect to continue to incur substantial costs for these purposes. If the total costs of the proposed acquisition exceed estimates or if the benefits of the proposed acquisition do not exceed the total costs of the proposed acquisition, our financial results could be adversely affected.

Item 2. UNREGISTERED SALE OF EQUITY SECURITIES AND USE OF PROCEEDS

During the quarter ended June 30, 2011, pursuant to the OraSure Technologies, Inc. Stock Award Plan, and in connection with the vesting of restricted shares, we retired 2,735 shares of our Common Stock to satisfy minimum tax withholding obligations at an average price paid per share of $8.50.

Item 6. EXHIBITS

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

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SIGNATURES

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

ORASURE TECHNOLOGIES, INC.

Date: August 5, 2011

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

Date: August 5, 2011

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

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EXHIBIT INDEX

Exhibit	
2.1	Support Agreement, dated July 25, 2011, by and among OraSure Technologies, Inc., 7924569 Canada Inc., DNA Genotek, Inc. (DNAG), 1548674 Ontario Inc., the shareholders of 1548674 Ontario Inc. and certain representatives of DNAG shareholders, is incorporated by reference to Exhibit 2.1 to the Company s Current Report on Form 8-K filed July 25, 2011.
2.2	Form of Offer to Purchase and Share Purchase Agreement, between 7924569 Canada Inc. and the DNAG shareholder signatory thereto is incorporated by reference to Exhibit 2.2 to the Company s Current Report on Form 8-K filed July 25, 2011.
10.1	OraSure Technologies, Inc. Stock Award Plan, amended and restated effective as of May 17, 2011, is incorporated by reference to Exhibit 10 to the Company s Current Report on Form 8-K filed May 5, 2011.*
10.2	Form of Restricted Share Grant Agreement (Executive Officers).*
10.3	Form of Restricted Share Grant Agreement (Non-Employee Directors).*
10.4	Nonqualified Stock Option Award General Terms and Conditions (Executive Officers).*
10.5	Nonqualified Stock Option Award General Terms and Conditions (Non-Employee Directors).*
10.6	Sixth Amendment to Loan and Security Agreement, dated as of June 24, 2011, between OraSure Technologies, Inc. and Comerica Bank is incorporated by reference to Exhibit 10 to the Company s Current Report on Form 8-K filed June 27, 2011.
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.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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* Management contract or compensatory plan or arrangement.