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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 September 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 ☒ 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 ☒ 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 ☒
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 November 3, 2011: 47,221,549

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PART I. FINANCIAL INFORMATION

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Item 1. FINANCIAL STATEMENTS

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(Unaudited)

	SEPTEMBER 30, 2011	DECEMBER 31, 2010
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 21,374,355	$ 73,843,402
Short-term investments	—	1,895,000
Accounts receivable, net of allowance for doubtful accounts of $132,539 and $105,954	14,361,295	12,471,249
Inventories	9,447,934	7,345,594
Prepaid expenses	1,522,837	1,579,513
Other current assets	716,037	350,595
Total current assets	47,422,458	97,485,353
PROPERTY AND EQUIPMENT, net	20,000,180	19,610,583
INTANGIBLE ASSETS, net	29,245,948	4,806,919
GOODWILL	25,938,724	—
OTHER ASSETS	199,612	617,238
	$ 122,806,922	$ 122,520,093
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	$ 7,416,680	$ 7,791,680
Accounts payable	3,484,981	2,898,846
Accrued expenses and other	9,397,149	8,986,879
Total current liabilities	20,298,810	19,677,405
DEFERRED INCOME TAXES	6,533,755	—
COMMITMENTS AND CONTINGENCIES (Note 8)		
STOCKHOLDERS' EQUITY		
Preferred stock, par value $.000001, 25,000,000 shares authorized,none issued	—	—
Common stock, par value $.000001, 120,000,000 shares authorized, 47,057,513 and 46,225,622 shares issued and outstanding	47	46
Additional paid-in capital	246,581,391	241,663,337
Accumulated other comprehensive loss	(3,065,772)	(235,264)
Accumulated deficit	(147,541,309)	(138,585,431)
Total stockholders' equity	95,974,357	102,842,688
	$ 122,806,922	$ 122,520,093

See accompanying notes to the financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
REVENUES:				
Product	$ 21,435,359	$ 18,399,281	$ 57,184,756	$ 52,675,838
Licensing and product development	278,543	634,829	1,006,434	3,521,632
	21,713,902	19,034,110	58,191,190	56,197,470
COST OF PRODUCTS SOLD	8,120,148	7,220,383	21,069,641	20,802,046
Gross profit	13,593,754	11,813,727	37,121,549	35,395,424
OPERATING EXPENSES:				
Research and development	5,546,435	3,008,359	15,109,662	9,143,792
Sales and marketing	5,742,248	4,593,270	16,025,965	15,897,966
General and administrative	6,510,050	3,923,348	15,103,177	12,775,932
	17,798,733	11,524,977	46,238,804	37,817,690
Operating income (loss)	(4,204,979)	288,750	(9,117,255)	(2,422,266)
INTEREST EXPENSE	(85,105)	(77,562)	(242,848)	(231,312)
INTEREST INCOME	3,208	48,465	60,628	139,283
FOREIGN CURRENCY GAIN (LOSS)	51,520	(6,004)	33,146	22,922
OTHER INCOME (EXPENSE)	673	20,305	(4,857)	17,147
Income (loss) before income taxes	(4,234,683)	273,954	(9,271,186)	(2,474,226)
INCOME TAX BENEFIT	(315,308)	—	(315,308)	—
NET INCOME (LOSS)	$ (3,919,375)	$ 273,954	$(8,955,878)	$ (2,474,226)
EARNINGS (LOSS) PER SHARE:				
BASIC AND DILUTED	$ (0.08)	$ 0.01	$ (0.19)	$ (0.05)
SHARES USED IN COMPUTING EARNINGS (LOSS) PER SHARE				
BASIC	47,027,612	46,213,539	46,788,456	46,176,118
DILUTED	47,027,612	46,566,386	46,788,456	46,176,118

See accompanying notes to the financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine Months Ended September 30, 2011	2010
OPERATING ACTIVITIES:		
Net loss	$ (8,955,878)	$ (2,474,226)
Adjustments to reconcile net loss to net cash		
(used in) provided by operating activities:		
Stock-based compensation	3,016,366	2,478,653
Depreciation and amortization	3,010,784	2,100,788
Deferred income taxes	(299,184)	—
Inventory purchase accounting step-up adjustment	762,853	—
Changes in assets and liabilities, net of effects from acquisition:		
Accounts receivable	(647,388)	543,131
Inventories	(1,491,932)	865,136
Prepaid expenses and other assets	794,554	1,133,331
Accounts payable	268,266	(588,573)
Accrued expenses and other liabilities	(536,953)	(3,817,040)
Net cash (used in) provided by operating activities	(4,078,512)	241,200
INVESTING ACTIVITIES:		
Proceeds from maturities and redemptions of short-term investments	1,895,000	2,741,000
Acquistion of DNA Genotek Inc., net of cash acquired	(49,973,200)	—
Payments for patents and product rights	—	(3,500,000)
Purchases of property and equipment	(1,806,369)	(1,643,266)
Net cash used in investing activities	(49,884,569)	(2,402,266)
FINANCING ACTIVITIES:		
Repayments of long-term debt	(375,000)	(384,760)
Proceeds from exercise of stock options	2,762,289	3,722
Repurchase of common stock	(883,565)	(693,022)
Net cash provided by (used in) financing activities	1,503,724	(1,074,060)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	(9,690)	—
NET DECREASE IN CASH AND CASH EQUIVALENTS	(52,469,047)	(3,235,126)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	73,843,402	74,933,630
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 21,374,355	$ 71,698,504
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid (received) for:		
Interest	$ 245,130	$ 256,670
Income taxes	$ 28,000	$ (585,893)

See accompanying notes to the financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
Notes to the Consolidated Financial Statements
(Unaudited)

1. The Company

OraSure Technologies, Inc. ("OraSure") manufactures and markets 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.

On August, 17, 2011, we completed our acquisition of DNA Genotek, Inc. ("DNAG"). DNAG is based in Ottawa, Canada and manufactures and sells oral fluid collection devices used to collect samples of genetic material for molecular testing in the academic research, clinical genetic testing, pharmacogenomics, personalized medicine, and animal genetics markets. DNAG's lead product, the OraGene® DNA sample collection kit, provides an all-in-one system for the collection, stabilization, transportation and purification of DNA from saliva. DNAG will operate as a wholly-owned subsidiary of OraSure.

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

Principles of Consolidation and Basis of Presentation. The consolidated financial statements include the accounts of OraSure and its wholly-owned subsidiary, DNAG (collectively, the "Company"). All intercompany transactions and balances have been eliminated.

The accompanying consolidated 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 nine months ended September 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 December 31, 2010, cash equivalents consisted of money market accounts. We had no cash equivalents at September 30, 2011.

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 September 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 that 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:

	September 30, 2011	December 31, 2010
Raw materials	$5,355,290	$4,453,560
Work in process	529,422	258,335
Finished goods	3,563,222	2,633,699
	$9,447,934	$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 two 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 September 30, 2011 and December 31, 2010 was $21,607,916 and $20,204,317, respectively.

Intangible Assets. Intangible assets consist of the following:

		September 30, 2011		
	Amortization Period (Years)	Gross	Accumulated Amortization	Net
Customer lists	10	$ 11,346,192	$ (131,863)	$ 11,214,329
Patent and product rights	3-10	10,448,620	(6,199,701)	4,248,919
Acquired technology	7	8,752,804	(143,115)	8,609,689
Tradename	15	4,319,441	(34,694)	4,284,747
Non-compete agreements	1-3	937,219	(48,955)	888,264
		$ 35,804,276	$ (6,558,328)	$ 29,245,948

As of December 31, 2010, intangible assets of $10,448,620 consisted of only patent and product rights. Accumulated amortization of the patent and product rights as of December 31, 2010 was $5,641,701.

Goodwill. Goodwill represents the excess of the purchase price we paid over the fair value of the net tangible and identifiable intangible assets acquired and liabilities assumed in our acquisition of DNAG. Goodwill is not amortized but rather is tested annually for impairment or more frequently if we believe that indicators of impairment exist. Performance of a goodwill impairment test involves a two-step process. The first step involves comparing the fair values of the applicable reporting units with their aggregate carrying values, including goodwill. If the carrying value of a reporting unit exceeds the reporting unit's fair value, we perform the second step of the test to determine the amount of the impairment loss. The second step involves measuring the impairment by comparing the implied fair values of the affected reporting unit's goodwill and intangible assets with the respective carrying values.

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 intangible assets, 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.

Customer and Vendor Concentrations. We had no significant concentrations (greater than 10%) in accounts receivable as of September 30, 2011 or in revenues for either the three or nine months ended September 30, 2011 or 2010. As of December 31, 2010, one of our customers, Quest Diagnostics, Incorporated, accounted for approximately 10% of our accounts receivable balances.

We currently purchase certain products and critical components of our products from sole-supply vendors, and if these vendors are unable or unwilling to supply the required components and products, this could subject us to substantial delays in the delivery of our products to our customers and increased costs. Furthermore, our subsidiary, DNAG, uses two third-party suppliers to manufacture its products. Our inability to have a timely supply of any of these components and products could have a material adverse effect on our business, as well as our financial condition and results of operations.

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.

Income Taxes. We follow the asset and liability method for accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and the respective tax basis of assets and liabilities, and operating loss and credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates for the respective taxing jurisdiction that are expected to apply to taxable income in the years in which those temporary differences and operating loss and credit carryforwards are expected to be recovered, settled or utilized. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

We assess the realizability of our net deferred tax assets on a quarterly basis. If, after considering all relevant positive and negative evidence, it is more likely than not that some portion or all of the net deferred tax assets will not be realized we reduce our net deferred tax assets by a valuation allowance. The realization of the net deferred tax assets is dependent on several factors, including the generation of sufficient taxable income prior to the expiration of the net operating loss carryforwards.

Earnings (loss) Per Share. Basic and diluted earnings (loss) per share is computed by dividing net income (loss) by the weighted-average number of shares of common stock outstanding during the period. Diluted earnings (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 6,820,601 and 6,664,923 shares were outstanding as of September 30, 2011 and 2010, respectively. As a result of our net losses for the three months ended September 30, 2011 and the nine months ended September 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.

The computation of basic and diluted earnings per share for the three months ended September 30, 2010 is as follows:

Net income	$ 273,954
Weighted average shares of common stock outstanding:	
Basic	46,566,386
Dilutive effect of stock options, warrants and restricted stock	(352,847)
Diluted	46,213,539
Earnings per share:	
Basic and Diluted	$ 0.01

Foreign Currency Translation. Results of foreign operations are translated into U.S. dollars using average exchange rates during the period, while assets and liabilities are translated into U.S. dollars using exchange rates in effect at the balance sheet date. The resulting translation adjustments are recorded in accumulated other comprehensive loss. As of September 30, 2011 and December 31, 2010, the accumulated foreign currency adjustments included in other comprehensive loss amounted to $3,065,772 and $235,264, respectively.

Transaction gains and losses resulting from exchange rate changes on transactions denominated in currencies other than functional currency are included in income in the period in which the change occurs.

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 September 30, 2011 and December 31, 2010 consisted of currency translation adjustments. Comprehensive income (loss) was $(6,571,318) and $257,158 for the three months ended September 30, 2011 and 2010, respectively, and $(11,786,386) and $(2,492,720) for the nine months ended September 30, 2011 and 2010, respectively.

Recent Accounting Pronouncements. In June 2011, the Financial Accounting Standards Board ("FASB") issued guidance amending the *Other Comprehensive Income* topic of the FASB Codification. The guidance provides an entity with the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. This guidance will be effective for us in the first quarter of 2012 and is not expected to have a material impact on our financial position, results of operations or cash flows.

In September 2011, the FASB issued guidance amending the *Testing Goodwill for Impairment* topic of the FASB Codification. The new guidance allows companies to make a qualitative evaluation about the likelihood of goodwill impairment. If a company concludes that it is more likely than not that the carrying amount of a reporting unit is greater than its fair value, then it will be required to perform the first step of the two-step quantitative impairment test by calculating the fair value of the reporting unit and comparing the fair value with the carrying amount. Otherwise, performing the two-step impairment test is unnecessary. This new guidance is effective for annual and interim goodwill impairment tests beginning after December 15, 2011, with early adoption permitted. We do not expect the adoption of the standard update to have a significant impact on our financial position, results of operations or cash flows.

3. Business Combination

On August 17, 2011 (the “Acquisition Date”), OraSure, through a wholly-owned subsidiary, acquired all of the outstanding capital stock of DNAG, pursuant to the terms of a Support Agreement dated July 25, 2011. The purchase price was $50 million CDN (approximately $50.7 million in U.S. dollars at the Acquisition Date exchange rate) and was funded by OraSure with cash on hand. Of the $50 million CDN purchase price, $5 million CDN (or approximately $5.1 million in U.S. dollars at the Acquisition Date exchange rates) was deposited in escrow for a limited period after closing, pursuant to DNAG’s indemnification obligations under the Support Agreement.

The acquisition of DNAG strengthens OraSure’s leadership in oral fluid diagnostics, by providing OraSure with a complementary portfolio of products that enable easy and reliable collection, stabilization, transportation and storage of high quality nucleic acid (DNA and RNA) samples. These samples can then be used for a wide range of research and diagnostic applications.

We have accounted for the acquisition of DNAG using the purchase method of accounting, in accordance with U.S. GAAP. Under the purchase method of accounting, the total purchase price is allocated to the tangible and identifiable intangible assets acquired and the liabilities assumed based upon their respective estimated fair values as of the Acquisition Date. The excess of the fair value of the consideration paid over the estimated fair value of the assets acquired and liabilities assumed was recorded as goodwill. For purposes of the purchase price allocation, fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. The fair value guidance also requires that the fair value measurements reflect the assumptions market participants use in pricing an asset or liability based upon the best information available. Under the purchase method of accounting, acquisition related transaction costs, such as success-based banking fees and professional fees, are not included as a component of consideration transferred, but rather are accounted for as expenses in the periods in which the costs are incurred.

Through September 30, 2011, we have incurred a total of $2.5 million of acquisition related costs, including success-based investment banking fees and accounting, legal and other professional fees, related to the DNAG acquisition, all of which were expensed and reported as a component of general and administrative expenses in the consolidated statement of operations for the nine months ended September 30, 2011.

The $50.7 million purchase price has been allocated based upon a preliminary estimate of the fair values of the tangible and intangible assets acquired and the liabilities assumed. The determination of the estimated fair value allocation of the purchase price required us to make significant estimates and assumptions. These estimates and assumptions are preliminary and are subject to change. An independent valuation specialist used these estimates and assumptions to conduct analyses to assist us in determining the estimated fair value of acquired intangibles. The work performed by the independent valuation specialists, while not yet finalized, has been considered in our estimates of the fair values reflected. Finalization of the valuation analysis by the independent valuation specialist may result in asset and liability fair values that are different than the preliminary estimates of the amounts included herein.

The following table summarizes the allocation of the estimated fair values of the assets acquired and the liabilities assumed at the Acquisition Date:

Current assets	$ 4,270,685
Property, plant and equipment	714,965
Other assets	1,691
Acquired intangible assets	26,862,000
Goodwill	27,493,114
Total assets acquired	59,342,455
Current liabilities	(1,559,776)
Deferred tax liability	(7,072,679)
Total liabilities assumed	(8,632,455)
Purchase price	50,710,000
Less cash acquired	(736,800)
Net cash paid	$49,973,200

The following represents details of the purchased intangible assets as part of the acquisition:

Description	Estimated Useful Life (in yrs)	Amount
Customer List	10	$12,020,000
Acquired Technology	7	9,273,000
Tradename	15	4,576,000
Non-compete Agreements	1-3	993,000
Total acquired intangible assets		$26,862,000

The acquisition of DNAG will provide us with an opportunity to access and expand its business in the molecular diagnostic marketplace. This factor contributed to a purchase price resulting in goodwill. The acquired goodwill will not be amortized, and also will not be deductible for income tax purposes.

Included in the current assets acquired in the DNAG acquisition was inventory having an estimated fair value of $1,412,755. This fair value includes an $892,276 “step-up” adjustment to capitalize the estimated manufacturing profit in acquired finished goods inventory as of the Acquisition Date, of which we expensed $762,853 to cost of products sold during the three and nine months periods ended September 30, 2011. We will record an additional non-cash charge to cost of products sold over the period in which the remainder of the stepped-up inventory is sold.

The results of operations associated with DNAG have been consolidated with those of the Company since the Acquisition Date. Total revenues of $2,021,580 and a net loss of $800,755, including $762,853 of inventory step-up as noted above, attributable to DNAG were recognized in the consolidated statements of operations for the three and nine months ended September 30, 2011.

The following unaudited condensed pro forma consolidated information sets forth the combined revenues, net loss and net loss per share of the Company and DNAG for the three and nine month periods ended September 30, 2011 and 2010, as if the acquisition had occurred on January 1, 2010. The unaudited pro forma information presented below is not necessarily indicative of the results that would have been attained had the transaction occurred at an earlier date, nor are these results necessarily indicative of future consolidated results of operations of the Company.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Total revenues	$ 22,198,612	$ 21,521,716	$ 66,239,991	$ 66,195,597
Net loss	$ (2,479,590)	$ (268,056)	$ (8,140,783)	$ (2,941,959)
Loss per share:				
Basic and diluted	$ (0.05)	$ (0.01)	$ (0.17)	$ (0.06)

The supplemental pro forma results depicted above for the three and nine months ended September 30, 2011 were adjusted to exclude $5.7 million and $5.9 million, respectively, of transaction costs incurred by both OraSure and DNAG and that were recorded in operating expenses.

4. 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 of OraSure and its affiliates, outside directors and consultants or other third-party advisors. Awards that 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 September 30, 2011 and 2010 was $3.14 and $1.47 per share, respectively. The weighted average grant date fair value of stock options granted during the nine months ended September 30, 2011 and 2010 was $2.89 and $2.24 per share, respectively.

Total compensation cost related to stock options for the three months ended September 30, 2011 and 2010 was $435,076 and $219,477, respectively, of which $14,432 and $8,897 was capitalized into inventory during the quarters ended September 30, 2011 and 2010, respectively. The amounts recognized in cost of products sold for amounts previously capitalized were $1,657 and $18,379 for the three months ended September 30, 2011 and 2010, respectively.

Total compensation cost related to stock options for the nine months ended September 30, 2011 and 2010 was $1,119,838 and $695,096, respectively, of which $38,702 and $35,671 was capitalized into inventory during the nine months ended September 30, 2011 and 2010, respectively. The amounts recognized in cost of products sold for amounts previously capitalized were $26,603 and $50,366 for the nine months ended September 30, 2011 and 2010, respectively.

The following table summarizes the stock option activity for the nine months ended September 30, 2011:

	Options
Outstanding on January 1, 2011	5,503,533
Granted	1,103,225
Exercised	(548,468)
Forfeited	(125,735)
Outstanding on September 30, 2011	5,932,555

As of September 30, 2011, there was $3,940,603 of unrecognized compensation expense related to unvested option awards that is expected to be recognized over a remaining weighted average period of 2.1 years.

Net cash proceeds from the exercise of stock options were $2,762,289 and $3,722 for the nine months ended September 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 nine months ended September 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 $650,593 and $562,557 related to restricted shares was recognized during the three months ended September 30, 2011 and 2010, respectively. Compensation cost of $1,896,528 and $1,783,556 related to restricted shares was recognized during the nine months ended September 30, 2011 and 2010, respectively.

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

	Shares
Issued and unvested, January 1, 2011	792,156
Granted	525,880
Vested	(414,990)
Forfeited	(15,000)
Issued and unvested, September 30, 2011	888,046

As of September 30, 2011, there was $3,700,599 of unrecognized compensation expense related to unvested restricted stock awards that is expected to be recognized over a remaining weighted average period of 2.0 years. In connection with the vesting of restricted shares, during the nine months ended September 30, 2011 and 2010, 131,567 and 133,345 shares, respectively, with aggregate values of $883,563 and $693,022, respectively, were withheld and retired in satisfaction of minimum tax withholding obligations.

5. Accrued Expenses

	September 30, 2011	December 31, 2010
Payroll and related benefits	$4,201,672	$4,343,350
Royalties	1,683,699	1,985,799
Deferred revenue	1,735,490	896,531
Professional fees	510,370	213,308
Clinical research obligations	106,181	400,860
Other	1,159,737	1,147,031
	$9,397,149	$8,986,879

Deferred revenue at September 30, 2011 and December 31, 2010 included customer prepayments of $1,707,490 and $851,031, respectively.

6. Long-term Debt

As of September 30, 2011, we had in place a $10,000,000 credit facility (the “Credit Facility”), as amended, 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 September 27, 2011. As most recently extended, the Credit Facility has a maturity date of November 27, 2011. As of September 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.

All borrowings under the Credit Facility are collateralized by a first priority security interest in all OraSure 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 September 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.

7. Income Taxes

During the three and nine months ended September 30, 2011, we recorded a foreign deferred tax benefit of $315,308. This tax benefit relates primarily to the foreign tax impact associated with the amortization of intangibles and the inventory fair value adjustment recorded in connection with the DNAG acquisition.

Deferred income taxes reflect the tax effects of temporary differences between the basis of assets and liabilities recognized for financial reporting purposes and tax purposes, and net operating loss and tax credit carryforwards. The significant components of our total deferred tax liabilities as of September 30, 2011 relate to the tax effects of the basis differences between the intangible assets and inventories acquired in the DNAG acquisition for financial reporting and tax purposes. The deferred tax liability of $7,072,679 resulted in our recording an increase to goodwill, pursuant to purchase accounting guidance.

In 2008, we established a full valuation allowance against our U.S. net deferred tax asset, and management continues to evaluate whether the full valuation allowance is appropriate. As of September 30, 2011 and December 31, 2010, we concluded that the full valuation allowance remains appropriate since the facts and circumstances necessitating the allowance have not changed. As a result, no U.S. federal or state income tax benefit was recorded for the three and nine months ended September 30, 2011.

8. 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.

9. Geographic Information

Our products are sold principally in the United States and Europe. The following table represents total revenues by geographic area, based on the location of the customer (amounts in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
United States	$17,571	$16,398	$48,151	$47,723
Europe	2,302	1,598	5,567	4,792
Other regions	1,841	1,038	4,473	3,682
	$21,714	$19,034	$58,191	$56,197

As of September 30, 2011, total assets held by DNAG were $55,823,264.

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 integrate and realize the full benefits of the Company's acquisition of DNA Genotek; ability to identify, complete, integrate and realize the full benefits of future acquisitions; 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 products and 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; adverse movements in foreign currency exchange rates; 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

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.

On August 17, 2011, we completed our acquisition of DNA Genotek Inc. ("DNAG"). DNAG is based in Ottawa, Canada and manufactures and sells oral fluid collection devices that are used to collect samples of genetic material for molecular testing in the academic research, clinical genetic testing, pharmacogenomics, personalized medicine, animal and livestock genetics markets. DNAG's lead product, the OraGene® DNA sample collection kit, provides an all-in-one system for the collection, stabilization, transportation and purification of DNA from saliva. DNAG serves customers in over 100 countries worldwide, including many of the top research universities and hospitals in the world.

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 have engaged distributors to sell our OraQuick® rapid HIV and HCV tests 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 and expense incurred to develop replacements and obtain the required U.S. Food and Drug Administration ("FDA") approvals could disrupt our ability to sell the affected products and could adversely impact our revenues and results of operations. Our OraSure QuickFlu™ test is manufactured and supplied by a sole source supplier and DNAG also utilizes contract manufacturers to supply all of its products and certain components to these products. Any disruption in the ability of these parties to manufacture and supply finished goods or product components for us or DNAG could adversely impact our revenues and results of operations.

Current Consolidated Financial Results

During the nine months ended September 30, 2011, our total revenues were $58.2 million compared to $56.2 million in the nine months ended September 30, 2010. Total revenues in 2011 included $2.0 million from DNAG operations. Excluding the DNAG sales, product revenues during the nine months ended September 30, 2011 increased 5% when compared to the first nine months of 2010. Licensing and product development revenues in 2011

decreased primarily as a result of 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 nine months of 2010 for the development and promotion of our OraQuick® rapid HCV test in Europe.

Our net loss for the nine months ended September 30, 2011 was $8.9 million, or $0.19 per share, compared to a net loss of $2.5 million, or $0.05 per share, for the nine months ended September 30, 2010. Net loss for the current period incorporated the operating results for DNAG, including a purchase accounting adjustment discussed below, and transaction costs we incurred in connection with the acquisition.

Cash used in operating activities for the nine months ended September 30, 2011 was approximately $4.1 million, compared to the $241,000 provided by operating activities for the nine months ended September 30, 2010. As of September 30, 2011, we had $21.4 million in cash, cash equivalents and short-term investments, compared to $75.7 million at December 31, 2010. During the third quarter of 2011, we used $53.0 million of our cash to fund the DNAG acquisition and related transaction expenses.

Other Recent Developments

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 had received a request for additional data from the FDA, which required us to conduct an additional reproducibility study. That study has been completed and the results were submitted to the FDA. We believe we have provided all data required by the FDA to complete its review of our application.

OraQuick® HIV OTC Test

We completed the final phase of clinical testing for an OraQuick® HIV OTC test. In this study, individuals conducted 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 total, we enrolled and tested over 5,600 subjects, and identified more than 100 previously undiagnosed HIV infected individuals. Testing at all clinical sites in the study is complete, the database of study results is locked and we are analyzing the final data, which will be used to prepare a final report.

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 filed in August 2011, contained data from all studies performed prior to the final phase. The second module will contain information about our manufacturing and Customer Care Call Center and is expected to filed by the end of November. The final module will contain the results of the unobserved clinical trial and is expected to be filed near the end of this year.

During the third quarter, we continued planning for the commercial launch of our HIV OTC test. We are completing an intensive interview process to select both an advertising agency and public relations firm to help market our test and we are nearing a final decision on the selection of a third party to manage our Customer Care Call Center. In addition, we initiated a new round of market research to refresh our messaging and product positioning and to sharpen our demand forecast. These activities are expected to result in higher expenses in the fourth quarter of 2011, and these expenses are expected to significantly increase during 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 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® HCV 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, one of these competitors has received 510(k) clearance of its product and this 510(k) cleared product is being 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.

DNAG’s primary product, the Oragene® DNA collection system, competes against other types of collection devices used for molecular testing, such as blood collection devices and buccal swabs, that often are sold for prices lower than the prices charged for the Oragene® product. Although we believe the OraGene® device offers a number of advantages over these other products, the availability of lower price competitive devices can result in lost sales and degradation in pricing and profit margin.

Finally, current economic conditions, including disruptions in the capital and credit markets, may continue for the foreseeable future and intensify, and have 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 federal, 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 September 30, 2011 compared to September 30, 2010

Total revenues increased to $21.7 million in the third quarter of 2011 from $19.0 million in the comparable quarter of 2010. Revenues for the third quarter of 2011 included $2.0 million attributable to DNAG operations. Excluding the DNAG sales, product revenues during the three months ended September 30, 2011 increased 6% when compared to the third quarter of 2010. Increased sales of our infectious disease testing and cryosurgical systems products were partially offset by lower sales of our substance abuse and insurance risk assessment products. In addition, higher product revenues were partially offset by a reduction in licensing and product development revenues.

Revenues derived from products sold to customers outside the U.S. were $4.1 million and $2.6 million, or 19% and 14% of total revenues, in the third quarters of 2011 and 2010, respectively. 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.

	Three Months Ended September 30,				
	Dollars			Percentage of Total Revenues	
Market	2011	2010	% Change	2011	2010
Infectious disease testing	$11,854	$10,843	9%	55%	57%
Substance abuse testing	2,765	3,019	(8)	13	16
Cryosurgical systems	3,395	3,008	13	16	16
Molecular collection systems	2,022	—	100	9	0
Insurance risk assessment	1,399	1,529	(9)	6	8
Product revenues	21,435	18,399	17	99	97
Licensing and product development	279	635	(56)	1	3
Total revenues	$21,714	$19,034	14%	100%	100%

Infectious Disease Testing Market

Sales to the infectious disease testing market increased 9% to $11.9 million in the third quarter of 2011. OraQuick® sales totaled $11.3 million and $10.5 million in the third quarters of 2011 and 2010, respectively.

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

	Three Months Ended September 30,		
Market	2011	2010	% Change
Domestic	$10,342	$10,102	2%
International	971	436	123
Total OraQuick® revenues	$11,313	$10,538	7%

OraQuick® revenues for the three months ended September 30, 2011 included $425,000 of sales of our OraQuick® HCV test. Sales of our HCV test were minimal in the third quarter of 2010. In addition, sales of our OraQuick® HIV test in the international market increased 108% to $878,000 for the three months ended September 30, 2011, from $422,000 for the three months ended September 30, 2010. This increase reflects higher product sales in Asia, Africa and Europe, as certain private and government customers were able to fund purchases during the current three-month period.

Sales of our OraSure® oral fluid collection device increased 38% from $306,000 in the third quarter of 2010 to $422,000 in the third quarter of 2011 largely due to customer ordering patterns.

Substance Abuse Testing Market

Substance abuse testing revenues decreased 8% from $3.0 million in the third quarter of 2010 to $2.8 million in the third quarter of 2011 as a result of lower sales of our Q.E.D.® rapid point-of-care saliva alcohol test and our Intercept® drug testing system. During the third quarter of 2011, we experienced a temporary disruption of Q.E.D.® production, which resulted in an approximate $274,000 decrease in Q.E.D.® sales. Production resumed in October 2011 and we are filling a small backlog of Q.E.D.® orders.

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

	Three Months Ended September 30,		
Market	2011	2010	% Change
Domestic	$ 1,947	$ 1,913	2 %
International	438	562	(22)
Total Intercept® revenues	$ 2,385	$ 2,475	(4)%

Domestic Intercept® revenues remained relatively flat at $1.9 million in the third quarter of 2011 and 2010. International Intercept® revenues decreased 22% from $562,000 in the third quarter of 2010 to $438,000 in the third quarter of 2011 as result of variability in distributor 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 has issued 510(k) clearances 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. One of these products has received 510(k) clearance and is being offered by one of our laboratory distributors. 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) increased 13% to $3.4 million in the third quarter of 2011, compared to $3.0 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 third quarters of 2011 and 2010.

Market	Three Months Ended September 30, 2011	2010	% Change
Professional domestic	$ 2,042	$ 1,690	21 %
Professional international	402	326	23
Over-the-counter	951	992	(4)
Total cryosurgical systems revenues	$ 3,395	$ 3,008	13 %

Domestic physicians' office sales increased 21% or $352,000 for the third quarter of 2011 as compared to the third quarter of 2010, as a result of increased market penetration resulting from the continued efforts of our manufacturers' sales representatives, improved focus by our distributors and an increase in sales to governmental entities. 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 three months ended September 30, 2011, sales of Histofreezer® in the international market increased 23% as compared to the third quarter of 2010. International sales increased largely as a result of higher sales in Australia, as our new distributor in that country placed an initial stocking order, and because of higher sales in France.

Sales of our cryosurgical OTC products during the third quarter of 2011 decreased $41,000 largely as a result of lower sales to both our European OTC distributor, Reckitt Benckiser (formerly, SSL International), and to our Latin American distributor, Genomma.

Our distribution contract with Reckitt Benckiser is subject to renewal at the end of 2011. We are currently in negotiations to extend this contract.

Molecular Collection Systems

Molecular collection systems revenues represent sales of DNAG's Oragene® product line in the molecular diagnostics and research markets. The $2.0 million in revenues recorded in the current three-month period represents DNAG sales from the August 17, 2011 acquisition date through September 30, 2011.

Insurance Risk Assessment Market

Sales to the insurance risk assessment market decreased 9% to $1.4 million in the third quarter of 2011 from $1.5 million in the third quarter of 2010, largely the result of the loss of one of our customers who changed its underwriting methodologies to move away from oral fluid testing.

Licensing and Product Development

Licensing and product development revenues decreased $356,000 during the third quarter of 2011 as compared to the third quarter of 2010 due a decrease in royalties received on domestic outsales of Merck's OTC cryosurgical wart removal product, pursuant to a license and settlement agreement executed in January 2008.

Gross Margin

Gross margin in the third quarter of 2011 was 63% compared to 62% for the third quarter of 2010. Margin for our core OraSure business benefited from improved product mix, more efficient manufacturing operations, lower direct labor costs, improved absorption of overhead costs as a result of staffing optimization, and a change to automated manufacturing during 2011. DNAG's gross margin included $763,000 of increased cost of products sold due to a non-cash inventory adjustment. We expect the remaining inventory step-up will amortized to cost of products sold

in the fourth quarter. DNAG gross margin also included approximately $155,000 of amortization expense related to the acquisition. Ongoing amortization expense related to the DNAG acquisition will continue to adversely impact gross margins in future periods.

Operating Expenses

Research and development expenses increased 84% from $3.0 million in the third quarter of 2010 to $5.5 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 and the inclusion of $432,000 of DNAG research and development expenses.

Sales and marketing expenses increased 25% to $5.7 million in the third quarter of 2011 from $4.6 million in the third quarter of 2010, as a result of higher consulting and staffing costs and the inclusion of DNAG sales and marketing expenses of $768,000. Included in the DNAG expenses was approximately $150,000 of amortization expense related to the acquisition. Ongoing amortization expense related to the DNAG acquisition will continue to impact sales and marketing expenses in future periods.

General and administrative expenses increased 66% to $6.5 million in the third quarter of 2011 from $3.9 million in the third quarter of 2010, as a result of $2.1 million of transaction costs associated with the DNAG acquisition and the inclusion of DNAG general and administrative expenses of $338,000. The DNAG expenses included approximately $62,000 of amortization expense related to the acquisition. Ongoing amortization expense related to the DNAG acquisition will continue to impact general and administrative expenses in future periods.

Income Taxes

In connection with the DNAG acquisition, a deferred income tax liability was recorded to reflect the tax effects of the basis differences of the intangible assets and inventories for financial reporting and income tax purposes. An income tax benefit of $315,000 was recorded for the three months ended September 30, 2011. This income tax benefit relates primarily to the deferred tax impact of the amortization of intangibles and the non-cash inventory adjustment recorded in connection with the DNAG acquisition.

Nine months ended September 30, 2011 compared to September 30, 2010

Total revenues increased to $58.2 million in the first nine months of 2011 from $56.2 million in the comparable period of 2010. Revenues for the nine months ended September 30, 2011 included $2.0 million attributable to DNAG's operations. Excluding the DNAG sales, product revenues during the nine months ended September 30, 2011 increased 5% when compared to product revenues in the first nine months 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 partially offset by a $2.5 million reduction in licensing and product development revenues during the first nine months of 2011 as compared to 2010.

Revenues derived from products sold to customers outside the U.S. were $10.0 million and $8.5 million, or 17% and 15% of total revenues, in the first nine months of 2011 and 2010, respectively. 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.

Market	Nine Months Ended September 30, Dollars 2011	2010	% Change	Percentage of Total Revenues 2011	2010
Infectious disease testing	$33,100	$30,297	9 %	57 %	54 %
Substance abuse testing	9,011	8,785	3	15	16
Cryosurgical systems	8,907	9,122	(2)	15	16
Molecular collection systems	2,022	—	100	3	0
Insurance risk assessment	4,145	4,471	(7)	7	8
Product revenues	57,185	52,675	9	97	94
Licensing and product development	1,006	3,522	(71)	2	6
Total revenues	$58,191	$56,197	4 %	100 %	100 %

Infectious Disease Testing Market

Sales to the infectious disease testing market increased 9% to $33.1 million in the first nine months of 2011. OraQuick® sales totaled $32.0 million and $29.2 million in the first nine months of 2011 and 2010, respectively.

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

Market	Nine Months Ended September 30, 2011	2010	% Change
Domestic	$29,411	$28,083	5 %
International	2,574	1,089	136
Total OraQuick® revenues	$31,985	$29,172	10 %

OraQuick® revenues for the nine months ended September 30, 2011 included $748,000 of sales of our OraQuick® HCV test, compared to $59,000 in the same nine month period of 2010. During the nine months ended September 30, 2011, sales of our OraQuick® HIV test in the U.S. market increased by 3%, or $867,000, when compared to the same period of 2010. International sales of our OraQuick® HIV test increased 122% to $2.3 million for the nine months ended September 30, 2011 from $1.0 million for the nine months ended September 30, 2010. This increase reflects higher product sales in Asia, Africa, and Europe, as certain private and government customers were able to fund purchases.

Sales of our OraSure® oral fluid collection device decreased 12% from $1.1 million in the first nine months of 2010 to $996,000 in the first nine months 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 3% from $8.8 million in the first nine months of 2010 to $9.0 million in the first nine months of 2011, as a result of higher domestic sales of our Intercept® drug testing system partially offset by lower sales of our Q.E.D.® rapid point-of-care saliva alcohol test. During the third quarter of 2011, we experienced a temporary disruption of Q.E.D.® production, which resulted in an approximate $375,000 decrease in Q.E.D.® sales. Production resumed in October 2011 and we are filling a small backlog of Q.E.D.® orders.

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

Market	Nine Months Ended September 30, 2011	2010	% Change
Domestic	$ 5,909	$ 5,391	10 %
International	1,472	1,522	(3)
Total Intercept® revenues	$ 7,381	$ 6,913	7 %

Domestic Intercept® revenues increased 10% from $5.4 million in the first nine months of 2010 to $5.9 million in the first nine months of 2011. This increase was largely the result of variability in the ordering patterns of one of our larger laboratory customers and growth achieved within the workplace market segment as hiring conditions have slowly begun to improve when compared to the year-ago period.

International Intercept® revenues for the first nine months of 2011 remained relatively flat at $1.5 million for the nine months ended September 30, 2011 and 2010.

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 has issued 510(k) clearances 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. One of these products has received 510(k) clearance and is being offered by one of our laboratory distributors. 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 2% to $8.9 million in the first nine months of 2011, compared to $9.1 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 nine months of 2011 and 2010.

Market	Nine Months Ended September 30, 2011	2010	% Change
Professional domestic	$ 5,097	$ 4,476	14 %
Professional international	989	865	14
Over-the-counter	2,821	3,781	(25)
Total cryosurgical systems revenues	$ 8,907	$ 9,122	(2)%

Domestic physicians' office sales increased 14% or $621,000 for the first nine months of 2011 as compared to the same nine months of 2010, as a result of increased market penetration resulting from the continued efforts of

our manufacturers' sales representatives, improved focus by our distributors and an increase in sales to governmental entities. 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 nine months ended September 30, 2011, sales of Histofreezer® in the international market increased 14% or $124,000 as compared to the same nine months of 2010. This increase was largely experienced in the European market as a result of higher pricing and improved economic conditions in some local markets coupled with increased sales in Australia, as our new distributor in that country placed an initial stocking order.

Sales of our cryosurgical OTC products during the first nine months of 2011 decreased 25% primarily due to a decline in sales to both our Latin American distributor, Genomma, and our European distributor, Reckitt Benckiser (formerly, SSL International).

In the first nine months of 2010, Genomma had purchases totaling $1.7 million compared to $686,000 in the first nine months 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 nine 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 $137,000 during the first nine months of 2011 compared to the first nine months of 2010, largely due to variability in ordering patterns. Our distribution contract with Reckitt Benckiser is subject to renewal at the end of 2011. We are currently in negotiations to extend this contract.

Molecular Collection Systems

Molecular collection systems revenues represent sales of DNAG's Oragene® product line in the molecular diagnostics and research markets. The $2.0 million in revenues recorded in the current nine-month period represents DNAG sales from the August 17, 2011 acquisition date through September 30, 2011.

Insurance Risk Assessment Market

Sales to the insurance risk assessment market decreased 7% to $4.1 million in the first nine months of 2011 from $4.5 million in the first nine months of 2010 as a result of variability in the timing of orders, general softness in the life insurance market, and the loss of one of our customers who changed its underwriting methodologies to move away from oral fluid testing.

Licensing and Product Development

Licensing and product development revenues decreased 71% to $1.0 million during the first nine months of 2011 from $3.5 million during the first nine months of 2010. During the first nine months of 2010, we received $2.0 million in milestone 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 a license and settlement agreement executed in January 2008.

Gross Margin

Gross margin in the nine months ended September 30, 2011 was 64% compared to 63% for the comparable nine months of 2010. Margin for our core OraSure business benefited from improved product mix, more efficient

manufacturing operations, lower direct labor costs, improved absorption of overhead costs as a result of staffing optimization and a change to automated manufacturing during 2011. These improvements more than offset the negative margin impact associated with the absence of the HCV milestone payments in 2011.

DNAG's gross margin included $763,000 of increased cost of products sold due to a non-cash inventory adjustment. We expect the remaining inventory step-up will amortized to cost of products sold in the fourth quarter. DNAG's gross margin also included approximately $155,000 of amortization expense related to the acquisition. Ongoing amortization expense related to the DNAG acquisition will continue to adversely impact gross margins in future periods.

Operating Expenses

Research and development expenses increased 65% from $9.1 million in the first nine months of 2010 to $15.1 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 and the inclusion of $432,000 of DNAG research and development expenses.

Sales and marketing expenses remained relatively flat at $16.0 million in the nine months of 2011 and 2010. The 2011 amount included $768,000 of DNAG sales and marketing expenses, of which approximately $150,000 represented amortization expense related to the acquisition. Ongoing amortization expense related to the DNAG acquisition will continue to impact sales and marketing expenses in future periods.

General and administrative expenses increased 18% to $15.1 million in the first nine months of 2011 from $12.8 million in the comparable period of 2010, as a result of $2.5 million of transaction costs associated with the DNAG acquisition and the inclusion of DNAG general and administrative expenses of $338,000. The DNAG expenses included approximately $62,000 of amortization expense related to the acquisition. Ongoing amortization expense related to the DNAG acquisition will continue to impact general and administrative expenses in future periods.

Income Taxes

In connection with the DNAG acquisition, a deferred income tax liability was recorded to reflect the tax effects of the basis differences of the intangible assets and inventories for financial reporting and income tax purposes. An income tax benefit of $315,000 was recorded for the nine months ended September 30, 2011. This income tax benefit relates primarily to the deferred tax impact of the amortization of intangibles and the non-cash inventory adjustment recorded in connection with the DNAG acquisition.

Liquidity and Capital Resources

	September 30, 2011	December 31, 2010
	(In thousands)	
Cash and cash equivalents	$ 21,374	$ 73,843
Short-term investments	—	1,895
Working capital	27,124	77,808

Our cash, cash equivalents and short-term investments decreased $54.4 million from $75.7 million at December 31, 2010 to $21.4 million at September 30, 2011, largely due to the use of $53 million in cash to fund the DNAG acquisition and related transaction expenses. Our working capital likewise declined from $77.8 million at December 31, 2010 to $27.1 million at September 30, 2011 as a result of this significant use of cash.

During the first nine months of 2011, we used $4.1 in cash to finance our operating activities. Our net loss of $8.9 million, partially offset by non-cash stock-based compensation expense of $3.0 million, depreciation and amortization of $3.0 million, a non-cash inventory purchase accounting adjustment of $763,000 and a deferred income tax benefit of $299,000, resulted in a $2.5 million use of cash to fund operations. Additional uses of cash in operating activities included a $1.5 million increase in inventory largely due to stocking of our OraQuick® HIV and

HCV tests, a $647,000 increase in accounts receivable balances largely caused by end of the quarter customer shipments and a $537,000 decrease in accrued expenses and other liabilities. Offsetting these uses of cash were a $795,000 decrease in prepaid expenses and other assets, reflecting the ratable reduction in prepaid insurances, and a $268,000 increase in accounts payable.

We used a total of $49.9 million in investing activities during the first nine months of 2011. In order to acquire DNAG we used approximately $50.0 million of cash, net of DNAG cash acquired. We also purchased $1.8 million of property and equipment offset by the maturity of $1.9 million of certificates of deposit.

Net cash provided by financing activities was $1.5 million for the nine months ended September 30, 2011, primarily as a result of $2.8 million in proceeds received from the exercise of stock options, partially offset by $375,000 in loan principal repayments and $884,000 used for the repurchase of common stock related to the vesting of restricted shares.

As of September 30, 2011, we had in place a $10,000,000 credit facility (the “Credit Facility”) as amended 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 September 27, 2011. As most recently extended, the Credit Facility has a maturity date of November 27, 2011. As of September 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.

All borrowings from Comerica are collateralized by a first priority security interest in all of OraSure 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 September 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.

Our cash, cash equivalents and short-term investments decreased $54.4 million from $75.7 million at December 31, 2010 to $21.4 million at September 30, 2011, largely due to the use of $53 million in cash to fund the DNAG acquisition and related transaction expenses. 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. 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 including our OraQuick® HIV OTC test, 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 September 30, 2011, there were no significant changes to this information, including the absence of any off-balance sheet arrangements.

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

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. As of September 30, 2011, two additional critical accounting policies were added, as described below:

Business Combinations. We account for acquisitions or business combinations in accordance with Accounting Standards Codification 805, "Business Combinations." Pursuant to the purchase method of accounting included in that guidance, we allocate the purchase price of a business combination to the tangible and identifiable intangible assets acquired and the liabilities assumed, based on their estimated fair values. The excess purchase price over those fair values is then recorded as goodwill. In accounting for business combinations, we make valuation assumptions that require significant estimates, especially with respect to intangible assets. These critical estimates are based on historical experience; information obtained from management of the acquired company or third-party advisors; and expectations of future cash flows to be derived from customer contracts, customer lists, and acquired developed technologies or products, evaluated at various discount rates. Management estimates fair value based upon assumptions we believe to be reasonable, but which are inherently uncertain and unpredictable. As such, actual results may differ from these estimates. Estimates associated with the accounting for a business combination may also change as additional information becomes available regarding the assets acquired and the liabilities assumed.

Goodwill. Goodwill represents the excess of the purchase price we paid over the fair value of the net tangible and identifiable intangible assets acquired and liabilities assumed in our acquisition of DNAG. Goodwill is not amortized but rather is tested annually for impairment, or more frequently if we believe that indicators of impairment exist. Performance of the goodwill impairment test involves a two-step process. The first step involves comparing the fair values of the applicable reporting units with their aggregate carrying values, including goodwill. If the carrying value of a reporting unit exceeds the reporting unit's fair value, we perform the second step of the test to determine the amount of the impairment loss. The second step involves measuring the impairment by comparing the implied fair values of the affected reporting unit's goodwill and intangible assets with the respective carrying values.

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.

In January 2008, we elected to fix the interest rate on our long-term debt at 4.15%. As a result, we have no exposure to interest rate changes.

As of September 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 Canada, Europe and Africa, which are subject to foreign currency fluctuations. Sales denominated in a foreign currency were 4% as a percentage of our total revenues for the three months ended September 30, 2011 and 2% as a percentage of our total revenues for the nine months ended September 30, 2011. We do not expect the risk of foreign currency fluctuations to be material to us 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, evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) as of September 30, 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 September 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. The acquisition of DNA Genotek Inc. ("DNAG") on August 17, 2011 represents a material change in internal control over financial reporting since management's last assessment of the effectiveness of the Company's internal control over financial reporting which was as of June 30, 2011. As allowed under the SEC's guidance, management's assessment of and conclusion regarding the design and effectiveness of internal control over financial reporting excluded the internal control over financial reporting of DNAG. The financial reporting systems of DNAG have not yet been integrated into the Company's financial reporting systems and, as such, the Company did not have the practical ability to perform an assessment of DNAG's internal control over financial reporting in time for the current period. Management expects to complete its assessment of the effectiveness of internal control over financial reporting for the acquired business within one year of the date of the acquisition. DNAG operations contributed approximately $2 million in revenues to our consolidated financial results for the third quarter of 2011 (representing the period following the August 17, 2011 acquisition date) and DNAG had total assets of $55.8 million as of September 30, 2011 (of which approximately $50.9 million represented goodwill and identifiable intangible assets). With the exception of the DNAG acquisition as noted above, there were no changes in our internal control over financial reporting during the fiscal quarter ended September 30, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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 and in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2011:

Reductions in Government Funding and Research Budgets Could Adversely Affect Our Business and Financial Results.

We sell our OraQuick *ADVANCE*® HIV-1/2 test and certain other products into the public health market which consists of state, county and other governmental public health agencies, community based organizations, service organizations and similar entities. We also sell these products into the hospital market, including to hospitals owned or operated by agencies of the U.S. government such as the Veterans Administration. Many of these customers depend to a significant degree on grants or funding provided by governmental agencies to run their operations including programs that use our products. In international markets, we often sell our products to or through foreign governmental agencies or parties funded by such agencies.

Our subsidiary, DNAG, sells many of its products to researchers at academic institutions, pharmaceutical and biotechnology companies, government laboratories and private foundations. In 2010, DNAG reported total revenues of approximately $14.3 million, approximately 68% of which was derived from the academic and research markets. Many research customers are dependent for their funding on grants from U.S. governmental agencies such as the U.S. National Institutes of Health and agencies in other countries.

The level of available government grants or funding in the U.S. and elsewhere is unpredictable and may be affected by various factors including the current economic downturn, future economic conditions, legislative and regulatory developments, political changes, civil unrest and changing priorities for research and development activities. Any reduction or delay in government funding could cause our customers to delay, reduce or forego purchases of our products.

On August 2, 2011 President Obama signed into law the Budget Control Act of 2011, which is designed to reduce federal spending over the next 10 years by $2.5 trillion. Under that law, a select committee of Congress has been tasked with identifying and recommending $1.5 trillion in spending cuts by late November 2011. If the committee does not agree on these cuts, or if its recommendations do not pass Congress by the end of 2011, then automatic cuts would be triggered. Although the full impact is uncertain, additional spending cuts implemented under this new law could adversely affect our customers' ability to purchase our products. In addition, other legislative or regulatory changes may be adopted which could adversely affect our ability to sell our current products or successfully develop and commercialize new products.

The Failure or Delay to Obtain FDA 510(k) Clearance for Our Oragene® DNA Product Could Adversely Affect Our Financial Performance.

The primary product currently sold by our wholly-owned subsidiary, DNAG, is the Oragene® DNA collection device. This product is an all-in-one system for the collection, stabilization, transportation and purification of DNA from oral fluid samples for human genetic applications. The Oragene® DNA device accounted for virtually all of DNAG's 2010 revenues. Because DNAG's customer base for this product initially consisted of customers using the product for academic and research purposes only, the Oragene® DNA device was initially registered with the FDA as a Class I medical device. As customers increasingly began to use the product for clinical and diagnostic purposes, it was determined that 510(k) clearance as a Class II medical device would be needed for this expanded market use in the U.S. As a result, an application for 510(k) clearance of the Oragene® DNA product was filed by DNAG and is under active review by the FDA. If the FDA does not grant 510(k) clearance or the receipt of such clearance is delayed, DNAG's ability to sell its Oragene® DNA product into the U.S. clinical and diagnostic market could be limited or precluded. This could have an adverse impact on our future consolidated revenues and results of operations and could diminish the benefit we expected from our acquisition of DNAG.

Changes in Foreign Currency Exchange Rates Could Negatively Affect Our Operating Results.

Our financial statements are stated in U.S. Dollars and, historically, most of our international sales have also been denominated in U.S. Dollars. As a result, in the past our exposure to foreign currency exchange rate risk has not been material. However, in August 2011 we acquired DNAG, a Canadian company. DNAG's revenues and operating results are reported in Canadian Dollars and certain of its international sales are denominated in local currencies, including the Euro, British Pound and Australian Dollar. In 2010, DNAG reported total revenues of approximately U.S. $14.3 million. Our expectation is that the DNAG business will continue to grow and our exposure to foreign currency exchange rates will be more significant than in past years.

Exchange rate fluctuations may affect DNAG's revenues and expenses and the translation of DNAG's financial results into U.S. Dollars. Unfavorable currency exchange rate fluctuations could negatively affect our consolidated financial statements including our balance sheet, revenues and results of operations. In the past, we have not generally entered into hedging instruments to manage our currency exchange rate risk, but we may need to do so in the future. However, our attempts to hedge against these risks may not be successful. If we are unable to successfully hedge against unfavorable foreign currency exchange rate movements, our consolidated financial results may be adversely impacted.

The Use of Sole Supply Sources or Third-Party Suppliers To Manufacture Our Products or Supply Critical Components of Our Products Could Adversely Affect Our Business.

We currently purchase certain critical components of our products from sole supply sources or other third party suppliers. For example, all of the HIV antigen and nitrocellulose required to make our OraQuick *ADVANCE*® HIV-1/2 test and OraQuick® HCV test is currently purchased from sole source suppliers. Our OraSure QuickFlu™ test is manufactured and supplied by a sole source supplier and the conjugates used in our MICROPLATE oral fluid drugs of abuse assays are obtained from third party suppliers.

In addition, our subsidiary, DNAG, uses two third party manufacturers to supply virtually all of its products, including its Oragene® DNA collection system. Many of the raw materials and components used in its products are also purchased from third parties, a critical one of which is obtained from a sole source supplier.

If these suppliers are unable or unwilling to supply the required component or manufacture product or if they make changes in the component, product or manufacturing process or do not supply materials meeting our specifications, we may need to find another source and/or manufacturer. This could require that we perform additional development work. We may also need to obtain FDA or other regulatory approvals for the use of the alternative component or changes to our products or manufacturing process. Completing that development and obtaining such approvals could require significant time and expense and such approvals may not occur at all. The availability of critical components and products from sole supply sources or other third parties could also reduce our control over pricing, quality and timely delivery. These events could either disrupt our ability to manufacture and sell certain of our products into one or more markets or completely prevent us from doing so, and could increase our costs. Any such event could have a material adverse effect on our consolidated results of operations, cash flow and business.

To the Extent Our Products Become Commoditized, We Could Face Increased Competition and Experience Lower Prices, Which Could Adversely Affect Our Operating Results.

We believe our products provide distinct advantages to our customers when compared to competing products and, as a result, warrant higher prices that are commensurate with the additional benefits they provide. For example, our OraQuick *ADVANCE*® test is the only rapid, point-of-care HIV test that is approved by the FDA for use with both oral fluid and blood samples. Because of the flexibility these multiple approved applications provide and, in particular, the simplicity and non-invasive nature of oral fluid testing, we believe our product offers significant advantages over competing rapid blood HIV tests. Similarly, the Oragene® DNA product sold by our subsidiary, DNAG, provides significant advantages over competing technologies, such as blood collection products and buccal swabs. These advantages include the simplicity and non-invasiveness of oral fluid collection, the ability to store

samples for up to five years without refrigeration, the reliable collection of sufficient quantities of high quality genetic material with little risk of contamination and the use of a standardized format that is compatible with high throughput laboratory processing.

Despite these advantages, however, customers may become more interested in reducing their costs than in obtaining products with the most attractive features and benefits on the market. In these circumstances, customers may not be willing to pay a premium price for the advantages offered by our products and may instead treat our products as a commodity comparable to other, less expensive products that have fewer benefits and features. In such circumstances, we may experience lower sales or a reduction in the prices received for our products which could adversely affect our consolidated revenues and results of operations.

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

During the quarter ended September 30, 2011, pursuant to the OraSure Technologies, Inc. Stock Award Plan, and in connection with the vesting of restricted shares, we retired 4,720 shares of our Common Stock to satisfy minimum tax withholding obligations at an average price paid per share of $7.57.

Item 6. EXHIBITS

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

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SIGNATURES

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

ORASURE TECHNOLOGIES, INC.

/s/ Ronald H. Spair

Date: November 9, 2011

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

/s/ Mark L. Kuna

Date: November 9, 2011

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

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.
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

Exhibit 31.1

Certification

I, Douglas A. Michels, certify that:

1. I have reviewed this report on Form 10-Q of OraSure Technologies, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d –15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within the entity, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2011

/s/ Douglas A. Michels
Douglas A. Michels
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification

I, Ronald H. Spair, certify that:

1. I have reviewed this report on Form 10-Q of OraSure Technologies, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d –15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within the entity, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2011

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

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. §1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of OraSure Technologies, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2011 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Douglas A. Michels, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Douglas A. Michels

Douglas A. Michels
President and Chief Executive Officer

November 9, 2011

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. §1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of OraSure Technologies, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2011 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ronald H. Spair, Chief Operating Officer and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Ronald H. Spair

Ronald H. Spair
Chief Operating Officer and
Chief Financial Officer

November 9, 2011