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, 2012.

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 5, 2012: 55,188,765 shares.

PART I. FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS
(Unaudited)

	SEPTEMBER 30, 2012	DECEMBER 31, 2011
ASSETS		
CURRENT ASSETS:		
Cash	$ 89,415,510	$ 23,878,002
Accounts receivable, net of allowance for doubtful accounts of $164,354 and $169,916	19,310,071	17,158,751
Inventories	12,844,652	9,620,556
Prepaid expenses	1,497,417	1,682,325
Other current assets	540,150	495,981
Total current assets	123,607,800	52,835,615
PROPERTY AND EQUIPMENT, net	18,810,755	19,855,456
INTANGIBLE ASSETS, net	28,351,190	30,383,112
GOODWILL	25,681,979	24,739,776
OTHER ASSETS	105,087	47,383
	$ 196,556,811	$ 127,861,342
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	$ —	$ 7,291,680
Accounts payable	5,132,329	4,142,173
Accrued expenses and other	11,867,111	10,542,155
Total current liabilities	16,999,440	21,976,008
OTHER LIABILITIES	67,355	—
DEFERRED INCOME TAXES	4,705,185	5,635,633
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, 55,187,833 and 47,392,711 shares issued and outstanding	55	47
Additional paid-in capital	331,692,460	249,639,955
Accumulated other comprehensive loss	(232,199)	(1,964,251)
Accumulated deficit	(156,675,485)	(147,426,050)
Total stockholders' equity	174,784,831	100,249,701
	$ 196,556,811	$ 127,861,342

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
REVENUES:				
Product	$ 21,728,742	$ 21,435,359	$ 63,806,187	$ 57,184,756
Licensing and product development	386,580	278,543	1,869,204	1,006,434
	22,115,322	21,713,902	65,675,391	58,191,190
COST OF PRODUCTS SOLD	8,226,922	8,120,148	23,355,736	21,069,641
Gross profit	13,888,400	13,593,754	42,319,655	37,121,549
OPERATING EXPENSES:				
Research and development	2,993,839	5,546,435	9,550,655	15,109,662
Sales and marketing	8,602,488	5,742,248	25,490,182	16,025,965
General and administrative	5,220,168	6,510,050	17,398,352	15,103,177
	16,816,495	17,798,733	52,439,189	46,238,804
Operating loss	(2,928,095)	(4,204,979)	(10,119,534)	(9,117,255)
INTEREST EXPENSE	(22,592)	(85,105)	(171,663)	(242,848)
INTEREST INCOME	5,000	3,208	10,440	60,628
FOREIGN CURRENCY GAIN (LOSS)	(16,748)	51,520	(107,104)	33,146
OTHER INCOME (EXPENSE)	8	673	—	(4,857)
Loss before income taxes	(2,962,427)	(4,234,683)	(10,387,861)	(9,271,186)
INCOME TAX BENEFIT	(526,997)	(315,308)	(1,138,426)	(315,308)
NET LOSS	$ (2,435,430)	$ (3,919,375)	$ (9,249,435)	$ (8,955,878)
LOSS PER SHARE:				
BASIC	$ (0.04)	$ (0.08)	$ (0.18)	$ (0.19)
DILUTED	$ (0.04)	$ (0.08)	$ (0.18)	$ (0.19)
SHARES USED IN COMPUTING LOSS PER SHARE:				
BASIC	54,440,963	47,027,612	50,176,601	46,788,456
DILUTED	54,440,963	47,027,612	50,176,601	46,788,456

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
NET LOSS	$ (2,435,430)	$ (3,919,375)	$ (9,249,435)	$ (8,955,878)
OTHER COMPEHENSIVE INCOME (LOSS)				
Currency translation adjustments	1,485,814	(2,831,943)	1,732,052	(2,830,508)
Other comprehensive income (loss)	1,485,814	(2,831,943)	1,732,052	(2,830,508)
COMPREHENSIVE LOSS	$ (949,616)	$ (6,751,318)	$ (7,517,383)	$ (11,786,386)

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine Months Ended September 30,	
	2012	2011
OPERATING ACTIVITIES:		
Net loss	$ (9,249,435)	$ (8,955,878)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	3,845,476	3,016,366
Depreciation and amortization	5,455,108	3,010,784
Deferred income taxes	(1,138,426)	(299,184)
Inventory purchase accounting step-up adjustment	15,874	762,853
Changes in assets and liabilities		
Accounts receivable	(2,052,636)	(647,388)
Inventories	(3,221,749)	(1,491,932)
Prepaid expenses and other assets	92,187	794,554
Accounts payable	953,116	268,266
Accrued expenses and other liabilities	1,294,238	(536,953)
Net cash used in operating activities	(4,006,247)	(4,078,512)
INVESTING ACTIVITIES:		
Proceeds from maturities and redemptions of short-term investments	—	1,895,000
Acquisition of DNA Genotek Inc., net of cash acquired	—	(49,973,200)
Purchases of property and equipment	(1,401,706)	(1,806,369)
Net cash used in investing activities	(1,401,706)	(49,884,569)
FINANCING ACTIVITIES:		
Repayments of long-term debt	(7,291,680)	(375,000)
Proceeds from the issuance of common stock, net of expenses	70,292,665	—
Proceeds from exercise of stock options	9,456,631	2,762,289
Repurchase of common stock	(1,539,477)	(883,565)
Net cash provided by financing activities	70,918,139	1,503,724
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	27,322	(9,690)
NET INCREASE (DECREASE) IN CASH	65,537,508	(52,469,047)
CASH, BEGINNING OF PERIOD	23,878,002	73,843,402
CASH, END OF PERIOD	$89,415,510	$ 21,374,355
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for:		
Interest	$ 199,402	$ 245,130
Income taxes	$ 20,119	$ 28,000

See accompanying notes to the consolidated financial statements.

1. The Company

OraSure Technologies, Inc. ("OraSure" and together with its wholly-owned subsidiaries, the "Company") manufactures and markets oral fluid diagnostic products and specimen collection devices using its 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 cryosurgery products has been sold in the over-the-counter ("OTC") or consumer retail markets in North America, Europe, Central and South America and Australia. In September 2012 we began selling our OraQuick® In-Home HIV Test in the domestic OTC marketplace.

We also manufacture and sell oral fluid collection devices used to collect, stabilize and store samples of genetic material for molecular testing in the academic research, clinical genetic testing, pharmacogenomics, personalized medicine, and animal genetics markets. Our OraGene® DNA sample collection kit provides an all-in-one system for the collection, stabilization and transportation of DNA in saliva.

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, DNA Genotek, Inc. ("DNAG"). 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, 2011. Results of operations for the three and nine months ended September 30, 2012 are not necessarily indicative of the results of operations expected for the full year.

Use of Estimates. The preparation of consolidated 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 and inventories and assumptions utilized in impairment testing for intangible assets and goodwill, as well as calculations related to contingencies and accruals, 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, reductions in government funding, and declines in consumer spending have combined to increase the uncertainty inherent in such estimates and assumptions. As future events and their effects cannot be determined with precision, actual results could differ significantly from these estimates. Changes in those estimates resulting from continuing changes in the economic environment and other factors will be reflected in the consolidated financial statements in those future periods.

Fair Value of Financial Instruments. As of September 30, 2012, the carrying values of cash, accounts receivable, accounts payable and accrued expenses approximate their respective fair values based on their short-term nature.

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).

Effective January 3, 2012, we implemented a nonqualified Deferred Compensation Plan for highly compensated employees. The assets of the plan are held in the name of the Company at a third-party financial institution. Separate accounts are maintained for each participant to reflect the amounts deferred by the participant and all earnings and losses on those deferred amounts. The assets of the plan are held in mutual funds. The fair value of the plan assets as of September 30, 2012 was $67,355 and was calculated using the market price of the mutual funds as of that date. All investments in the plan are classified as trading securities and measured as Level 1 instruments.

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, 2012	December 31, 2011
Raw materials	$ 6,856,380	$5,767,735
Work in process	555,083	497,277
Finished goods	5,433,189	3,355,544
	$12,844,652	$9,620,556

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, 2012 and December 31, 2011 was $24,973,053 and $22,497,107, respectively.

Intangible Assets. Intangible assets consist of the following:

	Amortization Period (Years)	September 30, 2012		
		Gross	Accumulated Amortization	Net
Customer list	10	$12,737,218	$ (1,379,361)	$11,357,857
Patents and product rights	3-10	10,448,620	(6,790,701)	3,657,919
Acquired technology	7	9,893,508	(1,507,372)	8,386,136
Tradename	15	4,882,193	(365,407)	4,516,786
Non-compete agreements	1-3	849,961	(417,469)	432,492
		$38,811,500	$(10,460,310)	$28,351,190

	Amortization Period (Years)	December 31, 2011		
		Gross	Accumulated Amortization	Net
Customer list	10	$12,269,923	$ (440,758)	$11,829,165
Patents and product rights	3-10	10,448,620	(6,385,701)	4,062,919
Acquired technology	7	9,530,541	(481,662)	9,048,879
Tradename	15	4,703,079	(116,761)	4,586,318
Non-compete agreements	1-3	1,020,535	(164,704)	855,831
		$37,972,698	$ (7,589,586)	$30,383,112

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 in August 2011. Goodwill is not amortized but rather is tested annually for impairment or more frequently if we believe that indicators of impairment exist. Performance of goodwill impairment testing permits us to first make a qualitative evaluation about the likelihood of goodwill impairment. If we conclude that it is more likely than not that the fair value of a reporting unit is greater than its carrying amount, then we would not be required to perform the two-step quantitative impairment test. Otherwise, performing the two-step impairment test is necessary. The first step of the two-step quantitative impairment test 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, if any. The second step involves measuring any impairment by comparing the implied fair values of the affected reporting unit's goodwill and intangible assets with the respective carrying values.

We performed the annual assessment for impairment test of goodwill assets as of July 31, 2012 and determined there was no impairment. Our assessment determined that our DNAG reporting unit had a fair value in excess of its carrying value (including goodwill of $25,179,303), of approximately 13%. We believe we have made reasonable estimates and assumptions to calculate the fair value of our reporting unit. If actual future results are not consistent with management's estimates and assumptions, we may have to take an impairment charge in the future related to our goodwill. Future impairment tests will be performed annually in the fiscal third quarter, or sooner if a triggering event occurs. Goodwill changed by $942,203 from $24,739,776 at December 31, 2011 to $25,681,979 at September 30, 2012 as a result of foreign currency translation.

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

(other than for our OraQuick® In-Home HIV Test, which began to the sold in the fourth quarter of 2012) 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.

Our revenue practices with respect to the OraQuick® In-Home HIV Test will initially be different than those customarily used in the consumer package goods industry. Because this is a new product for which we do not have a track record of returns, we will initially only recognize revenue upon the consummation of a sale to the retail customer either in a store or over the internet. As of September 30, 2012 there has not been any material amount of revenues recognized related to the OraQuick® In-Home HIV Test and $3,571,436 is recorded in accounts receivable and accrued in deferred revenue related to shipments of this product in late September 2012.

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. As of September 30, 2012, one of our customers, CVS Distribution, Inc. accounted for approximately 10% of our accounts receivable balances. We had no significant concentrations (greater than 10%) in accounts receivable as of December 31, 2011 or in revenues for the three or nine months ended September 30, 2012 or 2011.

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 or interruptions in the delivery of our products to our customers and increased costs. We also use third-party suppliers to manufacture some of our 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.

Loss Per Share. Basic and diluted loss per share is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during the period. Diluted loss per share is generally computed assuming the exercise or vesting of all dilutive securities such as common stock options and unvested restricted stock. Common stock options and unvested restricted stock totaling 5,437,409, and 6,820,601 shares were outstanding as of September 30, 2012 and 2011, respectively. As a result of our net losses for the three and nine months ended September 30, 2012 and 2011, these shares were excluded from the computation of diluted loss per share, as their inclusion would have been anti-dilutive.

Foreign Currency Translation. The assets and liabilities of our foreign operations are translated into U.S. dollars at current exchange rates as of the balance sheet date, and revenues and expenses are translated at average exchange rates for the period. Resulting translation adjustments are reflected in accumulated other comprehensive loss, which is a separate component of stockholders' equity.

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.

We have defined Canadian dollars as the functional currency of our Canadian subsidiary, DNAG, and as such, the results of its operations for DNAG are translated into U.S. dollars, which is the reporting currency of the Company. The $1,732,052 currency translation adjustment recorded in the first nine months of 2012 and included in the Statement of Other Comprehensive Loss is largely the result of the translation of our Canadian operation's financial statements into U.S. dollars.

3. Business Combination

On August 17, 2011 (the "Acquisition Date"), we acquired all of the outstanding capital stock of DNAG, a manufacturer of oral fluid collection kits that are used to collect, stabilize and store samples of genetic material. DNAG is located in Ottawa, Canada. The purchase price was $49,750,000 CDN ($50,466,725 in U.S. dollars at the Acquisition Date exchange rate) and was funded by OraSure with cash on hand. The purchase price consisted of $50.0 million CDN ($50,710,000 in U.S. dollars at the Acquisition Date exchange rate) less a $250,000 CDN ($253,550 U.S. dollars) working capital adjustment received in the fourth quarter of 2011. Of the original $50.0 million CDN purchase price, $5,000,000 CDN (or $5,071,000 in U.S. dollars at the Acquisition Date exchange rate) was deposited in escrow pursuant to the related support agreement. The payment for the working capital adjustment was funded from the escrow account. Subject to certain adjustments and the processing of any indemnification claims, $2,500,000 CDN will be released from the escrow fund in February 2013 with the balance released in February 2014.

The results of operations associated with DNAG have been consolidated with those of OraSure since the Acquisition Date.

The following unaudited condensed pro forma consolidated information sets forth the combined revenues, net loss and net loss per share of OraSure and DNAG for the three and nine months ended September 30, 2011, 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, 2011	Nine Months Ended September 30, 2011
Total revenues	$ 22,198,612	$ 66,239,991
Net loss	(2,479,590)	(8,140,783)
Loss per share:		
Basic and diluted	$ (0.05)	$ (0.17)

4. Stockholders' Equity

Stock-Based Awards

We grant stock-based awards under the OraSure Technologies, Inc. Stock Award Plan, as amended and restated (the "Stock Plan"). The Plan permits stock-based awards to employees, outside directors and consultants or other third-party advisors. Awards which may be granted under the Stock 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.

Total compensation cost related to stock options for the nine months ended September 30, 2012 and 2011 was $1,682,369 and $1,119,838, respectively. Net cash proceeds from the exercise of stock options were $9,456,631 and $2,762,289 for the nine months ended September 30, 2012 and 2011, 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.

Compensation cost of $2,163,107 and $1,896,528 related to restricted shares was recognized during the nine months ended September 30, 2012 and 2011, respectively. In connection with the vesting of restricted shares, during the nine months ended September 30, 2012 and 2011, 138,775 and 131,567 shares, respectively, with aggregate values of $1,539,477 and $883,563, respectively, were withheld and retired in satisfaction of minimum tax withholding obligations.

Public Equity Offering

On July 11, 2012, we completed a public equity offering of 6,100,000 common shares, at a price of $12.30 per share, raising $75,030,000 before expenses of the offering. In connection with the offering, we paid $4,501,800 in underwriting discounts and commissions and incurred approximately $236,000 in additional offering expenses.

5. Accrued Expenses

	September 30, 2012	December 31, 2011
Deferred revenue	$ 4,787,298	$ 1,318,546
Payroll and related benefits	3,834,567	4,866,812
Royalties	1,480,609	1,985,875
Professional fees	401,511	834,657
Other	1,363,126	1,536,265
	$ 11,867,111	$ 10,542,155

Deferred revenue at September 30, 2012 and December 31, 2011 included customer prepayments of $1,215,862 and $1,318,546, respectively.

6. Long-term Debt

On July 30, 2012, we repaid the $7,041,680 principal balance outstanding under our $10,000,000 credit facility, as amended (the “Credit Facility”), with Comerica Bank (“Comerica”) and we can make no further borrowings under this Credit Facility.

7. Income Taxes

During the three and nine months ended September 30, 2012, we recorded a foreign deferred tax benefit of $526,997 and $1,138,426, respectively. During the three and nine months ended September 30, 2011, we recorded a foreign deferred tax benefit of $315,308. These foreign deferred tax benefits are associated with DNAG’s loss before income taxes and certain Canadian research and development and investment tax credits. The income tax benefit associated with DNAG was considered realizable based upon the estimated scheduled reversal of the deferred tax liabilities recorded in connection with the acquisition of DNAG.

The income tax benefit for the nine months ended September 30, 2012 was negatively impacted by a $427,633 adjustment made in the second quarter of 2012 to DNAG’s deferred tax liability to reflect a change in the enacted Canadian provincial tax rates.

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, 2012 relate to the tax effects of the basis differences between the intangible assets acquired in the DNAG acquisition for financial reporting and tax purposes.

In 2008, we established a full valuation allowance against our U.S. net deferred tax asset, and management believes the full valuation allowance is still appropriate as of September 30, 2012 and December 31, 2011 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, 2012 or 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. Business Segment Information

We operate our business within two reportable segments: our “OraSure” business, which consists of the development, manufacture and sale of oral fluid diagnostic products and specimen collection devices and the manufacture and sale of medical devices used for the removal of benign skin lesions by cryosurgery; and our molecular collection systems or “DNAG” business, which consists of the manufacture, development and sale of oral fluid collection devices that are used to collect, stabilize and store samples of genetic material for molecular testing. OraSure revenues consist primarily of product sold in the United States and internationally to various clinical laboratories, hospital, clinics, community-based organizations and other public health organizations, distributors, government agencies, physicians’ offices, and commercial and industrial entities. OraSure also derives revenues from licensing and product development activities. DNAG revenues consist primarily of product sold into the academic research, clinical genetic testing, pharmacogenomics, personalized medicine, animal and livestock genetics markets.

We organized our operating segments according to the nature of the products included in those segments. The accounting policies of the segments are the same as those described in the summary of significant accounting policies (see Note 2). We evaluate performance of our operating segments based on revenue and operating loss. We do not allocate interest income, interest expense, other income, other expenses or income taxes to our operating segments. Reportable segments have no inter-segment revenues.

The following table summarizes segment information for the three and nine months ended September 30, 2012 and 2011. The DNAG business was acquired on August 17, 2011. Prior to that date, we operated within only one reportable segment.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Revenues				
OraSure	$ 18,762,012	$ 19,692,322	$ 55,683,472	$ 56,169,610
DNAG	3,353,310	2,021,580	9,991,919	2,021,580
Total	$ 22,115,322	$ 21,713,902	$ 65,675,391	$ 58,191,190
Operating loss				
OraSure	$ (2,155,697)	$ (3,325,863)	$ (7,441,546)	$ (8,238,139)
DNAG	(772,398)	(879,116)	(2,677,988)	(879,116)
Total	$ (2,928,095)	$ (4,204,979)	$(10,119,534)	$ (9,117,255)
Depreciation and amortization				
OraSure	$ 798,300	$ 910,639	$ 2,594,999	$ 2,594,594
DNAG	1,042,752	416,190	2,860,109	416,190
Total	$ 1,841,052	$ 1,326,829	$ 5,455,108	$ 3,010,784
Capital expenditures				
OraSure	$ 644,095	$ 617,533	$ 1,291,135	$ 1,797,351
DNAG	27,525	9,018	110,571	9,018
Total	$ 671,620	$ 626,551	$ 1,401,706	$ 1,806,369

	September, 2012	December 31, 2011
Total assets		
OraSure	$141,992,690	$ 71,326,343
DNAG	54,564,121	56,534,999
Total	$196,556,811	$ 127,861,342

Our products are sold principally in the United States, Canada 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,	
	2012	2011	2012	2011
United States	$ 17,323	$ 17,571	$ 49,855	$ 48,151
Europe	1,847	2,302	7,376	5,567
Other regions	2,945	1,841	8,444	4,473
	$ 22,115	$ 21,714	$ 65,675	$ 58,191

The following table represents total long-lived assets by geographic area (amounts in thousands):

	September 30, 2012	December 31, 2011
United States	$ 18,137	$ 18,954
Canada	560	706
Other regions	114	195
	$ 18,811	$ 19,855

10. RETIREMENT PLANS:

In addition to our existing 401(k) plan, effective January 3, 2012, we implemented a nonqualified Deferred Compensation plan to permit eligible highly compensated employees of the Company to defer receipt and taxation of their compensation each year. We may make discretionary contributions to the accounts of the participating employees in any amount either in cash or stock. Participants in the plan may not purchase OraSure stock as an investment vehicle. As of September 30, 2012, the value of the assets associated with the plan was $67,355 and is included in other assets in our consolidated balance sheet. Our obligation related to the deferred compensation plan is included in other liabilities in our consolidated balance sheet. As of September 30, 2012, our total obligation under this plan was $67,355.

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 of DNA Genotek to achieve its financial and strategic objectives; 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, including the OraQuick® In-Home HIV Test; 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 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, 2011, 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 our consolidated 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 cryosurgery products is sold in the over-the-counter ("OTC") or consumer retail market in North America, Europe, Central and South America, and Australia. In September 2012, we began selling our OraQuick® In-Home HIV Test in the domestic OTC marketplace.

We also manufacture and sell kits that are used to collect, stabilize, and store samples of genetic material for molecular testing in the academic research, clinical genetic testing, pharmacogenomics, personalized medicine, animal and livestock genetics markets. Our OraGene® DNA sample collection kit provides an all-in-one system for the collection, stabilization and transportation of DNA from human saliva. We serve customers in multiple countries worldwide, including many leading research universities and hospitals.

In vitro diagnostic testing is the process of analyzing oral fluid, blood, urine and other bodily fluids or tissue for the presence of specific substances or markers for infectious diseases, drugs of abuse or other conditions. However, we have targeted the use of oral fluid in our products as a differentiating factor and believe that it provides a significant competitive advantage over blood and urine. Our oral fluid tests have sensitivity and specificity comparable to blood and/or urine tests. When combined with their ease of use, non-invasive nature, and cost effectiveness, our oral fluid tests represent a very competitive alternative to the more traditional testing methods in the diagnostic space.

We rely heavily on distributors to purchase and resell many of our products. For example, Genomma Labs ("Genomma") has exclusive rights to our wart removal product in the OTC market in Mexico, Argentina, Brazil and various other Central and South American countries and Reckitt Benckiser (formerly SSL International plc) has similar rights to our wart removal product in the OTC footcare market in Europe, Australia and New Zealand. We have contracted with several distributors to sell our OraQuick *ADVANCE*® HIV-1/2 test to the U.S. physician office market and our Intercept® and OraSure® product lines are sold by several laboratory distributors. We use distributors to sell our Histofreezer® product into the domestic and international physician office markets and we 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 OraQuick® In-Home HIV 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 and expense required to develop replacements and obtain the required U.S. Food and Drug Administration ("FDA") approvals could disrupt our ability to sell the affected products and could adversely impact our revenues and results of operations. We also utilize contract manufacturers to supply all of the OraGene® DNA and Oragene® RNA 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 could adversely impact our revenues and results of operations.

Current Consolidated Financial Results

During the nine months ended September 30, 2012, our total consolidated revenues were $65.7 million compared to $58.2 million in the nine months ended September 30, 2011. The first nine months of 2012 included $10.0 million in revenues from our molecular collection systems subsidiary, DNAG, acquired on August 17, 2011. DNAG revenues from the acquisition date through September 30, 2011 were $2.0 million. Product revenues during the nine months ended September 30, 2012 increased 12% when compared to the first nine months of 2011, primarily as a result of the inclusion of DNAG revenues for all of 2012.

Licensing and product development revenues for the first nine months of 2012 increased primarily as a result of a $1.0 million milestone payment received as a result of our achievement of certain regulatory and commercial objectives pursuant to the terms of our HCV collaboration agreement with Merck & Co., Inc. ("Merck"). The milestone payment was partially offset by a decrease in royalties paid on domestic outsales of Merck's OTC cryosurgical wart removal product, pursuant to a license and settlement agreement executed in January 2008.

Our consolidated net loss for the nine months ended September 30, 2012 was $9.2 million, or $0.18 per share, compared to a net loss of $8.9 million, or $0.19 per share, for the nine months ended September 30, 2011. Our consolidated net loss for the nine months ended September 30, 2011 included transaction costs associated with the acquisition of DNAG.

Cash used in operating activities for the nine months ended September 30, 2012 was $4.0 million, compared to the $4.1 million used during the nine months ended September 30, 2011. As of September 30, 2012, we had $89.4 million in cash compared to $23.9 million at December 31, 2011. During the third quarter of 2012, we completed a public offering of 6,100,000 common shares and received $70.3 million in proceeds, net of offering expenses. During the third quarter of 2011, we used $53.0 million of our cash to fund the DNAG acquisition and related transaction expenses.

Recent Developments

OraQuick® In-Home HIV Test

On July 3, 2012, the FDA issued a pre-market approval ("PMA") for our OraQuick® In-Home HIV Test for sale directly to consumers in the OTC market, making it the first and only rapid OTC HIV test approved in the U.S. The OraQuick® In-Home HIV Test can detect antibodies to both HIV-1 and HIV-2 with an oral swab, providing a confidential in-home testing option with results in as little as 20 minutes. It is the first rapid diagnostic test for any infectious disease that has been approved by the FDA for sale over the counter. This test was approved following extensive clinical trials conducted during the past several years. The test was approved by the FDA for use by individuals who are 17 years old and older.

The OraQuick® In-Home HIV Test is an over-the-counter version of our OraQuick ADVANCE® HIV 1/2 Antibody Test, the market leading rapid HIV test with millions of units sold since 2002 to hospitals, clinics, community-based organizations and physician offices.

The OraQuick® In-Home HIV Test has been available for purchase since October at retailers throughout the country, such as CVS, Walgreens, Rite Aid, Wal-Mart and Kroger. The product is also available for purchase on-line through certain retailers and our website, www.oraquick.com.

We also began our national public relations and advertising campaign in connection with the October launch. These activites are expected to substantially increase our sales and marketing expenses during the fourth quarter of 2012 and in 2013, particularly during the first quarter of that year.

To support individuals that purchase and use our test, we have established a toll-free customer support center that operates on a 24/7, 365-day per year basis. Through this center, consumers will have access to highly trained, bi-lingual representatives who can answer questions about HIV/AIDS and the use of our test, and refer consumers to appropriate resources for follow-up confirmatory testing, counseling and medical treatment.

Our revenue recognition practices with respect to the OraQuick® In-Home HIV Test will initially be different than those customarily used in the consumer package goods industry. Because this is a new product for which we do not have a track record of returns, we will initially only recognize revenue upon the consummation of a sale to the retail customer either in a store or over the internet. We are working with our retail distribution partners to gain access to out-sales data to obtain greater transparency into the effectiveness of our launch and the actual uptake of our product in the hands of the consumer.

Competitive and Economic Outlook

Competition in the U.S. market for HIV testing in medical settings is intense and is expected to increase. We believe that our principal competition will come from existing and new point-of-care rapid blood tests, automated laboratory-based blood tests, 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 (and therefore the profit margin) we can charge for our product.

Outside the U.S., our rapid HIV and HCV tests compete against other rapid and laboratory-based tests. Significant sales of these products in Europe have not 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. In addition, many competing tests in international markets are sold at very low prices. We intend to continue to build awareness and develop strategies to expand sales of our OraQuick® HIV and HCV tests in European and other international markets.

In the substance abuse testing market, we expect competition for our products to intensify. Other domestic and international 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. This 510(k) cleared product is being offered by one of our large laboratory distributors and we expect this distributor to stop selling our Intercept® product during 2012. These new products will compete against our current Intercept® product.

Our professional cryosurgical product is sold primarily to physicians, including family practitioners, pediatricians and podiatrists. This product competes against portable cryosurgical systems used for the removal of benign skin lesions in both the U.S. and Europe. Our OTC cryosurgical products compete against other cryosurgical products in certain international OTC markets.

Our Oragene® 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® products. 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.

Current unfavorable economic conditions, may continue for the foreseeable future and could intensity. These conditions 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 recent years, there have been numerous initiatives on the federal and state levels for comprehensive reforms affecting the payment for, the availability of and reimbursement for healthcare services in the United States. One example is the Patient Protection and Affordable Care Act, the Federal healthcare reform law enacted in 2010 (“Affordable Care Act”). The Affordable Care Act imposes a 2.3% excise tax on certain transactions, including U.S. sales of many new medical devices, which we expect will include domestic non-retail sales of at least some of our products. This new tax is schedule to take effect in 2013.

Also, on August 2, 2011, President Obama signed into law the Budget Control Act of 2011, which was designed to reduce federal spending over the next 10 years by $2.5 trillion. Under that law, a select committee of Congress was tasked with identifying and recommending $1.2 trillion in spending cuts by late November 2011. Because the committee did not agree on spending cuts within that time frame, certain automatic cuts to discretionary, national defense and Medicare spending will be implemented beginning in January 2013 unless Congress takes further action. These cuts would result in Medicare payment reductions of up to 2% per fiscal year with a uniform percentage reduction across all Medicare programs starting in 2013. We cannot predict whether Congress will attempt to suspend or restructure the automatic budget cuts or what other deficit reduction initiatives may be proposed by Congress. Although the full impact is uncertain, spending cuts implemented under this new law could adversely affect our customers’ ability to purchase our products.

Results of Operations

Three months ended September 30, 2012 compared to September 30, 2011

Business Segments

We operate our business within two reportable segments: our "OraSure" business, which consists of the development, manufacture and sale of oral fluid diagnostic products, specimen collection devices, and medical devices used for the removal of benign skin lesions by cryosurgery; and our "DNAG" or molecular collection systems business, which consists of the development, manufacture and sale of oral fluid collection devices that are used to collect, stabilize, and store samples of genetic material for molecular testing. OraSure revenues consist primarily of product sold into 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. OraSure also derives revenues from licensing and product development activities. DNAG revenues consist of product sold into the academic research, clinical genetic testing, pharmacogenomics, personalized medicine, animal and livestock genetics markets.

Consolidated Revenues

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

	Three Months Ended September 30, 2012,				
	Dollars		%	Percentage of Total Revenues	
	2012	2011	Change	2012	2011
OraSure	$18,375	$19,413	(5)%	83%	90%
DNAG	3,353	2,022	66	15	9
Product revenues	21,728	21,435	1	98	99
Licensing and product development	387	279	39	2	1
Total revenues	$22,115	$21,714	2%	100%	100%

Consolidated revenues increased 2% to $22.1 million in the third quarter of 2012 from $21.7 million in the comparable quarter of 2011. The current quarter included $3.3 million in revenues from our molecular collection systems segment compared to $2.0 million in the third quarter of 2011. Our molecular collection systems business was acquired in August 2011. Product revenues increased 1% during the three months ended September 30, 2012 when compared to the third quarter of 2011, primarily as a result of the higher molecular collection system sales and higher sales of our cryosurgical systems products. These increases were partially offset by lower sales of our infectious disease testing, substance abuse testing and insurance risk assessment products. Licensing and product development revenues also increased in the quarter as compared to the prior year period.

Consolidated revenues derived from products sold to customers outside the U.S. were $4.8 million and $4.1 million, or 22% and 19% of total revenues, in the third quarters of 2012 and 2011, 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.

Revenues by Segment

OraSure Segment

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

	Three Months Ended September 30,				
	Dollars		%	Percentage of Total Revenues	
Market	2012	2011	Change	2012	2011
Infectious disease testing	$10,717	$11,854	(10)%	57%	61%
Substance abuse testing	2,331	2,765	(16)	12	14
Cryosurgical systems	4,199	3,395	24	22	17
Insurance risk assessment	1,128	1,399	(19)	6	7
Product revenues	18,375	19,413	(5)	97	99
Licensing and product development	387	279	39	2	1
Total revenues	$18,762	$19,692	(5)%	100%	100%

Infectious Disease Testing Market

Sales to the infectious disease testing market decreased 10% to $10.7 million in the third quarter of 2012 from $11.9 million in the third quarter of 2011, primarily due to lower OraQuick® sales. OraQuick® sales totaled $10.3 million in the third quarter of 2012 compared to $11.3 million in the third quarter of 2011.

The table below shows a breakdown of our total OraQuick® revenues (dollars in thousands) during the third quarters of 2012 and 2011.

	Three Months Ended September 30,		
Market	2012	2011	% Change
Domestic HIV	$ 8,527	$10,010	(15)%
International HIV	884	878	1
Domestic HCV	678	332	104
International HCV	241	93	159
Total OraQuick® revenues	$10,330	$11,313	(9)%

Domestic OraQuick® HIV sales decreased 15% to $8.5 million for the three months ended September 30, 2012 from $10.0 million for the three months ended September 30, 2011. The decrease in domestic sales was due to changes in public health testing programs and their timing of purchases, reductions in government funding, price competition and a shift to automated laboratory-based blood tests. International sales of our OraQuick® HIV test remained relatively flat.

OraQuick® revenues for the third quarter of 2012 included $919,000 from sales of our OraQuick® HCV test, compared to $425,000 in 2011. We received a CLIA waiver for this product in November 2011, enabling us to sell our HCV product to many non-CLIA certified customers, such as outreach clinics, community-based organizations and physician offices. While we believe the CLIA waiver provides an expanded opportunity for sales growth, demand for our HCV product has been, and will likely continue to be, tempered by the limited availability of government funding allocated to HCV testing efforts and the time and effort required to build awareness and demand for rapid HCV testing.

We previously entered into domestic and international collaboration agreements with Merck, under which Merck agreed to detail our OraQuick® HCV product to physician offices. The initial term of our domestic agreement

expired in September 2012 and will not be renewed. We are also in discussions with Merck regarding the termination of our international agreement, which has a longer term than the domestic agreement. Termination of these agreements is not expected to materially impact sales of our HCV test, either in the U.S. or in international markets.

Substance Abuse Testing Market

Substance abuse testing revenues decreased 16% to $2.3 million in the third quarter of 2012 from $2.8 million in the third quarter of 2011, primarily as a result of lower sales of our Intercept® drug testing system. These lower sales were partially offset by an increase in 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 $274,000 decrease in Q.E.D.® sales for that quarter. Production of our Q.E.D.® test resumed in October 2011.

The table below shows a breakdown of our total Intercept® revenues (dollars in thousands) generated in each market during the third quarters of 2012 and 2011.

	Three Months Ended September 30,		
Market	2012	2011	% Change
Domestic	$ 1,499	$ 1,947	(23)%
International	279	438	(36)
Total Intercept® revenues	$ 1,778	$ 2,385	(25)%

Domestic Intercept® revenues decreased 23% to $1.5 million in the third quarter of 2012 from $1.9 million in the third quarter of 2011. In 2011, our largest laboratory distributor began selling its own competing oral specimen collection device and a panel of oral fluid drug assays suitable for use on fully-automated high throughput homogenous processing systems. As a result, this distributor has reduced its purchases of Intercept® and is expected to completely stop purchasing this product line by the end of 2012. Sales of Intercept® to this distributor were $296,000 in the third quarter of 2012 compared to $759,000 in the third quarter of 2011.

International Intercept® revenues decreased 36% to $279,000 in the third quarter of 2012 from $438,000 in 2011, as a result of lower purchases by our UK distributor as it has also begun selling its own competing oral specimen collection device. We expect sales to this distributor to continue to decrease through the end of 2012 and into 2013. Sales of Intercept® to this distributor were $245,000 in the third quarter of 2012 compared to $438,000 in the third quarter of 2011.

Cryosurgical Systems Market

Sales in the cryosurgical systems market (which includes both the physicians' office and OTC markets) increased 24% to $4.2 million in the third quarter of 2012, compared to $3.4 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 2012 and 2011.

Market	Three Months Ended September 30, 2012	2011	% Change
Professional domestic	$ 2,025	$ 2,042	(1)%
Professional international	453	402	13
Over-the-counter	1,721	951	81
Total cryosurgical systems revenues	$ 4,199	$ 3,395	24%

Domestic Histofreezer® sales remained flat at $2.0 million in both the third quarter of 2012 and 2011. During the three months ended September 30, 2012, international sales of Histofreezer® increased 13% to $453,000 from $402,000 in 2011, largely as a result of higher sales in Europe, Australia, and Asia.

Sales of our OTC cryosurgical products during the third quarter of 2012 increased 81% to $1.7 million from $951,000 in the third quarter of 2011. This increase was largely the result of higher sales to both our Latin American distributor, Genomma, and our European distributor, Reckitt Benckiser.

In the third quarter of 2012, Genomma purchased $921,000 compared to $264,000 during the third quarter of 2011. Early in 2011, the Mexican government placed limitations on the advertising Genomma could use for our product. At the same time, the Brazilian government also required changes to our package insert. Both of these events negatively impacted sales of our product to Genomma during 2011, but were resolved by the end of that year.

Sales to Reckitt Benckiser increased to $750,000 in the third quarter of 2012 from $670,000 in the third quarter of 2011 as a result of increased advertising and promotional activities and expansion into additional European countries. Our distribution contract with Reckitt Benckiser has expired and we are currently negotiating the final terms of the renewal of this agreement.

Insurance Risk Assessment Market

Sales to the insurance risk assessment market decreased 19% to $1.1 million in the third quarter of 2012 from $1.4 million in the third quarter of 2011, largely due to the loss of one of our larger customers who changed its underwriting methodologies in 2011.

Licensing and Product Development

Licensing and product development revenues increased 39% to $387,000 in the third quarter of 2012 from $279,000 in the third quarter of 2011. Licensing revenues for these periods represent royalties paid on domestic outsales of Merck's OTC cryosurgical wart removal product, pursuant to a license and settlement agreement executed in January 2008. Royalties under this license will no longer be payable after certain of our cryosurgical patents expire in August 2013.

DNAG Segment

Molecular Collection Systems

Molecular collection systems revenues primarily represent sales of the Oragene® product line by our subsidiary, DNA Genotek, which we acquired in August 2011.

Consolidated Operating Results

Consolidated gross margin remained flat at 63% in the third quarters of 2012 and 2011.

Consolidated operating loss decreased $1.3 million to $2.9 million in the third quarter 2012, compared to $4.2 million in the third quarter of 2011. The loss was the result of lower research and development expenses and lower general and administrative costs, partially offset by higher sales and marketing expenses.

Operating Loss by Segment

OraSure Segment

OraSure's gross margin decreased to 62% in the third quarter of 2012 from 66% in the third quarter of 2011. The current quarter's gross margin was negatively impacted by the overall decrease in sales volume and an unfavorable change in product mix from our higher margin products, such as Intercept® devices and assays, to our lower margin cyrosurgical OTC products. The decrease in sales volume caused a decline in absorption of our labor and fixed overhead costs. In addition, during the quarter, we experienced an increase in scrap and spoilage expense related to our OraQuick® products.

Beginning in January 2013 and through February 2015, sales of our OraQuick® product into the professional market will be subject to an increase in lateral flow patent royalties which we agreed to as part of a litigation settlement in 2009. This increase will negatively impact our gross margin during those years.

Research and development expenses declined 56% to $2.3 million in the third quarter of 2012 from $5.1 million in the third quarter of 2011, primarily as a result of lower clinical trial costs related to the development of our OraQuick® In-Home HIV Test.

Sales and marketing expenses increased 42% to $7.1 million in the third quarter of 2012 from $5.0 million in the third quarter of 2011. This increase was primarily the result of approximately $1.8 million of spending associated with the commercialization of our OraQuick® In-Home HIV Test.

General and administrative expenses decreased 28% to $4.4 million in the third quarter of 2012 from $6.2 million in the third quarter of 2011. General and administrative expenses in the third quarter of 2011 included $2.1 million of transaction costs associated with the acquisition of DNAG.

All the above contributed to OraSure's operating loss of $2.2 million, which included $798,000 of depreciation and amortization expense and $1.3 million of stock-based compensation expense.

DNAG Segment

DNAG's gross margin increased to 68% in the third quarter of 2012 from 33% in the third quarter of 2011. DNAG's third quarter 2011 gross margin included $763,000 of increased product cost associated with non-cash fair-value inventory adjustments resulting from the acquisition. Third quarter 2012 gross margin included $337,000 of amortization expense compared to $164,000 recorded for the partial period in the third quarter of 2011.

DNAG incurred $3.1 million in operating expenses during the third quarter of 2012 compared to $1.5 million incurred during the 2011 period from the August 17, 2011 acquisition date through September 30, 2011. Third quarter 2012 expenses included $731,000 of research and development costs, $1.5 million of sales and marketing expenses and $801,000 of general and administrative expenses. Expenses for the period August 17, 2011 through September 30, 2011 included $432,000 of research and development costs, $768,000 of sales and marketing expenses and $338,000 of general and administrative expenses.

All of the above contributed to DNAG's 2012 third quarter operating loss of $772,000, which included $1.0 million of depreciation and amortization expense and $37,000 of stock-based compensation expense.

Consolidated Income Taxes

We continue to believe the full valuation allowance established in 2008 against OraSure's total net deferred tax asset is appropriate as the facts and circumstances necessitating the allowance have not changed. As a result, no U.S. income tax benefit was recorded for OraSure's pre-tax loss in the third quarter of 2012. A Canadian income tax benefit of $526,997 was recorded in the third quarter of 2012 which was associated with the DNAG loss before income taxes and certain Canadian research and development and investment tax credits.

Nine months ended September 30, 2012 compared to September 30, 2011

Consolidated Revenues

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

	Nine Months Ended September 30, 2012,				
	Dollars		%	Percentage of Total Revenues	
	2012	2011	Change	2012	2011
OraSure	$53,814	$55,163	(2)%	82%	95%
DNAG	9,992	2,022	394	15	3
Product revenues	63,806	57,185	12	97	98
Licensing and product development	1,869	1,006	86	3	2
Total revenues	$65,675	$58,191	13%	100%	100%

Consolidated revenues increased 13% to $65.7 million for the first nine months of 2012 from $58.2 million in the comparable period of 2011. The current period included $10.0 million in revenues from our molecular collection systems segment compared to $2.0 million in the comparative period of 2011. Our molecular collection systems business was acquired in August 2011. Product revenues increased 12% during the first nine months of 2012 when compared to the first nine months of 2011, primarily as a result of the higher molecular collection system sales and higher sales of our cryosurgical systems products. These increases were partially offset by lower sales of our infectious disease testing, substance abuse testing and insurance risk assessment products. Licensing and product revenues also increased in the current nine-month period as compared to the prior year period.

Consolidated revenues derived from products sold to customers outside the U.S. were $15.8 million and $10.0 million, or 24% and 17% of total revenues, during the nine months ended September 30, 2012 and 2011, 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.

Revenues by Segment

OraSure Segment

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

Market	Nine Months Ended September 30, Dollars 2012	Dollars 2011	% Change	Percentage of Total Revenues 2012	Percentage of Total Revenues 2011
Infectious disease testing	$30,880	$33,100	(7)%	56%	59%
Substance abuse testing	7,305	9,011	(19)	13	16
Cryosurgical systems	12,181	8,907	37	22	16
Insurance risk assessment	3,448	4,145	(17)	6	7
Product revenues	53,814	55,163	(2)%	97	98%
Licensing and product development	1,869	1,006	86	3	2
Total revenues	$55,683	$56,169	(1)%	100%	100%

Infectious Disease Testing Market

Sales to the infectious disease testing market decreased 7% to $30.9 million in the first nine months of 2012 from $33.1 million in the first nine months of 2011, primarily due to lower OraQuick® sales. OraQuick® sales totaled $30.1 million in first nine months of 2012 compared to $32.0 million in the first nine months of 2011.

The table below shows a breakdown of our total OraQuick® revenues (dollars in thousands) during the nine months ended September 30, 2012 and 2011.

Market	Nine Months Ended September 30, 2012	2011	% Change
Domestic HIV	$ 25,106	$ 28,948	(13)%
International HIV	2,287	2,290	0
Domestic HCV	1,958	464	322
International HCV	734	284	158
Total OraQuick® revenues	$ 30,085	$ 31,986	(6)%

Domestic OraQuick® HIV sales decreased 13% to $25.1 million for the nine months ended September 30, 2012 from $28.9 million for the nine months ended September 30, 2011. The decrease in domestic sales was due to changes in public health testing programs and their timing of purchases, reductions in government funding, price competition and a shift to automated laboratory-based blood tests. International sales of our OraQuick® HIV test remained flat.

OraQuick® revenues for the first nine months of 2012 included $2.7 million of sales of our OraQuick® HCV test, compared to $748,000 in 2011. We received a CLIA waiver for this product in November 2011, enabling us to sell our HCV product to many non-CLIA certified customers, such as outreach clinics, community-based organizations and physician offices. While we believe the CLIA waiver provides an expanded opportunity for sales growth, demand for our HCV product has been, and will likely continue to be, tempered by the limited availability of government funding allocated to HCV testing efforts and the time and effort required to build awareness and demand for rapid HCV testing.

We previously entered into domestic and international collaboration agreements with Merck, under which Merck agreed to detail our OraQuick® HCV product to physician offices. The initial term of our domestic agreement expired in September 2012 and will not be renewed. We are also in discussions with Merck regarding the termination of our international agreement, which has a longer term than the domestic agreement. Termination of these agreements is not expected to materially impact sales of our HCV test, either in the U.S. or in international markets.

Substance Abuse Testing Market

Substance abuse testing revenues decreased 19% to $7.3 million in the first nine months of 2012 from $9.0 million in the first nine months of 2011, primarily as a result of lower sales of our Intercept® drug testing system. The lower sales were partially offset by an increase in 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 a decrease in Q.E.D.® sales for the nine month period ended September 30, 2011. Production of our Q.E.D. test resumed in October 2011.

The table below shows a breakdown of our total Intercept® revenues (dollars in thousands) generated in each market during the nine months ended September 30, 2012 and 2011.

	Nine Months Ended September 30,		
Market	2012	2011	% Change
Domestic	$ 4,981	$ 5,909	(16)%
International	616	1,472	(58)
Total Intercept® revenues	$ 5,597	$ 7,381	(24)%

Domestic Intercept® revenues decreased 16% to $5.0 million in the first nine months of 2012 from $5.9 million in the first nine months of 2011. In 2011, our largest laboratory distributor began selling its own competing oral specimen collection device and a panel of oral fluid drug assays suitable for use on fully-automated high throughput homogenous processing systems. As a result, this distributor has reduced its purchases of Intercept® and is expected to completely stop purchasing this product line by the end of 2012. Sales of Intercept® to this distributor were $1.4 million in the first nine months of 2012 compared to $2.5 million in the first nine months of 2011.

International Intercept® revenues decreased 58% to $616,000 in the first nine months of 2012 from $1.5 million in 2011, as a result of lower purchases by our UK distributor as it has also begun selling its own competing oral specimen collection device. We expect sales to this distributor to continue to decrease through the end of 2012 and into 2013. Sales of Intercept® to this distributor were $534,000 in the first nine months of 2012 compared to $1.5 million in the first nine months of 2011.

Cryosurgical Systems Market

Sales in the cryosurgical systems market (which includes both the physicians' office and OTC markets) increased 37% to $12.2 million in the nine months ended September 30, 2012, compared to $8.9 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 nine months ended September 30, 2012 and 2011.

Market	Nine Months Ended September 30, 2012	2011	% Change
Professional domestic	$ 5,342	$5,097	5%
Professional international	1,110	989	12
Over-the-counter	5,729	2,821	103
Total cryosurgical systems revenues	$12,181	$8,907	37%

Domestic Histofreezer® sales increased 5% to $5.3 million in the first nine months of 2012 from $5.1 million in the first nine months of 2011 due to the increased success of the sales and promotional efforts of our distributors and manufacturers' sales representatives. During the nine months ended September 30, 2012, international sales of Histofreezer® increased 12% to $1.1 million compared to $989,000 in the same period of the prior year, largely as a result of higher sales in Australia and Africa.

Sales of our OTC cryosurgical products during the first nine months of 2012 increased 103% to $5.7 million in the first nine months of 2012 from $2.8 million in the first nine months of 2011. This increase was largely the result of higher sales to both our Latin American distributor, Genomma, and our European distributor, Reckitt Benckiser.

In the first nine months of 2012, Genomma purchased $2.6 million compared to $686,000 during the first nine months of 2011. Early in 2011, the Mexican government placed limitations on the advertising Genomma could use for our product. At the same time, the Brazilian government also required changes to our package insert. Both of these events negatively impacted sales of our product to Genomma during 2011, but were resolved by the end of that year.

Sales to Reckitt Benckiser increased to $3.0 million in the first nine months of 2012 from $1.9 million in the first nine months of 2011 as a result of increased advertising and promotional and expansion into additional European countries. Our distribution contract with Reckitt Benckiser has expired and we are currently negotiating the final terms of the renewal of this agreement.

Insurance Risk Assessment Market

Sales to the insurance risk assessment market decreased 17% to $3.4 million in the first nine months of 2012 from $4.1 million in the first nine months of 2011, largely the result of the loss of one of our larger customers who changed its underwriting methodologies in 2011.

Licensing and Product Development

Licensing and product development revenues increased 86% to $1.9 million in the first nine months of 2012 from $1.0 million in the first nine months of 2011. During the first quarter of 2012, we received a $1.0 million milestone payment 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 international markets. No such milestone payments were received in the prior year.

The remaining licensing revenues for these periods represent royalties paid on domestic outsales of Merck's OTC cryosurgical wart removal product, pursuant to a license and settlement agreement executed in January 2008. In the latter half of 2011, the royalty rate decreased pursuant to the terms of our license. Royalties under this license will no longer be payable after certain of our cryosurgical patents expire in August 2013.

DNAG Segment

Molecular Collection Systems

Molecular collection systems revenues primarily represent sales of the Oragene® product line by our subsidiary, DNA Genotek, which we acquired in August 2011.

Consolidated Operating Results

Consolidated gross margin remained unchanged at 64% for the first nine months of 2012 and 2011.

Consolidated operating loss increased $1.0 million to $10.1 million in the nine months ended September 30, 2012, compared to $9.1 million in the nine months ended September 30, 2011. The increased loss was primarily caused by higher sales and marketing expenses and higher general and administrative costs, partially offset by a decrease in research and development expenses.

Operating Loss by Segment

OraSure Segment

OraSure's gross margin was 64% in first nine months of 2012 compared to 65% in the first nine months of 2011. The current period's gross margin was negatively impacted by the overall decrease in sales volume which caused a decline in absorption of our labor and fixed overhead costs. This decline in margin was partially offset by the beneficial impact of the $1.0 million HCV milestone payment received in the first quarter of 2012.

Beginning in January 2013 and through February 2015, sales of our OraQuick® product into the professional market will be subject to an increase in certain lateral flow patent royalties which we agreed to as part of a litigation settlement in 2009. This increase will negatively impact our gross margin during those years.

Research and development expenses declined 50% to $7.3 million in the first nine months of 2012 from $14.7 million in the first nine months of 2011, primarily as a result of lower clinical trial costs related to the development of our OraQuick® In-Home HIV Test.

Sales and marketing expenses increased 35% to $20.6 million in the first nine months of 2012 from $15.3 million in the first nine months of 2011. This increase was primarily the result of approximately $4.7 million of spending associated with the commercialization of our OraQuick® In-Home HIV Test.

General and administrative expenses increased 2% to $15.0 million in the first nine months of 2012 from $14.8 million in the first nine months of 2011. Expenses in 2011 included $2.5 million of transaction costs associated with the DNAG acquisition. The absence of DNAG transaction costs were more than offset by higher staffing, consulting, and administrative costs during the 2012 period.

All the above contributed to OraSure's operating loss of $7.4 million, which included $2.6 million of depreciation and amortization expense and $3.7 million of stock-based compensation expense.

DNAG Segment

DNAG's gross margin increased to 68% in first nine months of 2012 from 33% in comparative period of 2011. DNAG's 2011 gross margin included $763,000 of increased product cost associated with non-cash fair-value inventory adjustments resulting from the acquisition. 2012 gross margin included $1.0 million of amortization expense compared to $164,000 recorded for the period August 17, 2011 through September 30, 2011.

DNAG incurred $9.4 million in operating expenses during the nine months of 2012 compared to $1.5 million incurred during the 2011 period from the August 17, 2011 acquisition date through September 30, 2011. Expenses for 2012 included $2.2 million of research and development costs, $4.9 million of sales and marketing expenses and $2.4 million of general and administrative expenses. Expenses for the period August 17, 2011 through September 30, 2011 included $432,000 of research and development costs, $768,000 of sales and marketing expenses and $338,000 of general and administrative expenses.

All of the above contributed to DNAG's 2012 operating loss of $2.7 million, which included $2.9 million of depreciation and amortization expense and $115,000 of stock-based compensation expense.

Consolidated Income Taxes

We continue to believe the full valuation allowance established in 2008 against OraSure's total net deferred tax asset is appropriate as the facts and circumstances necessitating the allowance have not changed. As a result, no U.S. income tax benefit was recorded for OraSure's pre-tax loss in the first nine month of 2012. A Canadian income tax benefit of $1.1 million was recorded in the nine months ended September 30, 2012 which was associated with the DNAG loss before income taxes and certain Canadian research and development and investment tax credits. The income tax benefit for the nine months ended September 30, 2012 was negatively impacted by an $427,633 adjustment recorded in the second quarter of 2012 to DNAG's deferred tax liability to reflect a change in the enacted Canadian provincial tax rates.

Liquidity and Capital Resources

	September 30, 2012	December 31, 2011
	(In thousands)	
Cash	$ 89,416	$ 23,878
Working capital	106,608	30,860

Our cash increased $65.5 to $89.4 million at September 30, 2012 from $23.9 million at December 31, 2011, primarily due to receipt of $70.3 million in net proceeds received from our public equity offering completed during the third quarter of 2012. Our working capital also increased to $106.6 million at September 30, 2012 from $30.9 million at December 31, 2011.

During the first nine months of 2012, we used $4.0 million in cash to finance our operating activities. Our net loss of $9.2 million and a deferred income tax benefit of $1.1 million were partially offset by non-cash stock-based compensation expense of $3.8 million and depreciation and amortization expense of $5.5 million. Additional uses of cash in operating activities included a $2.1 million increase in accounts receivable largely due to the shipment of our OraQuick® In-Home HIV test to retailers during the last week of September and a $3.2 million increase in inventory largely due to the stocking of our professional and OTC OraQuick® HIV tests. Offsetting these uses of cash were a $953,000 increase in accounts payable primarily related to inventory purchases, and a $3.4 million increase in deferred revenue related to the late September shipments of our OraQuick® In-Home test to retailers. During the current nine-month period, we also used $2.1 million in cash to pay our 2011 royalty obligations, management incentive bonuses and other year-end accruals.

We used a total of $1.4 million in investing activities during the first nine months of 2012 to acquire property and equipment.

Net cash provided by financing activities was $70.9 million for the nine months ended September 30, 2012, which primarily resulted from the $70.3 million of net proceeds received from our secondary offering of 6.1 million shares of our common stock in July 2012 and $9.5 million in proceeds received from the exercise of stock options. These increases in cash were partially offset by $7.3 million in loan principal repayments and $1.5 million used for the repurchase of common stock related to the vesting of restricted shares.

On July 30, 2012, we repaid the $7,041,680 principal balance outstanding under our $10,000,000 credit facility with Comerica Bank and we have no ability to make additional borrowings under this facility.

Our current cash balance is expected to be sufficient to fund our current 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 and amount of costs to commercially launch new products including our OraQuick® In-Home HIV 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, 2011 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, 2011. As of September 30, 2012, 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 consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these consolidated 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 the valuation of accounts receivable, inventories and intangible assets, as well as calculations related to contingencies and accruals. 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 2011 Annual Report on Form 10-K filed with the SEC. During the first nine months of 2012, there were no material changes in our critical accounting policies.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

As of September 30, 2012, 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. As currency rates change, translation of revenues and expenses for these operations from foreign currencies to U.S. dollars affects year-to-year comparability of operating results. Sales denominated in a foreign currency were 6% of our total revenues for the first nine months ended September 30, 2012 (including revenues from DNAG). We expect the DNAG business will continue to grow and our exposure to fluctuations in foreign currency exchange rates may increase.

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, 2012. 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, 2012 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. OraSure, through a wholly-owned subsidiary, acquired DNAG on August 17, 2011 and we are currently in the process of integrating DNAG's financial reporting systems into our existing internal controls and procedures. Other than the evaluation and integration of DNAG's internal controls, there were no changes in our internal control over financial reporting during the fiscal quarter ended September 30, 2012 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

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, 2011, as amended by the risk factor disclosed in Item 1A., entitled “Risk Factors,” in our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2012.

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

During the quarter ended September 30, 2012, pursuant to the OraSure Technologies, Inc. Stock Award Plan, and in connection with the vesting of restricted shares, we retired 4,942 shares of our common stock to satisfy minimum tax withholding obligations at an average price paid per share of $10.93.

Item 6. EXHIBITS

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

SIGNATURES

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

ORASURE TECHNOLOGIES, INC.

Date: November 9, 2012

/s/ Ronald H. Spair

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

/s/ Mark L. Kuna

Date: November 9, 2012

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

EXHIBIT INDEX

Exhibit	
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, 2012

/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, 2012

/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, 2012 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, 2012

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, 2012 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, 2012