ORASURE TECHNOLOGIES INC
Form 10-Q
May 09, 2012
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 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 x No ¨

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨	Smaller reporting company ¨

Indicate by checkmark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

Number of shares of Common Stock, par value $.000001 per share, outstanding as of May 4, 2012: 48,184,355 shares.

Table of Contents

PART I. FINANCIAL INFORMATION

		Page No.
Item 1.	**Financial Statements (unaudited)**	
Consolidated Balance Sheets at March 31, 2012 and December 31, 2011		3
Consolidated Statements of Operations for the three months ended March 31, 2012 and 2011		4
Consolidated Statements of Comprehensive Loss for the three months ended March 31, 2012 and 2011		5
Consolidated Statements of Cash Flows for the three months ended March 31, 2012 and 2011		6
Notes to Consolidated Financial Statements		7
Item 2.	**Management s Discussion and Analysis of Financial Condition and Results of Operations**	16
Item 3.	**Quantitative and Qualitative Disclosures About Market Risk**	25
Item 4.	**Controls and Procedures**	25
	PART II. OTHER INFORMATION	
Item 1.	**Legal Proceedings**	27
Item 1A.	**Risk Factors**	27
Item 2.	**Unregistered Sales of Equity Securities and Use of Proceeds**	27
Item 6.	**Exhibits**	27
Signatures		28

Table of Contents

Item 1. FINANCIAL STATEMENTS

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(Unaudited)

	MARCH 31, 2012	DECEMBER 31, 2011
ASSETS		
CURRENT ASSETS:		
Cash	$ 22,814,268	$ 23,878,002
Accounts receivable, net of allowance for doubtful accounts of $157,718 and $169,916	13,291,493	17,158,751
Inventories	10,817,952	9,620,556
Prepaid expenses	2,071,274	1,682,325
Other current assets	942,270	495,981
Total current assets	49,937,257	52,835,615
PROPERTY AND EQUIPMENT, net	19,376,018	19,855,456
INTANGIBLE ASSETS, net	29,988,146	30,383,112
GOODWILL	25,318,233	24,739,776
OTHER ASSETS	52,607	47,383
	$ 124,672,261	$ 127,861,342
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	$ 7,166,680	$ 7,291,680
Accounts payable	3,529,094	4,142,173
Accrued expenses and other	8,430,439	10,542,155
Total current liabilities	19,126,213	21,976,008
OTHER LIABILITIES	8,400	
DEFERRED INCOME TAXES	5,248,837	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, 48,086,177 and 47,392,711 shares issued and outstanding	48	47
Additional paid-in capital	251,825,144	249,639,955
Accumulated other comprehensive loss	(858,661)	(1,964,251)
Accumulated deficit	(150,677,720)	(147,426,050)
Total stockholders equity	100,288,811	100,249,701

	$ 124,672,261	$ 127,861,342

See accompanying notes to the consolidated financial statements.

Table of Contents

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended March 31, 2012	2011
REVENUES:		
Product	$ 19,738,589	$ 17,050,112
Licensing and product development	1,205,844	363,616
	20,944,433	17,413,728
COST OF PRODUCTS SOLD	7,212,044	6,146,897
Gross profit	13,732,389	11,266,831
OPERATING EXPENSES:		
Research and development	3,444,377	4,420,240
Sales and marketing	7,873,521	4,931,876
General and administrative	6,066,170	4,467,611
	17,384,068	13,819,727
Operating loss	(3,651,679)	(2,552,896)
INTEREST EXPENSE	(74,772)	(78,187)
INTEREST INCOME	2,607	38,945
FOREIGN CURRENCY LOSS	(50,338)	(8,178)
OTHER INCOME	1,657	2,213
Loss before income taxes	(3,772,525)	(2,598,103)
INCOME TAX BENEFIT	(520,855)	
NET LOSS	$ (3,251,670)	$ (2,598,103)
LOSS PER SHARE:		
BASIC	$ (0.07)	$ (0.06)
DILUTED	$ (0.07)	$ (0.06)
SHARES USED IN COMPUTING LOSS PER SHARE:		
BASIC	47,807,358	46,517,531
DILUTED	47,807,358	46,517,531

See accompanying notes to the consolidated financial statements.

Table of Contents

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

	Three Months Ended March 31,	
	2012	2011
NET LOSS	$ (3,251,670)	$ (2,598,103)
OTHER COMPREHENSIVE INCOME (LOSS)		
Currency translation adjustments	1,105,590	(269)
Other comprehensive income (loss)	1,105,590	(269)
COMPREHENSIVE LOSS	$ (2,146,080)	$ (2,598,372)

See accompanying notes to the consolidated financial statements.

Table of Contents

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Three Months Ended March 31, 2012	2011
OPERATING ACTIVITIES:		
Net loss	$ (3,251,670)	$ (2,598,103)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,192,031	972,552
Depreciation and amortization	1,809,037	829,079
Deferred income taxes	(520,855)	
Changes in assets and liabilities		
Accounts receivable	3,936,368	351,789
Inventories	(1,185,741)	(404,342)
Prepaid expenses and other assets	(539,229)	134,658
Accounts payable	(638,195)	606,497
Accrued expenses and other liabilities	(2,157,697)	(1,941,622)
Net cash used in operating activities	(1,355,951)	(2,049,492)
INVESTING ACTIVITIES:		
Purchases of property and equipment	(305,855)	(882,440)
Net cash used in investing activities	(305,855)	(882,440)
FINANCING ACTIVITIES:		
Repayments of long-term debt	(125,000)	(125,000)
Proceeds from exercise of stock options	2,162,484	582,375
Repurchase of common stock	(1,452,493)	(824,561)
Net cash provided by (used in) financing activities	584,991	(367,186)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	13,081	
NET DECREASE IN CASH	(1,063,734)	(3,299,118)
CASH, BEGINNING OF PERIOD	23,878,002	73,843,402
CASH, END OF PERIOD	$ 22,814,268	$ 70,544,284
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for:		
Interest	$ 76,074	$ 80,430
Income taxes	$ 20,316	$

See accompanying notes to the consolidated financial statements.

Table of Contents

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

(Unaudited)

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 our proprietary oral fluid technologies, as well as other diagnostic products, including immunoassays and *in vitro* diagnostic tests that are used on other specimen types. We also manufacture and sell medical devices used for the removal of benign skin lesions by cryosurgery, or freezing. Our diagnostic products include tests that are performed on a rapid basis at the point of care and tests that are processed in a laboratory. These products are sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, distributors, government agencies, physicians offices, and commercial and industrial entities. One of our products has been sold in the over-the-counter or consumer retail markets in North America, Europe, Central and South America and Australia.

We also manufacture and sell oral fluid collection devices used to collect samples of genetic material for molecular testing in the academic research, clinical genetic testing, pharmacogenomics, personalized medicine, and animal genetics markets. Our OraGene® DNA sample collection kit provides an all-in-one system for the collection, stabilization and transportation of DNA from 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 months ended March 31, 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, inventories and intangible assets, as well as calculations related to contingencies, accruals and indemnifications, among others. These estimates and assumptions are based on management s best estimates and judgment. Management evaluates its estimates and assumptions on an ongoing basis, using historical experience and other factors, which management believes to be reasonable under the circumstances, including the current economic environment. We adjust such estimates and assumptions when facts and circumstances dictate. Illiquid credit markets, volatile equity, foreign currency and energy markets, 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 will be reflected in the consolidated financial statements in those future periods.

Cash and Cash Equivalents. We consider all highly liquid investments with a purchased maturity of ninety days or less to be cash equivalents. We had no cash equivalents at March 31, 2012 or December 31, 2011.

Table of Contents

Fair Value of Financial Instruments. As of March 31, 2012, the carrying values of cash, accounts receivable, accounts payable and accrued expenses approximate their respective fair values based on their short-term nature. In addition, we believe the carrying value of our debt instrument, which does not have a readily ascertainable market value, approximates fair value, given that the interest rate on outstanding borrowings approximates current market rates and it matures in May 2012.

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 is calculated using the market price of the mutual funds as of the end of the period. All investments in the plan are classified 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:

	March 31, 2012	December 31, 2011
Raw materials	$ 5,863,205	$ 5,767,735
Work in process	665,873	497,277
Finished goods	4,288,874	3,355,544
	$ 10,817,952	$ 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 March 31, 2012 and December 31, 2011 was $23,301,610 and $22,497,107, respectively.

Table of Contents

Intangible Assets. Intangible assets consist of the following:

	Amortization Period (Years)	March 31, 2012 Gross	March 31, 2012 Accumulated Amortization	March 31, 2012 Net
Customer list	10	$ 12,556,814	$ (692,637)	$ 11,864,177
Patents and product rights	3-10	10,448,620	(6,571,700)	3,876,920
Acquired technology	7	9,753,381	(822,749)	8,930,632
Tradename	15	4,813,045	(199,446)	4,613,599
Non-compete agreements	1-3	1,044,397	(341,579)	702,818
		$ 38,616,257	$ (8,628,111)	$ 29,988,146

	Amortization Period (Years)	December 31, 2011 Gross	December 31, 2011 Accumulated Amortization	December 31, 2011 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 a goodwill impairment test requires a two-step process. The first step involves comparing the fair values of the applicable reporting units with their aggregate carrying values, including goodwill. If the carrying value of a reporting unit exceeds the reporting unit s fair value, we perform the second step of the test to determine the amount of the impairment loss, 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.

As of March 31, 2012, we believe no indicators of impairment exist.

Goodwill changed by $578,457 from $24,739,776 at December 31, 2011 to $25,318,233 at March 31, 2012 as a result of foreign currency translation.

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

Table of Contents

Revenue Recognition. We recognize product revenues when there is persuasive evidence that an arrangement exists, the price is fixed or determinable, title has passed and collection is reasonably assured. Product revenues are recorded net of allowances for any discounts or rebates. We do not grant price protection or product return rights to our customers, except for warranty returns. Historically, returns arising from warranty issues have been infrequent and immaterial. Accordingly, we expense warranty returns as incurred.

Royalty income from the grant of license rights is recognized during the period in which the revenue is earned and the amount is determinable from the licensee.

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

Customer and Vendor Concentrations. We had no significant concentrations (greater than 10%) in accounts receivable as of March 31, 2012 or December 31, 2011 or in revenues for the three months ended March 31, 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 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.

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

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

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

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

Table of Contents

stock options and unvested restricted stock totaling 6,441,130, and 7,205,126 shares were outstanding as of March 31, 2012 and 2011, respectively. For the three months ended March 31, 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 are translated into U.S. dollars, which is the reporting currency of the Company. The $1,105,590 currency translation adjustment recorded in the first quarter 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.

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

3. Business Combination

On August 17, 2011 (the Acquisition Date), we acquired all of the outstanding capital stock of DNAG, a manufacturer and seller of oral fluid collection kits that are used to collect 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 consists of $50 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 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 months ended March 31, 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.

Table of Contents

	Three Months Ended March 31, 2011
Total revenues	$ 21,573,863
Net loss	$ (2,859,986)
Loss per share:	
Basic and diluted	$ (0.06)

4. Stock-Based Compensation

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.

Under the terms of the Stock Plan, nonqualified options may be granted to eligible employees, including our officers, at a price not less than 100 percent of the fair market value of a share of common stock on the date of grant. The option term and vesting schedule of such awards may be either unlimited or have a specified period in which to vest and be exercised. To date, options generally have been granted with ten-year exercise periods and an exercise price equal to the fair market value on the date of grant. Options generally vest over four years, with one quarter of the options vesting one year after grant and the remainder vesting on a monthly basis over the next three years.

The fair value of each stock option is estimated on the date of the grant using the Black-Scholes option-pricing model. The weighted average grant date fair value of stock options granted during the three months ended March 31, 2012 and 2011 was $5.44 and $2.82 per share, respectively.

Total compensation cost related to stock options for the three months ended March 31, 2012 and 2011 was $490,817 and $341,948, respectively, of which $19,750 and $7,028 was capitalized into inventory during the three months ended March 31, 2012 and 2011, respectively. The amounts recognized in cost of products sold for amounts previously capitalized were $3,034 and $9,680 for the three months ended March 31, 2012 and 2011, respectively.

The following table summarizes the stock option activity for the three months ended March 31, 2012:

	Options
Outstanding on January 1, 2012	5,416,186
Granted	744,443
Exercised	(399,251)
Expired	(9,694)
Forfeited	(13,125)
Outstanding on March 31, 2012	5,738,559

As of March 31, 2012, there was $6,978,182 of unrecognized compensation expense related to unvested option awards that is expected to be recognized over a remaining weighted average period of 2.2 years.

Net cash proceeds from the exercise of stock options were $2,162,484 and $582,375 for the three months ended March 31, 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.

Table of Contents

As mentioned above, the Stock Plan also permits us to grant restricted shares of our common stock to eligible employees, including officers and outside directors. Generally, these shares are nontransferable until vested and are subject to vesting requirements and/or forfeiture, as determined by the Compensation Committee of our Board of Directors. The market value of these shares at the date of grant is recognized on a straight-line basis over the period during which the restrictions lapse. During the three months ended March 31, 2012, we granted 250,932 restricted shares of our common stock, with a weighted average grant date fair value of $11.30 per share, to certain key officers, members of management and outside directors. Compensation cost of $701,214 and $630,604 related to restricted shares was recognized during the three months ended March 31, 2012 and 2011, respectively.

The following table summarizes restricted stock award activity for the three months ended March 31, 2012:

	Shares
Issued and unvested, January 1, 2012	879,466
Granted	250,932
Vested	(425,091)
Forfeited	(2,736)
Issued and unvested, March 31, 2012	702,571

As of March 31, 2012, there was $5,181,404 of unrecognized compensation expense related to unvested restricted stock awards that is expected to be recognized over a remaining weighted average period of 2.1 years. In connection with the vesting of restricted shares, during the three months ended March 31, 2012 and 2011, 130,876 and 123,995 shares, respectively, with aggregate values of $1,452,493 and $824,561, respectively, were withheld and retired in satisfaction of minimum tax withholding obligations.

5. Accrued Expenses

	March 31, 2012	December 31, 2011
Payroll and related benefits	$ 2,647,928	$ 4,866,812
Royalties	1,356,214	1,985,875
Customer prepayments	1,397,931	1,318,546
Professional fees	965,187	834,657
Other	2,063,179	1,536,265
	$ 8,430,439	$ 10,542,155

6. Long-term Debt

As of March 31, 2012, we had in place a $10,000,000 credit facility, as amended (the Credit Facility), with Comerica Bank (Comerica). Pursuant to the terms of the Credit Facility, principal and interest fixed at 4.15% per annum are payable monthly through May 27, 2012, at which time the remaining unpaid principal balance is payable. As of March 31, 2012, we had no available borrowings under this Credit Facility. We are currently in negotiations to refinance this Credit Facility.

All borrowings under the Credit Facility are collateralized by a first priority security interest in all OraSure assets, including present and future accounts receivable, chattel paper, contracts and contract rights, equipment and accessories, general intangibles, investments, instruments, inventories, and a mortgage on our three facilities in Bethlehem, Pennsylvania. The Credit Facility contains certain covenants that set forth minimum requirements for our quick ratio, liquidity, and tangible net worth. We were in compliance with all covenants as of March 31, 2012. The Credit Facility also restricts our ability to pay dividends, to make certain investments, to incur additional indebtedness, to sell or otherwise dispose of a substantial portion of assets, and to merge or consolidate operations with an unaffiliated entity, without the consent of Comerica.

Table of Contents

7. Income Taxes

During the three months ended March 31, 2012, we recorded a foreign deferred tax benefit of $520,855 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.

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 March 31, 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 March 31, 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 months ended March 31, 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 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 production 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 they offer. 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 and income taxes to our operating segments. Reportable segments have no inter-segment revenues.

The following table summarizes segment information for the quarter ended March 31, 2012. During the quarter ended March 31, 2011 we operated within only one reportable segment.

Table of Contents

	OraSure	DNAG	Totals
Revenues	$ 17,646,556	$ 3,297,877	$ 20,944,433
Operating loss	2,748,177	903,502	3,651,679
Depreciation and amortization	889,108	919,929	1,809,037
Capital expenditures	267,161	38,694	305,855
Total assets	68,991,047	55,681,214	124,672,261

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 March 31,	
	2012	2011
United States	$ 15,636	$ 14,239
Europe	2,798	1,986
Other regions	2,510	1,189
	$ 20,944	$ 17,414

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

	March 31, 2012	December 31, 2011
United States	$ 18,539	$ 18,954
Canada	663	706
Other regions	174	195
	$ 19,376	$ 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 March 31, 2012, the value of the assets associated with the plan was $8,400 and is included in other assets in the consolidated balance sheets. Our obligation related to the deferred compensation plan is included in other liabilities in the consolidated balance sheet. As of March 31, 2012, our total obligation under this plan was $8,400.

Table of Contents

Item 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Statements below regarding future events or performance are forward-looking statements within the meaning of the Federal securities laws. These may include statements about our expected revenues, earnings/loss per share, net income (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 obtain FDA approval of the OraQuick® HIV test for use in the over-the-counter market; 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 DNAG; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; impact of the economic downturn, high unemployment and poor credit conditions; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products; market acceptance of oral fluid testing or other products; changes in market acceptance of products based on product performance, extended shelf life or other factors; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical products and components; availability of related products produced by third parties or products required for use of our products; history of losses and ability to achieve sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of our stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to meet financial covenants in agreements with financial institutions; ability to refinance outstanding debt under expiring credit facilities on acceptable terms or at all; ability to retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; and general political, business and economic conditions. These and other factors are discussed more fully in our Securities and Exchange Commission (SEC) filings, including our registration statements, Annual Report on Form 10-K for the year ended December 31, 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 the 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

Table of Contents

proprietary oral fluid technologies, as well as other diagnostic products including immunoassays and *in vitro* diagnostic tests that are used on other specimen types. We also manufacture and sell medical devices used for the removal of benign skin lesions by cryosurgery, or freezing. Our diagnostic products include tests which are performed on a rapid basis at the point of care and tests which are processed in a laboratory. These products are sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, distributors, government agencies, physicians offices, and commercial and industrial entities. One of our products is sold in the over-the-counter (OTC) or consumer retail market in North America, Europe, Central and South America, and Australia.

We also manufacture and sell kits that are used to collect samples of genetic material for molecular testing in the academic research, clinical genetic testing, pharmacogenomics, personalized medicine, animal and livestock genetics markets. 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 OraSure® oral fluid collection device and our oral fluid Western blot HIV-1 confirmatory product. If we are unable to obtain necessary components or materials from these sole sources, the time required and expense incurred to develop replacements and obtain the required U.S. Food and Drug Administration (FDA) approvals could disrupt our ability to sell the affected products and could adversely impact our revenues and results of operations. Our OraSure QuickFlu test is manufactured and supplied by a sole source supplier and 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 three months ended March 31, 2012, our total consolidated revenues were $20.9 million compared to $17.4 million in the three months ended March 31, 2011. The current quarter included $3.3 million in revenues from our molecular collection systems subsidiary acquired in August 2011. Product revenues during the three months ended March 31, 2012 increased 16% when compared to the first quarter of 2011. Licensing and product development revenues in 2012 increased primarily as a result of $1.0 million in milestone payments received as a result of our achievement of certain regulatory and commercial objectives pursuant to the terms of our collaboration agreement with Merck & Co., Inc. (Merck) for the development and promotion of our OraQuick® rapid HCV test in international markets.

Table of Contents

Our consolidated net loss for the three months ended March 31, 2012 was $3.3 million, or $0.07 per share, compared to a net loss of $2.6 million, or $0.06 per share, for the three months ended March 31, 2011.

Cash used in operating activities for the three months ended March 31, 2012 was $1.4 million, compared to the $2.0 million used during the three months ended March 31, 2011. As of March 31, 2012, we had $22.8 million in cash compared to $23.9 million at December 31, 2011.

Other Recent Developments

OraQuick® HIV OTC Test

On May 15, 2012, the FDA s Blood Products Advisory Committee (BPAC) will consider our application for approval of a rapid HIV test for use in the OTC market. Among other things, we will present to BPAC the findings from the final phase of clinical testing, which involved the use of our OraQuick® In-Home HIV Test, an OTC investigation use version of the OraQuick *ADVANCE*® Rapid HIV-1/2 test, by individuals in an unobserved setting.

Competitive and Economic Outlook

Competition in the U.S. market for HIV testing 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.

During 2011, our OraQuick® HCV test was sold primarily to customers operating CLIA-certified laboratories and competed against other laboratory-based HCV blood tests. However, in November 2011, we received a CLIA waiver for this product, which enables us to sell our HCV product to many other customers that perform CLIA waived tests, such as outreach clinics, community-based organizations and physician offices. The CLIA-waiver allows us to deploy the test more broadly in both the public health and hospital markets and, with the assistance of our collaborator, Merck & Co., Inc. (Merck), into the physician office market.

We believe the FDA approval in 2011 of two new therapeutic treatments for HCV, both of which are more effective than previously available treatments, will help drive awareness and testing for HCV, including with our OraQuick® HCV rapid test. While CLIA waiver opens the opportunity for significant sales growth in 2012, demand for our HCV product will ultimately depend on the availability of government funds allocated to HCV testing efforts. In addition, sales growth will depend on the success of Merck s detailing efforts into the physician offices under our HCV collaboration arrangement.

In Europe and other non-U.S. countries, 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 working 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 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 both our current Intercept® products and the high-throughput assays we intend to commercialize jointly with Roche Diagnostics.

Table of Contents

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.

Finally, current economic conditions, including disruptions in the capital and credit markets, may continue for the foreseeable future and intensify. 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 addition, demand for our products may also be adversely affected by current economic conditions.

Results of Operations

Three months ended March 31, 2012 compared to March 31, 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 and specimen collection devices and the manufacture and sale of 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 samples of genetic material for molecular testing. OraSure revenues consist primarily of product sold into 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 production 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

	Three Months Ended March 31, 2012,				
	Dollars			Percentage of Total Revenues	
(in thousands)	2012	2011	% Change	2012	2011
OraSure	$ 16,440	$ 17,050	(4)%	78%	98%
DNAG	3,298		N/A	16	
Product revenues	19,738	17,050	16	94	98
Licensing and product development	1,206	364	231	6	2
Total revenues	$ 20,944	$ 17,414	20%	100%	100%

Consolidated revenues increased 20% to $20.9 million in the first quarter of 2012 from $17.4 million in the comparable quarter of 2011. The current quarter included $3.3 million in revenues from our molecular collection systems business. Product revenues

Table of Contents

increased 16% during the three months ended March 31, 2012 when compared to the first quarter of 2011, primarily as a result of the $3.3 million of 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 quarter as compared to the comparable period of the prior year.

Consolidated revenues derived from products sold to customers outside the U.S. were $5.3 million and $3.2 million, or 25% and 18% of total revenues, in the first 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 March 31,				
	Dollars			Percentage of Total	
Market	2012	2011	Change	2012	2011
Infectious disease testing	$ 9,776	$ 9,962	(2)%	55%	57%
Substance abuse testing	2,087	3,061	(32)	12	17
Cryosurgical systems	3,478	2,710	28	20	16
Insurance risk assessment	1,099	1,317	(17)	6	8
Product revenues	16,440	17,050	(4)	93	98
Licensing and product development	1,206	364	231	7	2
Total revenues	$ 17,646	$ 17,414	1%	100%	100%

Infectious Disease Testing Market

Sales to the infectious disease testing market decreased 2% to $9.8 million in the first quarter of 2012 from $10.0 million in the first quarter of 2011. OraQuick® sales totaled $9.6 million in both the first quarters of 2012 and 2011.

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

	Three Months Ended March 31,		
Market	2012	2011	% Change
Domestic HIV	$ 8,148	$ 8,867	(8)%
International HIV	660	698	(5)
Domestic HCV	536	34	1,476
International HCV	282	48	488
Total OraQuick® revenues	$ 9,626	$ 9,647	0%

Domestic OraQuick® HIV sales decreased from $8.9 million for the three months ended March 31, 2011 to $8.1 million for the three months ended March 31, 2012. The decrease is primarily the result of ordering patterns by one of our large public health customers who placed a large order during the first quarter of 2011 which was not repeated

Table of Contents

in the first quarter of 2012. International sales of our OraQuick® HIV test decreased 5% to $660,000 for the three months ended March 31, 2012 from $698,000 for the three months ended March 31, 2011. Decreased sales in several countries were partially offset by an increase in sales to Africa in the first quarter of 2012.

OraQuick® revenues for the first quarter of 2012 included $818,000 of sales of our OraQuick® HCV test, compared to $82,000 in 2011. We received a CLIA waiver for this product in November 2011, enabling us to sell our HCV product to many other non-CLIA certified customers, such as outreach clinics, community-based organizations and physician offices. While we believe the CLIA waiver provides an opportunity for significant sales growth, demand for our HCV product could be tempered by the unavailability of government funding allocated to HCV testing efforts. In addition, sales growth will depend on the success of Merck s detailing efforts into physician offices.

Substance Abuse Testing Market

Substance abuse testing revenues decreased 32% from $3.1 million in the first quarter of 2011 to $2.1 million in the first quarter of 2012 primarily as a result of lower sales of our Intercept® drug testing system.

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

	Three Months Ended March 31,		
Market	**2012**	**2011**	**% Change**
Domestic	$ 1,523	$ 1,877	(19)%
International	46	519	(91)
Total Intercept® revenues	$ 1,569	$ 2,396	(35)%

Domestic Intercept® revenues decreased 19% from $1.9 million in the first quarter of 2011 to $1.5 million in the first quarter of 2012. In 2011, our largest laboratory distributor began selling a competing oral specimen collection device and a panel of oral fluid drug assays suitable for use on fully-automated homogenous assay systems. As a result, this distributor has reduced its purchases of Intercept® and is expected to completely stop purchasing this product line in 2012. Sales of Intercept® to this distributor decreased $365,000 from the first quarter of 2012 compared to the first quarter of 2011.

International Intercept® revenues decreased 91% due to a reduction in our UK distributor s target inventory levels. Although we anticipate increased purchases by this distributor over the remainder of 2012, we also expect the level of competition in substance abuse testing to increase in the UK with the potential to negatively impact our international revenues.

Pursuant to a development agreement with Roche Diagnostics, homogenous fully-automated oral fluid drugs of abuse assays have been developed for use with our Intercept® collection device. The FDA issued 510(k) clearances of high throughput assays for PCP, opiates, cocaine, methamphetamines, and amphetamines during 2011. The assays use Roche s technology and will run on various automated analyzers to allow oral fluid samples to be processed with the same efficiency currently achieved with urine-based drug tests. We have also entered into a commercialization agreement with Roche pursuant to which a drug testing system comprised of our Intercept® device and the newly developed homogenous assays will be marketed and sold on a worldwide basis.

Cryosurgical Systems Market

Sales in the cryosurgical systems market (which includes both the physicians office and OTC markets) increased 28% to $3.5 million in the first quarter of 2012, compared to $2.7 million in the same period of the prior year.

Table of Contents

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

Market	Three Months Ended March 31, 2012	2011	% Change
Professional domestic	$ 1,371	$ 1,342	2%
Professional international	287	339	(15)
Over-the-counter	1,820	1,029	77
Total cryosurgical systems revenues	$ 3,478	$ 2,710	28%

Domestic Histofreezer® sales increased slightly from $1.3 million in the first quarter of 2011 to $1.4 million in the first quarter of 2011. During the three months ended March 31, 2012, sales of Histofreezer® in the international market decreased 15% as compared to the first quarter of 2011, largely as a result of lower sales in Europe which were partially offset by higher sales in Australia and Africa.

Sales of our OTC cryosurgical products during the first quarter of 2012 increased 77% from $1.0 million in the first quarter of 2011 to $1.8 million in the first quarter of 2012. This increase was largely the result of higher sales to both our Latin American distributor, Genomma, and our European distributor, Reckitt Benckiser.

Genomma made no purchases from us during the first quarter of 2011 as a result of the Mexican government placing limitations on the advertising Genomma could use for our product. In addition, during the first quarter of 2011, Genomma informed us of some changes required by the Brazilian government to our package insert. Both events negatively impacted sales of our product during 2011, but were resolved by the end of that year. Sales to Genomma in the first quarter of 2012 were $633,000.

Sales to Reckitt Benckiser increased 35% from $863,000 in the first quarter of 2011 to $1.2 million in the first quarter of 2012 as a result of the timing of orders placed. Our distributor contract with Reckitt Benckiser was subject to renewal at the end of 2011 and extended through May 2012. We are currently in negotiations to further extend this contract.

Insurance Risk Assessment Market

Sales to the insurance risk assessment market decreased 17% to $1.1 million in the first quarter of 2012 from $1.3 million in the first quarter 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 to $1.2 million in the first quarter of 2012 from $364,000 in the first quarter 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.

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 received after certain of our cryosurgical patents expire in August 2013.

Table of Contents

DNAG Segment

Molecular Collection Systems

Molecular collection systems revenues primarily represent sales of our Oragene® product line in the molecular diagnostics and research markets. The $3.3 million in revenues includes a large order from a new commercial customer which made an initial purchase in the first quarter of 2012.

Consolidated Operating Results

Consolidated gross margin was 66% for the first quarter of 2012 compared to 65% in the first quarter of 2011.

Consolidated operating loss increased $1.1 million to $3.7 million in the first quarter 2012, compared to $2.6 million in the first quarter of 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 65% in the first quarter of both 2012 and 2011. The beneficial impact of the $1.0 million HCV milestone payment received in the first quarter of 2012 was offset by increased product support costs for our OraQuick® product and Intercept® assays and a decline in the absorption of labor costs when compared to the first quarter of 2011.

Research and development expenses declined 40% from $4.4 million in the first quarter of 2011 to $2.7 million in the first quarter of 2012, primarily as a result of a $1.8 million decrease in clinical trial costs related to the development of our OraQuick® HIV OTC test.

Sales and marketing expenses increased 28% to $6.3 million in the first quarter of 2012 from $4.9 million in the first quarter of 2011. This increase was primarily the result of higher spending as we prepare for the commercialization of our OraQuick® HIV OTC product.

General and administrative expenses increased 18% to $5.3 million in the first quarter of 2012 from $4.5 million in the first quarter of 2011, primarily as a result of increased consulting and staffing costs.

All the above contributed to OraSure s operating loss of $2.7 million.

DNAG Segment

DNAG s gross margin for the first quarter of 2012 was 67%.

DNAG incurred $3.1 million in operating expenses during the first quarter of 2012. This included $772,000 of research and development costs, $1.6 million of sales and marketing expenses and $773,000 of general and administrative expenses.

All of the above contributed to DNAG s operating loss of $904,000.

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 first quarter of 2012. A Canadian income tax benefit of $521,000 was recorded in the first quarter of 2012 associated with the DNAG loss before income taxes and certain Canadian research and development and investment tax credits.

Table of Contents

Liquidity and Capital Resources

	March 31, 2012	December 31, 2011
	(In thousands)	
Cash	$ 22,814	$ 23,878
Working capital	30,811	30,860

Our cash decreased $1.1 million from $23.9 million at December 31, 2011 to $22.8 million at March 31, 2012. Our working capital remained relatively flat at $30.8 million and $30.9 million at March 31, 2012 and December 31, 2011, respectively.

During the first quarter of 2012, we used $1.4 million in cash to finance our operating activities. Our net loss of $3.3 million was partially offset by non-cash stock-based compensation expense of $1.2 million, depreciation and amortization of $1.8 million, and a deferred income tax benefit of $521,000. Additional uses of cash in operating activities included a $1.2 million increase in inventory largely due to stocking of our OraQuick® HIV tests, a $539,000 increase in prepaid expenses and other current assets, a $638,000 decrease in accounts payable and a $2.2 million decrease in accrued expenses and other liabilities associated with payment of our 2011 royalty obligations, management incentive bonuses and other year-end accruals. Offsetting these uses of cash were a $3.9 million decrease in accounts receivable resulting from the collection of outstanding balances due at the end of 2011.

We used a total of $306,000 in investing activities during the first three months of 2012 to acquire property and equipment.

Net cash provided by financing activities was $585,000 for the first quarter ended March 31, 2012, primarily as a result of $2.2 million in proceeds received from the exercise of stock options, partially offset by $125,000 in loan principal repayments and $1.5 million used for the repurchase of common stock related to the vesting of restricted shares.

As of March 31, 2012, we had in place a $10,000,000 credit facility (the Credit Facility) with Comerica Bank (Comerica). Pursuant to the terms of the Credit Facility, principal and interest fixed at 4.15% per annum are payable monthly through May 27, 2012, at which time the remaining unpaid principal balance is payable. As of March 31, 2012, we had no available borrowings under this Credit Facility. We are currently in negotiations to refinance the Credit Facility.

All borrowings from Comerica are collateralized by a first priority security interest in all of OraSure s assets, including present and future accounts receivable, chattel paper, contracts and contract rights, equipment and accessories, general intangibles, investments, instruments, inventories, and a mortgage on our three facilities in Bethlehem, Pennsylvania. The Comerica agreement contains certain covenants that set forth minimum requirements for our quick ratio, liquidity, and tangible net worth. We were in compliance with all covenants as of March 31, 2012. The agreement also restricts our ability to pay dividends, to make certain investments, to incur additional indebtedness, to sell or otherwise dispose of a substantial portion of assets, and to merge or consolidate operations with an unaffiliated entity, without the consent of Comerica.

Our current cash is expected to be sufficient to fund our operating and capital needs through at least the next twelve months. Our cash requirements, however, may vary materially from those now planned due to many factors, including, but not limited to, the scope and timing of future strategic acquisitions, the cost and timing of the expansion of our manufacturing capacity, the progress of our research and development programs, the scope and results of clinical testing, the cost of any future litigation, the magnitude of capital expenditures, changes in existing and potential relationships with business partners, the time and cost of obtaining regulatory approvals, the costs involved in obtaining and enforcing patents, proprietary rights and any necessary licenses, the cost and timing of expansion of sales and marketing activities, the timing of market launch of new products including our OraQuick® HIV OTC test, market acceptance of new products, competing technological and market developments, the impact of the ongoing economic downturn and other factors.

Table of Contents

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 March 31, 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 bad debts, inventories, investments, intangible assets, income taxes and realization of the related deferred tax assets, revenue recognition, restructuring costs, contingencies and litigation. We base our judgments and estimates on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

A more detailed review of our critical accounting policies is contained in our 2011 Annual Report on Form 10-K filed with the SEC. During the first three 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.

The interest rate on our long-term debt is fixed at 4.15%. As a result, we have no exposure to interest rate changes.

As of March 31, 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 7.2% of our total revenues for the first quarter ended March 31, 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 March 31, 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 March 31, 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.

Table of Contents

(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 March 31, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II. OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

Cryosurgical Patent Infringement Litigation

In December 2009, we filed legal proceedings in the Patents Court of the High Court of England and Wales against D.D.D. Limited, DioMed Developments Limited and Sixtem Life Srl, alleging that the import and/or sale of the Bazuka Sub-Zero OTC cryosurgical product by the defendants in the United Kingdom infringes our European Patent (UK) 0 608 954. We were seeking injunctive relief and damages, among other remedies, in this matter. The defendants filed a response denying infringement and alleging that our Patent is invalid.

A trial commenced in late April 2012 and this matter has been settled by the parties. Under the terms of the settlement, the parties entered into mutual covenants not to sue and agreed to bear their own respective costs of the litigation.

Item 1A. RISK FACTORS

Except as noted below, there have been no material changes to the factors disclosed in Item 1A., entitled Risk Factors, in our Annual Report on Form 10-K for the year ended December 31, 2011.

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

During the quarter ended March 31, 2012, pursuant to the OraSure Technologies, Inc. Stock Award Plan, and in connection with the vesting of restricted shares, we retired 130,876 shares of our Common Stock to satisfy minimum tax withholding obligations at an average price paid per share of $11.10.

Item 6. EXHIBITS

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

Table of Contents

SIGNATURES

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

ORASURE TECHNOLOGIES, INC.

/s/ Ronald H. Spair
Date: May 9, 2012 Ronald H. Spair

Chief Operating Officer and

Chief Financial Officer

(Principal Financial Officer)

/s/ Mark L. Kuna
Date: May 9, 2012 Mark L. Kuna

Senior Vice President, Finance and Controller

(Principal Accounting Officer)

Table of Contents

EXHIBIT INDEX

Exhibit	
10.1	Ninth Amendment to Loan and Security Agreement, dated as of February 24, 2012, between OraSure Technologies, Inc. and Comerica Bank, is incorporated by reference to Exhibit 10 to the Company s Current Report on Form 8-K filed February 27, 2012.
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