ORASURE TECHNOLOGIES INC
Form 10-Q
August 06, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2014.

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	**(IRS Employer**
Incorporation or Organization)	**Identification No.)**

220 East First Street, Bethlehem, Pennsylvania	**18015**
(Address of Principal Executive Offices)	**(Zip code)**

(610) 882-1820

(Registrant s Telephone Number, Including Area Code)

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

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

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

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

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

Number of shares of Common Stock, par value $.000001 per share, outstanding as of August 1, 2014: 55,987,346 shares.

PART I. FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(Unaudited)

(in thousands, except per share amounts)

	JUNE 30, 2014	DECEMBER 31, 2013
ASSETS		
CURRENT ASSETS:		
Cash	$ 75,832	$ 93,191
Short-term investments	4,437	
Accounts receivable, net of allowance for doubtful accounts of $276 and $299	14,152	12,957
Inventories	13,229	11,444
Prepaid expenses	1,458	1,712
Deferred income taxes	70	71
Other current assets	6,627	200
Total current assets	115,805	119,575
PROPERTY AND EQUIPMENT, net	18,471	17,933
INTANGIBLE ASSETS, net	20,443	22,226
GOODWILL	23,674	23,782
OTHER ASSETS	1,172	729
	$ 179,565	$ 184,245
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 4,647	$ 4,834
Deferred revenue	694	1,119
Accrued expenses	9,366	13,032
Total current liabilities	14,707	18,985
OTHER LIABILITIES	1,157	677
DEFERRED INCOME TAXES	3,381	3,437
COMMITMENTS AND CONTINGENCIES (Note 6)		
STOCKHOLDERS EQUITY		
Preferred stock, par value $.000001, 25,000 shares authorized, none issued		

Common stock, par value $.000001, 120,000 shares authorized, 55,984 and 55,632 shares issued and outstanding		
Additional paid-in capital	341,106	338,674
Accumulated other comprehensive loss	(3,953)	(3,797)
Accumulated deficit	(176,833)	(173,731)
Total stockholders equity	160,320	161,146
	$ 179,565	$ 184,245

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(in thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
NET REVENUES:				
Product	$ 25,626	$ 24,063	$ 49,163	$ 45,025
Licensing and product development	775	274	775	476
	26,401	24,337	49,938	45,501
COST OF PRODUCTS SOLD	10,385	9,838	19,995	18,973
Gross profit	16,016	14,499	29,943	26,528
OPERATING EXPENSES:				
Research and development	2,771	2,693	5,252	6,050
Sales and marketing	10,272	12,369	21,612	26,243
General and administrative	5,976	5,013	11,700	10,400
Gain on contract termination settlement	(5,500)		(5,500)	
	13,519	20,075	33,064	42,693
Operating income (loss)	2,497	(5,576)	(3,121)	(16,165)
OTHER INCOME (EXPENSE)	(142)	42	(24)	(5)
Income (loss) before income taxes	2,355	(5,534)	(3,145)	(16,170)
INCOME TAX BENEFIT	(174)	(249)	(43)	(659)
NET INCOME (LOSS)	$ 2,529	$ (5,285)	$ (3,102)	$ (15,511)
EARNINGS (LOSS) PER SHARE:				
BASIC	$ 0.05	$ (0.10)	$ (0.06)	$ (0.28)
DILUTED	$ 0.04	$ (0.10)	$ (0.06)	$ (0.28)
SHARES USED IN COMPUTING EARNINGS (LOSS) PER SHARE:				
BASIC	55,907	55,559	55,846	55,504
DILUTED	57,243	55,559	55,846	55,504

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(Unaudited)

(in thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
NET INCOME (LOSS)	$ 2,529	$ (5,285)	$ (3,102)	$ (15,511)
OTHER COMPREHENSIVE INCOME (LOSS)				
Currency translation adjustments	1,622	(1,460)	(156)	(2,585)
Other comprehensive income (loss)	1,622	(1,460)	(156)	(2,585)
COMPREHENSIVE INCOME (LOSS)	$ 4,151	$ (6,745)	$ (3,258)	$ (18,096)

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(in thousands)

	Six Months Ended June 30,	
	2014	**2013**
OPERATING ACTIVITIES:		
Net loss	$ (3,102)	$ (15,511)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,869	2,835
Depreciation and amortization	3,108	3,221
Unrealized foreign currency loss	139	
Deferred income taxes	(43)	(659)
Changes in assets and liabilities		
Accounts receivable	(1,196)	2,030
Inventories	(1,789)	229
Prepaid expenses and other assets	(5,981)	(977)
Accounts payable	(179)	40
Deferred revenue	(418)	(1,165)
Accrued expenses and other liabilities	(3,805)	679
Net cash used in operating activities	(10,397)	(9,278)
INVESTING ACTIVITIES:		
Purchases of short term investments	(4,430)	
Purchases of property and equipment	(1,988)	(1,092)
Net cash used in investing activities	(6,418)	(1,092)
FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	202	301
Repurchase of common stock	(639)	(801)
Net cash used in financing activities	(437)	(500)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	(107)	(54)
NET DECREASE IN CASH	(17,359)	(10,924)
CASH, BEGINNING OF PERIOD	93,191	87,888
CASH, END OF PERIOD	$ 75,832	$ 76,964
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for:		
Income taxes	$ 42	$ 28

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

(Unaudited)

(in thousands, except per share amounts, unless otherwise indicated)

1. The Company

We develop, manufacture, market and sell oral fluid diagnostic products and specimen collection devices using our proprietary oral fluid technologies, as well as other diagnostic products, including immunoassays and other *in vitro* diagnostic tests that are used on other specimen types. 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. We sell the first and only rapid point-of-care HIV test approved for use in the domestic consumer retail or over-the-counter (OTC) market. We also manufacture and sell oral fluid collection devices used to collect, stabilize and store samples of genetic material for molecular testing in the consumer genetic, clinical genetic testing, academic research, pharmacogenomics, personalized medicine, and animal genetics markets. Lastly, we manufacture and sell medical devices used for the removal of benign skin lesions by cryosurgery, or freezing. Our products are sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations, public health organizations, research and academic institutions, distributors, government agencies, physicians offices, and commercial and industrial entities. Our OTC HIV and cryosurgical products are sold to retail pharmacies and mass merchandisers, and our OTC HIV product is also sold to consumers over the internet.

2. Summary of Significant Accounting Policies

Principles of Consolidation and Basis of Presentation. The consolidated financial statements include the accounts of OraSure Technologies, Inc. (OraSure) and its wholly-owned subsidiary, DNA Genotek, Inc. (DNAG). All intercompany transactions and balances have been eliminated. References herein to we, us, our, or the Company m OraSure and its consolidated subsidiaries, unless otherwise indicated.

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, 2013. Results of operations for the three and six months ended June 30, 2014 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 and foreign

currency 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 financial statements in those future periods.

Short-Term Investments. We consider all short-term investments to be available-for-sale securities. These securities are comprised of guaranteed investment certificates with purchased maturities greater than ninety days. Available-for-sale securities are carried at fair value, based upon quoted market prices, with unrealized gains and losses, if any, reported in stockholders equity as a component of accumulated other comprehensive loss.

Our available-for-sale securities as of June 30, 2014 consisted of guaranteed investment certificates with amortized cost and fair value of $4,437. As of December 31, 2013, we had no available-for-sale securities.

Fair Value of Financial Instruments. As of June 30, 2014, the carrying values of cash, short-term investments, 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 which are observable, either directly or indirectly, for substantially the full term of the asset or liability; and

Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

We offer a nonqualified deferred compensation plan for certain eligible employees and members of our Board of Directors. 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 and Company stock. The fair value of the plan assets as of June 30, 2014 and December 31, 2013 was $1,313 and $677, respectively, and was calculated using the quoted market prices of the assets as of those dates. All investments in the plan are classified as trading securities and measured as Level 1 instruments. The fair value of plan assets is included in other assets with the same amount included in other liabilities in the accompanying consolidated balance sheets.

All of our available-for-sale securities were classified and measured as Level 1 instruments as of June 30, 2014.

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

	June 30, 2014	December 31, 2013
Raw materials	$ 6,894	$ 6,700
Work in process	1,074	833
Finished goods	5,261	3,911
	$ 13,229	$ 11,444

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 consolidated statement of operations. Accumulated depreciation of property and equipment as of June 30, 2014 and December 31, 2013 was $29,843 and $28,390, respectively.

Intangible Assets. Intangible assets consist of the following:

	Amortization Period (Years)	June 30, 2014 Gross	Accumulated Amortization	Net
Customer list	10	$ 11,741	$ (3,250)	$ 8,491
Patents and product rights	3-10	10,449	(7,732)	2,717
Acquired technology	7	9,120	(3,551)	5,569
Tradename	15	4,500	(861)	3,639
Non-compete agreements	1-3	637	(610)	27
		$ 36,447	$ (16,004)	$ 20,443

	Amortization Period (Years)	December 31, 2013 Gross	Accumulated Amortization	Net
Customer list	10	$ 11,795	$ (2,701)	$ 9,094
Patents and product rights	3-10	10,449	(7,466)	2,983
Acquired technology	7	9,162	(2,952)	6,210
Tradename	15	4,521	(715)	3,806
Non-compete agreements	1-3	787	(654)	133
		$ 36,714	$ (14,488)	$ 22,226

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. Current U.S. generally accepted accounting principles permit us to 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 value of the applicable reporting unit with its aggregate carrying value, 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 their respective carrying values.

We performed our last annual impairment assessment as of July 31, 2013 utilizing a qualitative evaluation and concluded that it was more likely than not that the fair value of our DNAG reporting unit is greater than its carrying amount. We performed our last quantitative impairment test for goodwill as of July 31, 2012 and determined there was no impairment. That quantitative assessment determined that our DNAG reporting unit had a fair value in excess of its carrying value (including goodwill of $25,179) 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 continue to be performed annually in the fiscal third quarter, or sooner if a triggering event occurs. As of June 30, 2014, we believe no indicators of impairment exist.

The change in goodwill from $23,782 as of December 31, 2013 to $23,674 as of June 30, 2014 is 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. Other than for our OraQuick® In-Home HIV test, 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.

We began selling our OraQuick® In-Home HIV test in the third quarter of 2012. From launch through November 2013, our revenue recognition practices with respect to the OraQuick® In-Home HIV test were different than those customarily used in the consumer package goods industry. Under U.S. generally accepted accounting principles, product revenue cannot be recognized unless the amount of future returns can be reasonably estimated. Because our OraQuick® In-Home HIV test was a new product for which we did not have a historical record of returns, we did not believe we could reasonably determine a return rate. As a result, initially we did not recognize revenue when we shipped to the retail trade. For these product shipments, we invoiced the retailer or distributor, recorded deferred revenue at gross invoice sales price, and classified the cost basis of the product held by the retailer or distributor as a component of inventory. We then recognized revenue upon the consummation of a sale to the consumer either in a store or over the internet. With the passage of time, however, we concluded that we have sufficient data and visibility into our distribution channel to develop a reasonable estimate of the level of expected returns. As such, commencing in December 2013, we recognized previously deferred revenue and its related cost of goods sold, and began to recognize revenue for this product upon shipment to the retailers or distributors. Accordingly, revenues in the first half of 2014 were recorded based upon shipments into the distribution channel, while revenues in the first half of 2013 were recorded based upon the consummation of a sale to the consumer.

Our net revenues recorded on sales of the OraQuick® In-Home HIV test represent total gross revenues, less an allowance for expected returns, and customer allowances for cooperative advertising discounts, rebates, and chargebacks. All of these allowances are estimates established by management, based on currently available information and are adjusted to reflect known changes in the factors that impact those estimates. These allowances are recorded as a reduction of gross revenue when recognized in our statements of operations.

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.

On June 10, 2014, we entered into a Master Program Services and Co-Promotion Agreement with AbbVie Bahamas Ltd., a wholly-owned subsidiary of AbbVie Inc. (AbbVie), to co-promote our OraQuick® HCV Rapid Test in the United States. The product will be used to test individuals at-risk for the hepatitis C virus (HCV). We will be responsible for manufacturing and selling the product into all markets.

Under the agreement, we have granted exclusive promotion rights to AbbVie for the OraQuick® HCV test in certain markets and will provide certain additional services in support of HCV testing. In exchange for these exclusive rights and other services we will provide to AbbVie, we will receive up to $75,000 in payments over the term of the agreement, which runs through December 31, 2019. We plan to recognize the payments ratably on a monthly basis over the life of the agreement. In addition, if certain performance-based milestones are achieved, we will be eligible to receive additional payments annually ranging from $3,500 to $55,500 over the life of the agreement beginning in 2015. The agreement also contains certain termination, indemnification and other provisions, typical of agreements of this type. Payments received under this agreement will be recorded as licensing and product development revenue in our statements of operations.

Customer Sales Returns and Allowances. We do not grant return rights to our customers for any product, except for our OraQuick® In-Home HIV test. Accordingly, we have recorded an estimate of expected returns as a reduction of gross OraQuick® In-Home HIV product revenues in our consolidated statements of operations. This estimate reflects our historical sales experience to retailers and consumers, as well as other retail factors, and is reviewed regularly to ensure that it reflects potential product returns. As of June 30, 2014 and December 31, 2013, the reserve for sales returns and allowances was $363 and $279, respectively. If actual product returns differ materially from our reserve amount, or if a determination is made that this product s distribution would be discontinued in whole or in part by certain retailers, then we would need to adjust our reserve. Should the actual level of product returns vary significantly from our estimates, our operating and financial results could be materially affected.

Termination Settlement. On November 21, 2013, we terminated our assay collaboration agreement with Roche Diagnostics (Roche). Pursuant to this termination agreement, Roche paid us $8,300 which was recorded as a reduction of operating expense in our consolidated statement of operations for the year ended December 31, 2013. Roche agreed to provide certain transitional product support services to us and to continue to supply certain of the assays developed under the collaboration on a transitional basis for up to five years following the termination. We had the right to stop the supply of assays prior to the end of this five-year period and to receive an additional payment from Roche of up to $5,500 depending on how early in that five-year period the supply obligation was ended. During the second quarter of 2014, we issued our final purchase order for fully-automated assays previously developed under the terminated collaboration agreement and as such, have recorded $5,500 as a reduction of operating expense in our consolidated statement of operations and a receivable equal to the same amount in other current assets on our consolidated balance sheet. The $5,500 payment was made by Roche in July 2014.

Deferred Revenue. We record deferred revenue when funds are received prior to the recognition of the associated revenue. Deferred revenue at June 30, 2014 and December 31, 2013 included customer prepayments of $694 and $1,119, respectively.

Customer and Vendor Concentrations. One of our customers, Reckitt Benckiser, accounted for approximately 11% of our accounts receivable balance as of June 30, 2014. We had no significant concentrations in accounts receivable as of December 31, 2013. We had no significant concentrations (greater than 10%) in revenues for the three or six months ended June 30, 2014 or 2013.

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, we could be subject to increased costs and substantial delays in the delivery of our products to our customers. Also, our subsidiary, DNAG, uses two third-party suppliers to manufacture its products. Our inability to have a timely supply of any of these components and products could have a material adverse effect on our business, as well as our financial condition and results of operations.

Earnings (Loss) Per Share. Basic earnings (loss) per share is computed by dividing net income (loss) by the weighted-average number of shares of common stock outstanding during the period. Diluted earnings (loss) per share is computed in a manner similar to basic earnings (loss) per share except that the weighted average number of shares outstanding is increased to include incremental shares from the assumed vesting or exercise of dilutive securities, such as common stock options and unvested restricted stock, unless the impact is antidilutive. The number of incremental shares is calculated by assuming that outstanding stock options were exercised and unvested restricted shares were vested, and the proceeds from such exercises or vesting were used to acquire shares of common stock at the average market prices during the reporting period.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Net income (loss)	$ 2,529	$ (5,285)	$ (3,102)	$ (15,511)
Weighted average shares of common stock outstanding:				
Basic	55,907	55,559	55,846	55,504
Dilutive effect of stock options and restricted stock	1,336			
Diluted	57,243	55,559	55,846	55,504
Earnings (loss) per share:				
Basic	$ 0.05	$ (0.10)	$ (0.06)	$ (0.28)
Diluted	$ 0.04	$ (0.10)	$ (0.06)	$ (0.28)

For the three-month periods ended June 30, 2014 and 2013, outstanding common stock options and unvested restricted stock, representing 3,594 and 5,684 shares, respectively, were excluded from the computation of diluted earnings (loss) per share, as their inclusion would have been anti-dilutive. For the six months ended June 30, 2014 and 2013, outstanding common stock options and unvested restricted stock, representing 3,646 and 5,237 shares, respectively, were similarly excluded from the computation of diluted earnings (loss) per share.

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.

Accumulated 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 the Canadian dollar 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 $156 and $2,585 currency translation adjustments recorded in the first six months of 2014 and 2013, respectively, are largely the result of the translation of our Canadian operation s balance sheets into U.S. dollars.

Recent Accounting Pronouncements. In May 2014, the Financial Accounting Standards Board (FASB) issued converged guidance on recognizing revenue in contracts with customers, ASU 2014-09 *Revenue from Contracts with Customers*. The intent of the new standard is to improve financial reporting and comparability of revenue globally. The core principle of the standard is for a company to recognize revenue in a manner that depicts the transfer of goods or services to customers in an amount that reflects the consideration which the company expects to receive in exchange for those goods or services. The standard will be effective for the first interim period within annual reporting periods beginning after December 15, 2016, with no early adoption permitted. We will evaluate the effects, if any,

which adoption of this guidance will have on our consolidated financial statements.

3. 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 Stock 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 and restricted stock 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 six months ended June 30, 2014 and 2013 was $1,499 and $1,363, respectively. Net cash proceeds from the exercise of stock options were $202 and $301 for the six months ended June 30, 2014 and 2013, respectively. As a result of the Company s net operating loss carryforward position, no actual income tax benefit was realized from stock option exercises during these periods.

Compensation cost of $1,370 and $1,472 related to restricted shares was recognized during the six months ended June 30, 2014 and 2013, respectively. In connection with the vesting of restricted shares, during the six months ended June 30, 2014 and 2013, 106 and 120 shares, respectively, with aggregate values of $639 and $801, respectively, were withheld and retired in satisfaction of minimum tax withholding obligations.

4. Accrued Expenses

	June 30, 2014	December 31, 2013
Payroll and related benefits	$ 4,395	$ 5,827
Royalties	2,163	4,374
Professional fees	1,043	749
Other	1,765	2,082
	$ 9,366	$ 13,032

5. Income Taxes

During the three and six months ended June 30, 2014, we recorded foreign deferred tax benefits of $174 and $43, respectively. During the three and six months ended June 30, 2013, we recorded foreign deferred tax benefits of $249 and $659, respectively. The foreign deferred tax benefits are associated with certain Canadian research and development and investment tax credits and DNAG s loss before income taxes. The income tax benefits associated with DNAG are 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 and tax purposes, and net operating loss and tax credit carryforwards. The significant components of our total deferred tax liability as of June 30, 2014 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 June 30, 2014 and December 31, 2013 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 six month periods ended June 30, 2014 and 2013.

6. Commitments and Contingencies

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

7. Business Segment Information

We operate our business within two reportable segments: our OSUR 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. OSUR revenues are derived primarily from products sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations, public health organizations, distributors, government agencies, physicians offices, and commercial and industrial entities. Revenues from OSUR s OTC products result from sales to retail pharmacies and mass merchandisers, and to consumers over the internet. OSUR also derives revenues from licensing and product development activities. DNAG revenues result primarily from products sold into the commercial market which consists of companies and other entities engaged in consumer genetics, clinical genetic testing, pharmacogenomics, personalized medicine, and animal and livestock genetic testing. DNAG products are also sold into the academic research market, which consists of research laboratories, universities and hospitals.

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 income (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 six months ended June 30, 2014 and 2013:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Net revenues:				
OSUR	$ 21,505	$ 19,683	$ 39,283	$ 36,915
DNAG	4,896	4,654	10,655	8,586
Total	$ 26,401	$ 24,337	$ 49,938	$ 45,501
Operating income (loss):				
OSUR	$ 2,203	$ (5,456)	$ (4,190)	$ (15,496)
DNAG	294	(120)	1,069	(669)
Total	$ 2,497	$ (5,576)	$ (3,121)	$ (16,165)
Depreciation and amortization:				
OSUR	$ 790	$ 797	$ 1,566	$ 1,574
DNAG	779	822	1,542	1,647
Total	$ 1,569	$ 1,619	$ 3,108	$ 3,221
Capital expenditures:				
OSUR	$ 1,131	$ 484	$ 1,570	$ 727
DNAG	210	128	418	365
Total	$ 1,341	$ 612	$ 1,988	$ 1,092

	June 30, 2014	December 31, 2013
Total assets:		
OSUR	$ 125,845	$ 130,848
DNAG	53,720	53,397
Total	$ 179,565	$ 184,245

Our products are sold principally in the United States and Europe.

The following table represents total revenues by geographic area, based on the location of the customer:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
United States	$ 19,113	$ 18,959	$ 36,518	$ 34,999
Europe	3,681	2,438	7,682	5,284
Other regions	3,607	2,940	5,738	5,218

$ 26,401	$ 24,337	$ 49,938	$ 45,501

The following table represents total long-lived assets by geographic area:

	June 30, 2014	December 31, 2013
United States	$ 17,205	$ 16,925
Canada	1,244	975
Other regions	22	33
	$ 18,471	$ 17,933

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 our 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; ability to effectively resolve warning letters, audit observations and other findings or comments from the FDA or other regulators; 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; our ability to achieve financial and performance objectives under the HCV collaboration with AbbVie; failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our products; impact of replacing distributors; inventory levels at distributors and other customers; ability of DNA Genotek to achieve its financial and strategic objectives and continue to increase its revenues; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; impact of negative economic conditions, 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 or other factors, including changes in Centers for Disease Control and Prevention (CDC) or other testing guidelines, algorithms or other recommendations; 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 OraSure s 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 attract and 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, 2013, 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 develop, manufacture, market and sell oral fluid diagnostic products and specimen collection devices using our proprietary oral fluid technologies, as well as other diagnostic products including immunoassays and other *in vitro* diagnostic tests that are used on other specimen types. 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. We sell the OraQuick® In-Home HIV test, the first and only rapid point-of-care HIV test approved for use in the domestic consumer retail market. We also manufacture and sell oral fluid collection devices used to collect, stabilize, and store samples of genetic material for molecular testing in the clinical genetic testing, academic research, pharmacogenomics, personalized medicine, and animal genetics markets. Lastly, we manufacture and sell medical devices used for the removal of benign skin lesions by cryosurgery, or freezing. Our products are sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, research and academic institutions, distributors, government agencies, physicians offices, and commercial and industrial entities. Our over-the-counter (OTC) HIV and cryosurgery products are sold to retail pharmacies and mass merchandisers, and our OTC HIV product is also sold to consumers over the internet.

Recent Developments

HCV Co-Promotion Agreement

On June 10, 2014, we entered into a Master Program Services and Co-Promotion Agreement with AbbVie Bahamas Ltd., a wholly-owned subsidiary of AbbVie Inc. (AbbVie), to co-promote our OraQuick® HCV Rapid Test in the United States. The product will be used to test individuals at-risk for the hepatitis C virus (HCV). We will be responsible for manufacturing and selling the product into all markets.

Under the agreement, we have granted exclusive promotion rights to AbbVie for the OraQuick® HCV test in certain markets and will provide certain additional services in support of HCV testing. In exchange for these exclusive rights and other services we will provide to AbbVie, we will receive up to $75.0 million in aggregate payments over the term of the agreement, which runs through December 31, 2019. We plan to recognize the payments ratably on a monthly basis over the life of the agreement. As of June 30, 2014, we recognized $775,000 in revenues from payments due from AbbVie. The first $15.0 million payment was received in July 2014. In addition, if certain performance-based milestones are achieved, we will be eligible to receive additional payments annually ranging from $3.5 to $55.5 million over the life of the agreement beginning in 2015. The agreement also contains certain termination, indemnification and other provisions typical of agreements of this type. Payments received under this agreement will be recorded as licensing and product development revenue in our statements of operations.

Drugs-of-Abuse Assay Collaboration Agreements

We continue to make progress under our agreement with Thermo Fisher Scientific (Thermo Fisher) to develop and supply homogenous fully-automated oral fluid drugs of abuse assays to be used with a new version of our Intercept® oral fluid specimen collection device. As a result of this progress, in late June 2014 we issued our final purchase order for fully-automated assays previously developed under our now terminated collaboration agreement with Roche Diagnostics (Roche). Under the terms of the termination of our Roche collaboration, we received $5.5 million as a result of the submission of our final purchase order. This payment was recorded as a receivable on our balance sheet and as a reduction of operating expense on our consolidated statement of operations for the second quarter. The $5.5 million payment was received in July 2014.

Current Consolidated Financial Results

During the six months ended June 30, 2014, our consolidated net revenues were $49.9 million compared to $45.5 million in the six months ended June 30, 2013. Net product revenues during the six months ended June 30, 2014 increased 9% when compared to the first six months of 2013, primarily due to higher sales of our OraQuick® HCV, Oragene®, and cryosurgical systems products. Licensing and product development revenues for the first six months of 2014 increased 63% due to the recognition of $775,000 in exclusivity payments from AbbVie. Licensing and product development revenues for the first six months of 2013 represent royalties related to sales of Merck s OTC cryosurgical wart removal product.

Our consolidated net loss for the six months ended June 30, 2014 was $3.1 million, or $0.06 per share, compared to a net loss of $15.5 million, or $0.28 per share, for the six months ended June 30, 2013. Results for the six months end June 30, 2014 include the $5.5 million payment received pursuant to the termination of our collaboration agreement with Roche.

Cash used in operating activities for the six months ended June 30, 2014 was $10.4 million, compared to $9.3 million used during the six months ended June 30, 2013. As of June 30, 2014, we had $80.3 million in cash and short-term investments compared to $93.2 million at December 31, 2013.

Economic Outlook

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, these circumstances could adversely affect our access to liquidity that may be needed to conduct or expand our business, conduct future acquisitions or make other discretionary investments.

In 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, certain automatic cuts to discretionary, national defense and Medicare spending (often referred to as Federal sequestration) have become effective. 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 of sequestration is difficult to ascertain, the spending cuts implemented under this new law have adversely affected, and are expected to continue to adversely affect, our customers ability to purchase our products. In addition, other legislative or regulatory changes may be adopted which could adversely affect our ability to sell our current products or successfully develop and commercialize new products**.**

Business Segments

We operate our business within two reportable segments: our OSUR 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 primarily 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. OSUR revenues are derived primarily from products sold into the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations, public health organizations, distributors, government agencies, physicians offices, and commercial and industrial entities. Revenues from OSUR s OTC products result from sales to retail pharmacies and mass merchandisers and to consumers over the internet. DNAG revenues result primarily from products sold into the commercial market, which consists of companies and other entities engaged in consumer genetics, clinical genetic testing, pharmacogenomics, personalized medicine, and animal genetic testing, as well as products sold into the academic research market which consists of research laboratories, universities and hospitals.

Results of Operations

Three months ended June 30, 2014 compared to June 30, 2013

CONSOLIDATED NET REVENUES

The table below shows the amount of total net product revenues (dollars in thousands) generated by each of our business segments and net revenues from licensing and product development activities for the three months ended June 30, 2014 and 2013.

	Three Months Ended June 30,				
	Dollars		%	Percentage of Total Net Revenues	
	2014	2013	Change	2014	2013
OSUR	$ 20,730	$ 19,409	7%	78%	80%
DNAG	4,896	4,654	5	19	19
Net product revenues	25,626	24,063	6	97	99
Licensing and product development	775	274	183	3	1
Net revenues	$ 26,401	$ 24,337	8%	100%	100%

Consolidated net revenues increased 8% to $26.4 million in the second quarter of 2014 from $24.3 million in the comparable period of 2013, primarily as a result of higher sales of our OraQuick® HCV, cryosurgical systems, and molecular collection systems products. These increases were partially offset by lower domestic sales of our OraQuick® professional HIV product, OraQuick® In-Home HIV test and insurance risk assessment products. Licensing and product development revenues increased to $775,000 in the second quarter of 2014 from $274,000 in the second quarter of 2013. Licensing and product development revenues for the current quarter represent the recognition of payments from AbbVie for exclusive promotion rights and certain services we will provide under our HCV collaboration, while second quarter 2013 licensing and product development revenues represent royalties received on sales of Merck s OTC cryosurgical wart removal product.

Consolidated net revenues derived from products sold to customers outside the U.S. were $7.3 million and $5.4 million, or 28% and 22% of total net revenues, in the second quarters of 2014 and 2013, 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 total net revenues.

Net Revenues by Segment

OSUR Segment

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

	Three Months Ended June 30,				
	Dollars		%	Percentage of Total Net Revenues	
Market	2014	2013	Change	2014	2013
Infectious disease testing	$ 12,668	$ 11,966	6%	59%	61%
Substance abuse testing	2,208	2,113	4	10	11

Cryosurgical systems	4,920	4,177	18	23	21
Insurance risk assessment	934	1,153	(19)	4	6
Net product revenues	20,730	19,409	7	96	99
Licensing and product development	775	274	183	4	1
Net revenues	$ 21,505	$ 19,683	9%	100%	100%

Infectious Disease Testing Market

Sales to the infectious disease testing market increased 6% to $12.7 million in the second quarter of 2014 from $12.0 million in the second quarter of 2013, primarily due to higher sales of our OraQuick® HCV test in both domestic and international markets and our OraQuick® professional HIV product in the international market.

The table below shows a breakdown of our total net OraQuick® revenues (dollars in thousands) during the second quarters of 2014 and 2013.

	Three Months Ended June 30,		
Market	**2014**	**2013**	**% Change**
Domestic HIV	$ 7,720	$ 8,088	(5)%
International HIV	848	745	14
Domestic OTC HIV	1,669	1,993	(16)
Net HIV revenues	10,237	10,826	(5)
Domestic HCV	1,221	690	77
International HCV	974	247	294
Net HCV revenues	2,195	937	134
Net OraQuick® revenues	$ 12,432	$ 11,763	6%

Domestic OraQuick® HIV sales decreased 5% to $7.7 million for the three months ended June 30, 2014 from $8.1 million for the three months ended June 30, 2013. This decrease was primarily the result of some customer migration to automated 4th generation immunoassay HIV tests performed in a laboratory as recommended under new testing guidelines issued by the CDC. Also contributing to the lower domestic OraQuick® HIV sales were changes in customer ordering patterns. We anticipate that future sales of our professional HIV product will continue to be negatively affected as a result of the CDC s recommended use of automated laboratory-based blood tests and by reductions in government funding. International sales of our OraQuick® HIV test during the second quarter of 2014 increased 14% to $848,000 from $745,000 primarily due to sales in support of a significant African testing program.

During the second quarter of 2014, we recorded $1.9 million in gross revenues from sales of our OraQuick® In-Home HIV test. These revenues were partially offset by $196,000 in customer allowances, including cooperative advertising, cash discounts, and other allowances, which were netted against gross revenues in accordance with U.S. generally accepted accounting principles. Thus, net revenues from this product were $1.7 million for the second quarter of 2014 as compared to net revenues of $2.0 million in the second quarter of 2013 ($2.1 million in gross revenues, partially offset by $133,000 of allowances and discounts).

OraQuick® In-Home HIV revenues recorded in the current and prior year periods are not readily comparable due to the December 2013 change in our revenue recognition policy related to this product. Since the product launch in late 2012, revenues had been recognized upon consummation of a purchase by consumers either in a store or over the internet. In December 2013, as a result of our growing experience with this product and improved ability to estimate potential product returns, we began recognizing revenues upon shipment of product to the retailers or distributors. Based on available point-of-sale data, consumer purchases declined 1% in the second quarter of 2014 as compared to the second quarter of 2013 which we believe was due to a decrease in broad-based media advertising.

Sales of our OraQuick® In-Home HIV test in both the second quarter of 2014 and 2013 included approximately $67,000 and $255,000, respectively, of direct sales to public health customers. We anticipate that some public health entities may choose to use a portion of their funding to purchase our OTC product in lieu of professional rapid HIV testing products.

Domestic OraQuick® HCV sales increased 77% to $1.2 million in the second quarter of 2014 from $690,000 in the second quarter of 2013, primarily due to the addition of new HCV customers and higher sales to current customers who have expanded their HCV testing programs. International OraQuick® HCV sales increased 294% to $974,000 in the second quarter of 2014 from $247,000 in the second quarter of 2013, primarily as a result of purchases by a multi-national humanitarian organization that did not purchase product during the second quarter of 2013. We expect that purchases by this customer will be at a reduced rate over the balance of the year.

We believe our HCV product represents an opportunity for future sales growth, especially as new therapies for treating HCV come to market. We also expect that sales of our HCV product will be positively impacted as we implement our HCV collaboration with AbbVie. However, demand for our HCV product, particularly in the public health marketplace, 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**.**

International orders for both our HIV and HCV products can be sporadic in nature and are often predicated upon the availability of governmental funding, the impact of competition and other factors. As such, there is no assurance that such sales will continue at the same levels in future periods.

Substance Abuse Testing Market

Sales to the substance abuse testing market increased 4% to $2.2 million in the second quarter of 2014 from $2.1 million in the second quarter of 2013, primarily as a result of higher sales of our Intercept® drug testing system. The table below shows a breakdown of our total net Intercept® revenues (dollars in thousands) generated in each market during the second quarters of 2014 and 2013.

	Three Months Ended June 30,		
Market	**2014**	**2013**	**% Change**
Domestic	$ 1,616	$ 1,342	20%
International	33	98	(66)
Net Intercept® revenues	$ 1,649	$ 1,440	15%

Domestic Intercept® sales for the second quarter of 2014 increased to $1.6 million compared to $1.3 million for the second quarter of 2013 largely due to the recovery of customers that were previously lost to competition. International Intercept® sales decreased 66% to $33,000 in the second quarter of 2014 from $98,000 in 2013 largely due the discontinuance of purchases by our UK distributor who in 2012 began selling its own competing oral specimen collection device. Sales to this distributor were $46,000 in the second quarter of 2013.

Cryosurgical Systems Market

Sales of our cryosurgical systems products (which includes both the physicians office and OTC markets) increased 18% to $4.9 million in the second quarter of 2014, compared to $4.2 million in the same period of the prior year.

The table below shows a breakdown of our total net cryosurgical systems revenues (dollars in thousands) generated in each market during the second quarters of 2014 and 2013.

	Three Months Ended June 30,		
Market	**2014**	**2013**	**% Change**
Domestic professional	$ 1,469	$ 1,497	(2)%
International professional	229	257	(11)
International OTC	3,222	2,423	33
Net cryosurgical systems revenues	$ 4,920	$ 4,177	18%

Sales of our Histofreezer® product to physicians offices in the United States remained relatively flat at $1.5 million in both the second quarters of 2014 and 2013. International sales of Histofreezer® decreased slightly to $229,000, compared to $257,000 in the same period of the prior year. Our long-term supply agreement for the Histofreezer® product with Koninklijke Utermöhlen, N.V., the party from whom we acquired the Histofreezer® business in 1998, terminated in late 2013, and Utermöhlen has indicated that it plans to sell a competing product similar to Histofreezer®. If Utermöhlen is successful in commercializing this product, we believe sales of our Histofreezer® product could be negatively impacted.

Sales of our OTC cryosurgical products during the second quarter of 2014 increased 33% to $3.2 million compared to $2.4 million in the second quarter of 2013, largely due to higher sales to both our European distributor, Reckitt Benckiser, and our Latin American distributor, Genomma.

Current quarter sales to Reckitt Benckiser increased to $1.7 million, compared to $1.2 million during the second quarter of 2013, primarily due to the launch of our product into new geographic territories and continued market penetration. Sales to Genomma increased to $1.5 million in the second quarter of 2014 from $1.2 million in the second quarter of 2013 due to customer ordering patterns.

Insurance Risk Assessment Market

Sales to the insurance risk assessment market decreased 19% to $934,000 in the second quarter of 2014 from $1.2 million in the second quarter of 2013, as a result of continued reduced demand in the domestic life insurance market, as well as the adoption by some underwriters of a Simplified Issues policy, pursuant to which testing for risk factors is replaced by having applicants respond to a questionnaire about their behaviors.

Licensing and Product Development

Licensing and product development revenues increased to $775,000 in the second quarter of 2014 from $274,000 in the second quarter of 2013. Licensing and product development revenues in the second quarter of 2014 represent the recognition of payments from AbbVie for exclusive promotion rights and certain services we will provide under our HCV collaboration. The first such payment of $15.0 million as required by the agreement was received in July 2014. Licensing and product development revenues in the second quarter of 2013 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. We stopped receiving royalties under this license when certain of our cryosurgical patents expired in August 2013.

DNAG Segment

Molecular Collection Systems

Net molecular collection systems revenues, which primarily represent sales of our Oragene® product line, increased 5% to $4.9 million in the second quarter of 2014 from $4.7 million in the second quarter of 2013. Sales of Oragene® in the commercial market remained flat at $2.8 million in both periods. Revenues in the second quarter of 2014 did not include any sales to DNAG s largest commercial customer, whereas revenues in the second quarter of 2013 included approximately $1.7 million in sales to this customer. Sales of Oragene® in the academic market increased 12% largely due to the timing of orders placed by our distributors and studies performed by several larger academic customers.

CONSOLIDATED OPERATING RESULTS

Consolidated gross margin was 61% for the second quarter of 2014 compared to 60% for the second quarter of 2013. Gross margin for the current quarter primarily benefited from a more favorable product mix driven largely by increased DNAG sales to higher margin customers.

Consolidated operating income for the second quarter of 2014 was $2.5 million, an $8.1 million improvement from the $5.6 million operating loss reported in the second quarter of 2013. The second quarter 2014 operating income was primarily the result of the $5.5 million payment received under the terms of the termination of our drug assay collaboration with Roche. Also contributing to this improvement in operating performance were increased revenues and lower HIV OTC marketing costs during the current quarter.

OPERATING INCOME (LOSS) BY SEGMENT

OSUR Segment

OSUR s gross margin was 58% in the second quarter of 2014 compared to 59% in the second quarter of 2013. OSUR s 2014 margin was negatively impacted by less efficient manufacturing, a shift in product mix to sales of product with lower gross margin partially offset by higher licensing and product development revenues.

Research and development expenses increased slightly to $2.1 million in the second quarter of 2014 from $2.0 million in the second quarter of 2013 largely due to higher supply costs. Sales and marketing expenses decreased 21% to $8.4 million in the second quarter of 2014 from $10.7 million in the second quarter of 2013. This decrease was primarily the result of lower advertising and promotional costs for our OraQuick® In-Home HIV test which totaled $3.0 million in the second quarter of 2014, compared to $5.4 million in second quarter of 2013. This reduction was the result of our decision to focus our marketing and promotional efforts at the retail outlet level and transition away from broad-based consumer advertising by the end of the second quarter of 2014. General and administrative expenses increased 21% to $5.2 million in the second quarter of 2014 from $4.3 million in the second quarter of 2013 due to higher legal expenses, staffing related costs and consulting costs.

All of the above, along with the $5.5 million payment from Roche, contributed to OSUR s second quarter 2014 operating income of $2.2 million, which included non-cash charges of $790,000 for depreciation and amortization and $1.4 million for stock-based compensation.

DNAG Segment

DNAG s gross margin was 72% in the second quarter of 2014 compared to 62% in the second quarter of 2013. This increase was directly attributable to an increased volume of high margin sales experienced in the second quarter of 2014 when compared to the second quarter of 2013.

DNAG operating expenses increased to $3.3 million in the second quarter of 2014 from $3.0 million in the second quarter of 2013. Research and development expenses remained relatively flat at $623,000 in the second quarter of 2014 compared to $655,000 in the second quarter of 2013. Sales and marketing expenses increased 12% to $1.9 million in the second quarter of 2014 from $1.7 million in the second quarter of 2013 due to higher staffing costs. General and administrative expenses increased to $761,000 in the second quarter of 2014 compared to $704,000 in the second quarter of 2013, also due to higher staffing costs.

All of the above contributed to DNAG s second quarter 2014 operating income of $294,000, which included non-cash charges of $779,000 for depreciation and amortization and $109,000 for stock-based compensation.

CONSOLIDATED INCOME TAXES

We continue to believe the full valuation allowance established in 2008 against OSUR s total U.S. 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 expense or benefit was recorded for OSUR s pre-tax income or loss in the second quarter of 2014 or 2013, respectively. A Canadian income tax benefit of $174,000 and $249,000 was recorded in the second quarter of 2014 and 2013, respectively, which was associated with certain Canadian research and development and investment tax credits and DNAG s loss before income taxes. The Canadian income tax benefits are considered realizable based upon the scheduled reversal of the deferred tax liabilities recorded in connection with the acquisition of DNAG.

Six months ended June 30, 2014 compared to June 30, 2013

CONSOLIDATED NET REVENUES

The table below shows the amount of total net product revenues (dollars in thousands) generated by each of our business segments and net revenues from licensing and product development activities for the six months ended June 30, 2014 and 2013.

	Six Months Ended June 30,				
	Dollars		%	Percentage of Total Net Revenues	
	2014	2013	Change	2014	2013
OSUR	$ 38,508	$ 36,439	6%	77%	80%
DNAG	10,655	8,586	24	21	19
Net product revenues	49,163	45,025	9	98	99
Licensing and product development	775	476	63	2	1
Net revenues	$ 49,938	$ 45,501	10%	100%	100%

Consolidated net revenues increased 10% to $49.9 million in the first half of 2014 from $45.5 million in the comparable period of 2013, primarily as a result of higher sales of our OraQuick® HCV, molecular collection systems products, and cryosurgical systems products. These increases were partially offset by lower sales of our OraQuick® professional product in the domestic market and lower substance abuse and insurance risk assessment product sales. Licensing and product development revenues increased to $775,000 in the first six months of 2014 from $476,000 in the first six months of 2013. Licensing and product development revenues for the current six-month period represent the recognition of payments from AbbVie for exclusive promotion rights and certain services we will provide under our HCV collaboration, while 2013 licensing and product development revenues represent royalties received on sales of Merck s OTC cryosurgical wart removal product.

Consolidated net revenues derived from products sold to customers outside the U.S. were $13.4 million and $10.5 million, or 27% and 23% of total net revenues, during the six months ended June 30, 2014 and 2013, 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 total net revenues.

Net Revenues by Segment

OSUR Segment

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

	Six Months Ended June 30,				
	Dollars			Percentage of Total Net Revenues	
Market	**2014**	**2013**	**%**	**2014**	**2013**
Infectious disease testing	$ 23,732	$ 22,654	5%	60%	61%
Substance abuse testing	4,038	4,362	(7)	10	12
Cryosurgical systems	8,887	7,261	22	23	20
Insurance risk assessment	1,851	2,162	(14)	5	6
Net product revenues	38,508	36,439	6%	98	99%
Licensing and product development	775	476	63	2	1
Net revenues	$ 39,283	$ 36,915	6%	100%	100%

Infectious Disease Testing Market

Sales to the infectious disease testing market increased 5% to $23.7 million in the first half of 2014 from $22.7 million in the first half of 2013, primarily due to higher sales of our OraQuick® HCV product and OraQuick® In-Home HIV test and higher sales of our OraQuick® professional HIV product in the international market.

The table below shows a breakdown of our total net OraQuick® revenues (dollars in thousands) during the six months ended June 30, 2014 and 2013.

	Six Months Ended June 30,		
			%
Market	**2014**	**2013**	**Change**
Domestic HIV	$ 14,339	$ 15,761	(9)%
International HIV	1,405	1,300	8
Domestic OTC HIV	3,622	3,435	5
Net HIV revenues	19,366	20,496	(6)
Domestic HCV	1,884	1,119	68
International HCV	1,870	486	285
Net HCV revenues	3,754	1,605	134
Net OraQuick® revenues	$ 23,120	$ 22,101	5%

Domestic OraQuick® HIV sales decreased 9% to $14.3 million for the six months ended June 30, 2014 from $15.8 million for the six months ended June 30, 2013. This decrease was primarily caused by our customers migration to automated 4th generation immunoassay HIV tests performed in a laboratory as recommended under new CDC testing guidelines. Also contributing to the lower domestic OraQuick® HIV sales were changes in customer ordering patterns. We anticipate that future sales of our professional HIV product will continue to be negatively affected as a result of the CDC s recommended use of automated laboratory-based blood tests and by reductions in government funding. International sales of our OraQuick® HIV test during the first half of 2014 increased slightly to $1.4 million from $1.3 million in the first half of 2013.

During the first half of 2014, we recorded $4.0 million in gross revenues from sales of our OraQuick® In-Home HIV test. These revenues were partially offset by $407,000 in customer allowances, including cooperative advertising, cash discounts, and other allowances, which were netted against gross revenues in accordance with U.S. generally accepted accounting principles. Thus, net revenues from this product were $3.6 million for the first half of 2014 as compared to net revenues of $3.4 million in the first half of 2013 ($3.7 million in gross revenues, partially offset by $242,000 of allowances and discounts).

OraQuick® In-Home HIV revenues recorded in the current and prior year periods are not readily comparable due to the December 2013 change in our revenue recognition policy related to this product. Since the product launch in late 2012, revenues had been recognized upon consummation of a purchase by consumers either in a store or over the internet. In December 2013, as a result of our growing experience with this product and improved ability to estimate potential product returns, we began recognizing revenues upon shipment of product to the retailers or distributors. Based on available point-of-sale data, consumer purchases increased 9% in the first half of 2014 as compared to the first half of 2013 due to increased awareness about the product.

Sales of our OraQuick® In-Home HIV test in both the first six months of 2014 and 2013 included approximately $250,000 and $383,000, respectively, of direct sales to public health customers. We anticipate that some public health entities may choose to use a portion of their funding to purchase our OTC product in lieu of professional rapid HIV testing products.

Domestic OraQuick® HCV sales increased 68% to $1.9 million in the first half of 2014 from $1.1 million in the first half of 2013, primarily due to the addition of new HCV customers and higher sales to current customers who have expanded their HCV testing programs. International OraQuick® HCV sales increased 285% to $1.9 million in the first half of 2014 from $486,000 in the first half of 2013, primarily as a result of purchases by a multi-national humanitarian organization which did not purchase product during the first six months of 2013. We expect that purchases by this customer will be at a reduced rate over the balance of the year.

We believe our HCV product represents an opportunity for future sales growth, especially as new therapies for treating HCV come to market. We also expect that sales of our HCV product will be positively impacted as we implement our HCV collaboration with AbbVie. However, demand for our HCV product, particularly in the public health marketplace, 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.

International orders for both our HIV and HCV products can be sporadic in nature and are often predicated upon the availability of governmental funding, the impact of competition and other factors. As such, there is no assurance that such sales will continue at the same levels in future periods.

Substance Abuse Testing Market

Sales to the substance abuse testing market decreased 7% to $4.0 million in the first six months of 2014 from $4.4 million in the first six months of 2013, primarily as a result of lower sales of our Intercept® drug testing system. The table below shows a breakdown of our total net Intercept® revenues (dollars in thousands) generated in each market during the six months ended June 30, 2014 and 2013.

	Six Months Ended June 30,		
Market	**2014**	**2013**	**% Change**
Domestic	$ 2,866	$ 2,745	4%
International	73	356	(79)
Net Intercept® revenues	$ 2,939	$ 3,101	(5)%

Domestic Intercept® sales for the first six months of 2014 decreased to $2.9 million compared to $3.1 million for the first six months of 2013, primarily because of lower international sales. International Intercept® sales decreased 79% to $73,000 in the first half of 2014 from $356,000 in 2013 largely due the discontinuance of purchases by our UK

distributor who in 2012 began selling its own competing oral specimen collection device. Sales to this distributor were $283,000 in the first half of 2013.

Cryosurgical Systems Market

Sales of our cryosurgical systems products (which includes both the physicians office and OTC markets) increased 22% to $8.9 million in the first half of 2014, compared to $7.3 million in the same period of the prior year.

The table below shows a breakdown of our total net cryosurgical systems revenues (dollars in thousands) generated in each market during the six months ended June 30, 2014 and 2013.

	Six Months Ended June 30,		
Market	**2014**	**2013**	**% Change**
Domestic professional	$ 3,011	$ 2,388	26%
International professional	538	605	(11)
International OTC	5,338	4,268	25
Net cryosurgical systems revenues	$ 8,887	$ 7,261	22%

Sales of our Histofreezer® product to physicians offices in the United States increased 26% to $3.0 million in the first half of 2014, compared to $2.4 million in the first half of 2013. This increase reflects below normal sales in the early months of 2013, resulting from higher distributor purchases in the fourth quarter of 2012 in advance of a price increase implemented in January 2013. During the first half of 2014, international sales of Histofreezer® decreased slightly to $538,000, compared to $605,000 in the same period of the prior year. Our long-term supply agreement for the Histofreezer® product with Koninklijke Utermöhlen, N.V., the party from whom we acquired the Histofreezer® business in 1998, terminated in late 2013, and Utermöhlen has indicated that it plans to sell a competing product similar to Histofreezer®. If Utermöhlen is successful in commercializing this product, we believe sales of our Histofreezer® product could be negatively impacted.

Sales of our OTC cryosurgical products during the first six months of 2014 increased 25% to $5.3 million compared to $4.3 million in the first six months of 2013, largely due to higher sales to both our European distributor, Reckitt Benckiser, and our Latin American distributor, Genomma.

Sales to Reckitt Benckiser increased to $3.0 million, compared to $2.2 during the first half of 2013, primarily due to the launch of our product into new geographic territories and new market segments. Sales to Genomma increased to $2.2 million in the first half of 2014 from $1.9 million in the first half of 2013 due to customer ordering patterns.

Insurance Risk Assessment Market

Sales to the insurance risk assessment market decreased 14% to $1.9 million in the first six months of 2014 from $2.2 million in the first six months of 2013, as a result of continued reduced demand in the domestic life insurance market, as well as the adoption by some underwriters of a Simplified Issues policy, pursuant to which testing for risk factors is replaced by having applicants respond to a questionnaire about their behaviors.

Licensing and Product Development

Licensing and product development revenues increased to $775,000 in the first half of 2014 from $476,000 in the first half of 2013. Licensing and product development revenues in 2014 represent the recognition of payments from AbbVie for exclusive promotion rights and certain services we will provide under our HCV collaboration. The first such payment of $15.0 million as required by the agreement was received in July 2014. Licensing and product development revenues in 2013 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. We stopped receiving royalties under this license when certain of our cryosurgical patents expired in August 2013.

DNAG Segment

Molecular Collection Systems

Net molecular collection systems revenues, which primarily represent sales of our Oragene® product line, increased 24% to $10.7 million in the first six months of 2014 from $8.6 million in the first six months of 2013. Sales of Oragene® in the commercial market increased approximately 31% in the first half of 2014 primarily as a result of the ordering patterns of a few of our larger commercial customers. Revenues in the first half of 2014 included approximately $1.3 million in sales to DNAG s largest commercial customer while revenues in the first half of 2013 included approximately $2.4 million in sales to this customer. Sales of Oragene® in the academic market increased 21% largely due to the timing of orders placed by our distributors and studies performed by several larger academic customers.

CONSOLIDATED OPERATING RESULTS

Consolidated gross margin was 60% for the first half of 2014 compared to 58% for the first half of 2013. Gross margin for the current period primarily benefited from a more favorable product mix driven largely by increased DNAG sales to higher margin customers.

Consolidated operating loss for the first half of 2014 was $3.1 million, a $13.1 million improvement from the $16.2 million operating loss reported in the first half of 2013. The current period operating results include the $5.5 million payment received under the terms of the termination of our drug assay collaboration with Roche. Also contributing to this improvement in operating loss were higher revenues and lower HIV OTC sales and marketing costs during the first six months of 2014.

OPERATING INCOME (LOSS) BY SEGMENT

OSUR Segment

OSUR s gross margin was 57% in both the first half of 2014 and 2013.

Research and development expenses decreased 17% to $4.0 million in the first half of 2014 from $4.8 million in the first half of 2013 largely due to lower clinical trial and staffing costs. Sales and marketing expenses decreased 21% to $17.9 million in the first half of 2014 from $22.8 million in the first half of 2013. This decrease was primarily the result of lower advertising and promotional costs for our OraQuick® In-Home HIV test which totaled $7.6 million in the first half of 2014, compared to $12.3 million in the first half of 2013. This reduction was the result of our decision to focus our marketing and promotional efforts at the retail outlet level and transition away from broad-based consumer advertising by the end of the first half of 2014. General and administrative expenses increased 13% to $10.1 million in the first half of 2014 from $8.9 million in the first half of 2013 due to higher legal expenses, staffing related costs and consulting costs.

All of the above, along with the $5.5 million payment from Roche, contributed to OSUR s operating loss of $4.2 for the first half of 2014, million, which included non-cash charges of $1.6 million for depreciation and amortization and $2.7 million for stock-based compensation.

DNAG Segment

DNAG s gross margin was 72% in the first half of 2014 compared to 65% in the first half of 2013. This increase was directly attributable to an increased volume of high margin sales experienced in the first half of 2014 when compared to the first half of 2013.

DNAG operating expenses increased to $6.6 million in the first half of 2014 from $6.2 million in the first half of 2013. Research and development expenses remained relatively flat at $1.3 million in the first half of 2014 and 2013. Sales and marketing expenses increased 6% to $3.7 million in the first half of 2014 from $3.5 million in the first half of 2013 largely due to higher staffing costs. General and administrative expenses increased 7% to $1.6 million in the first half of 2014 from $1.5 million in the first half of 2013 also due to higher staffing expenses.

All of the above contributed to DNAG s operating income of $1.1 million for the first half of 2014, which included non-cash charges of $1.5 million for depreciation and amortization and $206,000 for stock-based compensation.

CONSOLIDATED INCOME TAXES

We continue to believe the full valuation allowance established in 2008 against OSUR s total U.S. 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 OSUR s pre-tax loss in the first half of 2014 or 2013. For the six months ended June 30, 2014 and 2013, we recorded Canadian income tax benefits of $43,000 and $659,000, respectively, associated with certain Canadian research and development and investment tax credits and DNAG s loss before income taxes. The Canadian income tax benefits are considered realizable based upon the scheduled reversal of the deferred tax liabilities recorded in connection with the acquisition of DNAG.

Liquidity and Capital Resources

	June 30, 2014	December 31, 2013
	(In thousands)	
Cash	$ 75,832	$ 93,191
Working capital	101,098	100,590

Our cash balances decreased $17.4 million to $75.8 million at June 30, 2014 from $93.2 million at December 31, 2013. Our working capital increased to $101.1 million at June 30, 2014 from $100.6 million at December 31, 2013.

During the first six months of 2014, we used $10.4 million in cash to finance our operating activities. Our net loss of $3.1 million was partially offset by non-cash stock-based compensation expense of $2.9 million, depreciation and amortization expense of $3.1 million and unrealized foreign currency loss of $139,000. An additional large use of cash in operating activities included a $6.0 million increase in prepaid expenses and other current assets largely due to the $5.5 million receivable from Roche and the $775,000 exclusivity payment due from AbbVie. Also contributing to the use of cash was a $3.8 million decrease in accrued expenses and other liabilities associated with payment of our 2013 management incentive bonuses, royalty obligations, and certain year-end accruals, a $1.8 million increase in inventory associated with our infectious disease products, a $1.2 million increase in accounts receivable resulting from the timing of orders during the current quarter, a $418,000 increase in deferred revenues associated with increased customer prepayments, and a $179,000 decrease in accounts payable.

We used a total of $6.4 million in investing activities during the first six months of 2014 to purchase $4.4 million in short-term investments and $2.0 million to acquire property and equipment.

Net cash used in financing activities was $437,000 for the six months ended June 30, 2014, which resulted from the use of $639,000 for the repurchase of common stock related to the vesting of restricted shares, partially offset by $202,000 in proceeds received from the exercise of stock options.

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 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 timing 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, market acceptance of new

products, competing technological and market developments, the impact of the current economic environment and other factors.

Summary of Contractual Obligations

A summary of our obligations to make future payments under contracts existing at December 31, 2013 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, 2013. As of June 30, 2014, 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 2013 Annual Report on Form 10-K filed with the SEC. During the first six months of 2014, 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 June 30, 2014, we did not have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. We have operations in Canada and Europe, 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 comprised 7% of our total revenues for the six months ended June 30, 2014 (including revenues from DNAG). We expect our international 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 June 30, 2014. Based on that evaluation, the Company s management, including such officers, concluded that the Company s disclosure controls and procedures were adequate and effective as of June 30, 2014 to ensure that information required to be disclosed by the Company in the reports that we file or submit under the Securities Exchange Act of 1934 was accumulated and communicated to the Company s management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure and was recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC.

(b) Changes in Internal Control Over Financial Reporting. There was no change in the Company s internal control over financial reporting that occurred during the three months ended June 30, 2014 that has materially affected, or is reasonably likely to materially affect, the Company s 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, 2013.

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

During the quarter ended June 30, 2014, pursuant to the OraSure Technologies, Inc. Stock Award Plan, and in connection with the vesting of restricted shares, we retired 17,418 shares of our common stock to satisfy minimum tax withholding obligations at an average price paid per share of $6.76.

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: August 6, 2014

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

Date: August 6, 2014

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

EXHIBIT INDEX

Exhibit	
10.1	Master Program Services and Co-Promotion Agreement, dated as of June 10, 2014, between OraSure Technologies, Inc. and AbbVie Bahamas Ltd.*
10.2	Amendment to OraSure Technologies, Inc. Stock Award Plan, effective May 22, 2014.**
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

* Portions of this exhibit have been redacted pursuant to a confidential treatment request filed with the SEC on August 6, 2014.

** Compensation plan or arrangement.