

ORASURE TECHNOLOGIES INC
Form 10-Q
May 08, 2015
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2015.

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
(State or Other Jurisdiction of
Incorporation or Organization)

36-4370966
(IRS Employer
Identification No.)

220 East First Street, Bethlehem, Pennsylvania
(Address of Principal Executive Offices)
(610) 882-1820

18015
(Zip code)

(Registrant's Telephone Number, Including Area Code)

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

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

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

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

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

Number of shares of Common Stock, par value \$.000001 per share, outstanding as of May 5, 2015: 56,417,001 shares.

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Table of Contents**Item 1. FINANCIAL STATEMENTS****ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS****(Unaudited)****(in thousands, except per share amounts)**

	MARCH 31, 2015	DECEMBER 31, 2014
ASSETS		
CURRENT ASSETS:		
Cash	\$ 85,547	\$ 92,867
Short-term investments	3,942	5,000
Accounts receivable, net of allowance for doubtful accounts of \$543 and \$533	16,367	16,138
Inventories	15,619	15,763
Prepaid expenses	1,559	1,140
Other current assets	149	306
Total current assets	123,183	131,214
PROPERTY AND EQUIPMENT, net	17,645	17,934
INTANGIBLE ASSETS, net	15,581	17,505
GOODWILL	19,913	21,734
OTHER ASSETS	1,320	1,246
	\$ 177,642	\$ 189,633
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 5,037	\$ 7,148
Deferred revenue	5,492	8,043
Deferred income taxes	128	139
Accrued expenses	6,877	11,132
Total current liabilities	17,534	26,462
OTHER LIABILITIES	1,311	1,234
DEFERRED INCOME TAXES	2,970	3,236
COMMITMENTS AND CONTINGENCIES (Note 6)		
STOCKHOLDERS EQUITY		

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Preferred stock, par value \$.000001, 25,000 shares authorized, none issued		
Common stock, par value \$.000001, 120,000 shares authorized, 56,416 and 56,187 shares issued and outstanding		
Additional paid-in capital	345,718	344,894
Accumulated other comprehensive loss	(11,659)	(7,848)
Accumulated deficit	(178,232)	(178,345)
Total stockholders equity	155,827	158,701
	\$ 177,642	\$ 189,633

See accompanying notes to the consolidated financial statements.

Table of Contents**ORASURE TECHNOLOGIES, INC. AND SUBIDIARIES****CONSOLIDATED STATEMENTS OF OPERATIONS****(Unaudited)****(in thousands, except per share amounts)**

	Three Months Ended March 31,	
	2015	2014
NET REVENUES:		
Product	\$ 23,765	\$ 23,537
Other	3,323	
	27,088	23,537
COST OF PRODUCTS SOLD	10,090	9,610
Gross profit	16,998	13,927
OPERATING EXPENSES:		
Research and development	3,440	2,481
Sales and marketing	7,884	11,340
General and administrative	5,965	5,724
	17,289	19,545
Operating loss	(291)	(5,618)
OTHER INCOME	409	118
Income (loss) before income taxes	118	(5,500)
INCOME TAXES	5	131
NET INCOME (LOSS)	\$ 113	\$ (5,631)
EARNINGS (LOSS) PER SHARE:		
BASIC	\$ 0.00	\$ (0.10)
DILUTED	\$ 0.00	\$ (0.10)
SHARES USED IN COMPUTING EARNINGS (LOSS) PER SHARE:		
BASIC	56,343	55,762
DILUTED	57,173	55,762

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See accompanying notes to the consolidated financial statements.

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ORASURE TECHNOLOGIES, INC. AND SUBIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

(in thousands)

	Three Months Ended March 31,	
	2015	2014
NET INCOME (LOSS)	\$ 113	\$ (5,631)
OTHER COMPREHENSIVE LOSS		
Currency translation adjustments	(3,811)	(1,778)
Other comprehensive loss	(3,811)	(1,778)
COMPREHENSIVE LOSS	\$ (3,698)	\$ (7,409)

See accompanying notes to the consolidated financial statements.

Table of Contents**ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF CASH FLOWS****(Unaudited)****(in thousands)**

	Three Months Ended March 31,	
	2015	2014
OPERATING ACTIVITIES:		
Net income (loss)	\$ 113	\$ (5,631)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Stock-based compensation	1,475	1,406
Depreciation and amortization	1,409	1,539
Unrealized foreign currency gain	(71)	
Deferred income taxes	5	131
Changes in assets and liabilities		
Accounts receivable	(552)	(402)
Inventories	57	(586)
Prepaid expenses and other assets	(290)	(280)
Accounts payable	(2,062)	(683)
Deferred revenue	(2,542)	(153)
Accrued expenses and other liabilities	(4,133)	(3,009)
Net cash used in operating activities	(6,591)	(7,668)
INVESTING ACTIVITIES:		
Purchases of short term investments	(3,961)	
Proceeds from maturities of short term investments	5,000	
Purchases of property and equipment	(437)	(647)
Net cash provided by (used in) investing activities	602	(647)
FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	121	93
Repurchase of common stock	(772)	(521)
Net cash used in financing activities	(651)	(428)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	(680)	(255)
NET DECREASE IN CASH	(7,320)	(8,998)
CASH, BEGINNING OF PERIOD	92,867	93,191
CASH, END OF PERIOD	\$ 85,547	\$ 84,193

SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:

Cash paid for:

Income taxes	\$	81	\$	40
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See accompanying notes to the consolidated financial statements.

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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 diagnostic products and specimen collection devices using our proprietary 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, tests that are processed in a laboratory, and a 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, commercial and industrial entities, retail pharmacies and mass merchandisers, and 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 mean 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, 2014. Results of operations for the three months ended March 31, 2015 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.

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Our available-for-sale securities as of March 31, 2015 and December 31, 2014 consisted of guaranteed investment certificates with amortized cost and fair values of \$3,942 and \$5,000, respectively.

Fair Value of Financial Instruments. As of March 31, 2015 and December 31, 2014, the carrying values of cash, short-term investments, accounts receivable, and accounts payable 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 March 31, 2015 and December 31, 2014 was \$1,314 and \$1,234, 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 are measured as Level 1 instruments as of March 31, 2015 and December 31, 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:

	March 31, 2015	December 31, 2014
Raw materials	\$ 8,256	\$ 8,539
Work in process	764	898
Finished goods	6,599	6,326
	\$ 15,619	\$ 15,763

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 March 31, 2015 and December 31, 2014 was \$32,049 and \$31,416, respectively.

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Intangible Assets. Intangible assets consist of the following:

	Amortization Period (Years)	Gross	March 31, 2015 Accumulated	
			Amortization	Net
Customer list	10	\$ 9,876	\$ (3,449)	\$ 6,427
Patents and product rights	3-10	10,449	(8,069)	2,380
Acquired technology	7	7,671	(3,769)	3,902
Tradename	15	3,786	(914)	2,872
		\$ 31,782	\$ (16,201)	\$ 15,581

	Amortization Period (Years)	Gross	December 31, 2014 Accumulated	
			Amortization	Net
Customer list	10	\$ 10,779	\$ (3,508)	\$ 7,271
Patents and product rights	3-10	10,449	(7,957)	2,492
Acquired technology	7	8,372	(3,833)	4,539
Tradename	15	4,132	(929)	3,203
		\$ 33,732	\$ (16,227)	\$ 17,505

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, 2014 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 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 March 31, 2015, we believe no indicators of impairment exist.

The change in goodwill from \$21,734 as of December 31, 2014 to \$19,913 as of March 31, 2015 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.

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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 and is recorded as other revenue in our statements of operations.

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 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 covered by this agreement.

Pursuant to the Co-Promotion Agreement, we have granted exclusive co-promotion rights for the OraQuick® HCV test in certain markets to AbbVie and we have agreed to develop, implement, administer and maintain a patient care database for the exclusive use of AbbVie. This patient care database will be used to compile patient information regarding new individuals who have tested positive for HCV using our OraQuick® HCV test. We have also jointly agreed with AbbVie to co-promote our OraQuick® HCV test in certain market segments.

In exchange for these exclusive rights and other services, we are eligible to receive up to \$75,000 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 term of the agreement. In addition, if certain performance-based milestones are achieved, we may be eligible to receive additional milestone payments. These payments would be based upon the aggregate number of new patients enrolled in the patient care database, in a given calendar year, after exceeding a baseline threshold, and could range from \$3,500 to \$55,500 annually over the term of the agreement. The first performance-based milestone period ends on December 31, 2015. The agreement also contains certain termination, indemnification and other provisions, typical of agreements of this type. Amounts related to this agreement will be recorded as other 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 March 31, 2015 and December 31, 2014, the reserve for sales returns and allowances was \$387 and \$437, 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.

Deferred Revenue. We record deferred revenue when funds are received prior to the recognition of the associated revenue. Deferred revenue as of March 31, 2015 and December 31, 2014 includes customer prepayments of \$1,386 and \$613, respectively. Deferred revenue as of March 31, 2015 and December 31, 2014 also includes \$4,106 and \$7,430 from AbbVie, respectively, which represents the \$15,000 payment received in July 2014 under the terms of

our HCV co-promotion agreement with AbbVie, less amounts recognized ratably in revenue.

Customer and Vendor Concentrations. One of our customers, Reckitt Benckiser, accounted for approximately 13% of our accounts receivable balance as of March 31, 2015. We had no significant concentrations (greater than 10%) in accounts receivable as of December 31, 2014. AbbVie accounted for approximately 12% of our net revenues for the three months ended March 31, 2015. We had no significant concentrations (greater than 10%) in net revenues for the three months ended March 31, 2014.

We currently purchase certain products and critical components of our products from sole-supply vendors. 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

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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 price during the reporting period.

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

	Three Months Ended March 31,	
	2015	2014
Net income (loss)	\$ 113	\$ (5,631)
Weighted average shares of common stock outstanding:		
Basic	56,343	55,762
Dilutive effect of stock options and restricted stock	830	
Diluted	57,173	55,762
Earnings (loss) per share:		
Basic	\$ 0.00	\$ (0.10)
Diluted	\$ 0.00	\$ (0.10)

For the three-month periods ended March 31, 2015 and 2014, outstanding common stock options and unvested restricted stock, representing 2,702 and 3,698 shares, respectively, were excluded from the computation of diluted earnings (loss) per share, as their inclusion would have been anti-dilutive.

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

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

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 \$3,811 and \$1,778 currency translation adjustments recorded in the first three months of 2015 and 2014, respectively, are largely the result of the translation of our Canadian operation's balance sheets into U.S. dollars.

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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. However, the FASB has proposed a one-year deferral of the effective date of this standard. We are still evaluating 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 vesting of restricted stock, we issue new shares rather than purchase shares on the open market.

Total compensation cost related to stock options for the three months ended March 31, 2015 and 2014 was \$822 and \$719, respectively. Net cash proceeds from the exercise of stock options were \$121 and \$93 for the three months ended March 31, 2015 and 2014, 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.

The following table summarizes the stock option activity for the three months ended March 31, 2015:

	Options
Outstanding on January 1, 2015	5,740
Granted	767
Exercised	(74)
Expired	(35)
Forfeited	(29)
Outstanding on March 31, 2015	6,369

Compensation cost of \$653 and \$687 related to restricted shares was recognized during the three months ended March 31, 2015 and 2014, respectively. In connection with the vesting of restricted shares and exercise of stock options during the three months ended March 31, 2015 and 2014, we purchased and immediately retired 112 and 89 shares with aggregate values of \$772 and \$521, respectively, in satisfaction of minimum tax withholding and exercise obligations.

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The following table summarizes restricted stock award activity for the three months ended March 31, 2015:

	Shares
Issued and unvested, January 1, 2015	707
Granted	265
Vested	(267)
Forfeited	(9)
Issued and unvested, March 31, 2015	696

4. Accrued Expenses

	March 31, 2015	December 31, 2014
Payroll and related benefits	\$ 2,902	\$ 6,620
Royalties	1,703	2,285
Professional fees	758	480
Other	1,514	1,747
	\$ 6,877	\$ 11,132

5. Income Taxes

During the three months ended March 31, 2015 and 2014, we recorded foreign deferred tax expense of \$5 and \$131, respectively.

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 March 31, 2015 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. Management believes the full valuation allowance is still appropriate as of March 31, 2015 and December 31, 2014 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 month periods ended March 31, 2015 and 2014.

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 diagnostic products, specimen collection devices and medical devices; and our molecular collection systems or DNAG business, which primarily 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, commercial and industrial entities, retail pharmacies, mass merchandisers, and to consumers over the internet. OSUR also derives other revenues, including royalties from the grant of license

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rights, exclusivity payments for co-promotion rights, and other licensing and product development activities. DNAG revenues result primarily from products sold into the commercial market which consists of customers 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 operating segment information for the three months ended March 31, 2015 and 2014 and asset information as of March 31, 2015 and December 31, 2014:

	Three Months Ended March 31,	
	2015	2014
Net revenues:		
OSUR	\$ 20,371	\$ 17,778
DNAG	6,717	5,759
Total	\$ 27,088	\$ 23,537
Operating income (loss):		
OSUR	\$ (1,521)	\$ (6,394)
DNAG	1,230	776
Total	\$ (291)	\$ (5,618)
Depreciation and amortization:		
OSUR	\$ 726	\$ 776
DNAG	683	763
Total	\$ 1,409	\$ 1,539
Capital expenditures:		
OSUR	\$ 76	\$ 439
DNAG	361	208
Total	\$ 437	\$ 647
March 31, 2015 December 31, 2014		
Total assets:		
OSUR	\$ 127,273	\$ 136,542

DNAG	50,369	53,091
Total	\$ 177,642	\$ 189,633

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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 March 31,	
	2015	2014
United States	\$ 20,416	\$ 17,406
Europe	4,374	4,001
Other regions	2,298	2,130
	\$ 27,088	\$ 23,537

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

	March 31, 2015	December 31, 2014
United States	\$ 16,093	\$ 16,570
Canada	1,542	1,353
Other regions	10	11
	\$ 17,645	\$ 17,934

Table of Contents**Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

Statements below regarding future events or performance are forward-looking statements within the meaning of the Federal securities laws. These may include statements about our expected revenues, earnings/loss per share, net income (loss), expenses, cash flow or other financial performance or developments, clinical trial or development activities, expected regulatory filings and approvals, planned business transactions, views of future industry, competitive or market conditions, and other factors that could affect our future operations, results of operations or financial position. These statements often include the words believes, expects, anticipates, intends, plans, estimates, may, will, should, could, or similar expressions. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include, but are not limited to: ability to market and sell products, whether through 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 various arrangements; ability to achieve financial and performance objectives under the HCV co-promotion agreement 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; 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, 2014, 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.

Investors should also be aware that while we do, from time to time, communicate with securities analysts, it is against our policy to disclose any material non-public information or other confidential commercial information. Accordingly, stockholders should not assume that we agree with any statement or report issued by any analyst irrespective of the content of the statement or report. Furthermore, we have a policy against issuing or confirming financial forecasts or projections issued by others. Thus, to the extent that reports issued by securities analysts contain any projections, forecasts or opinions, such reports are not the responsibility of OraSure.

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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 diagnostic products and specimen collection devices using our proprietary 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 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. In addition, our OTC HIV and cryosurgical products are available at retail pharmacies and mass merchandisers, and our OTC HIV product is also sold to consumers over the internet.

Recent Developments

HCV Co-Promotion Agreement

A major focus of our HCV business has been the HCV co-promotion agreement with AbbVie. As a result of evolving conditions in the HCV drug therapy market, we have had to adjust our strategy in several of the initiatives we are pursuing under this agreement.

As a result of the launch of its new HCV drug therapy and the intense competition between manufacturers for preferred formulary status for their products, AbbVie reduced the physician detailing activities of its sales force for our OraQuick® HCV test during the first quarter of 2015. This reduced level of detailing has continued longer than expected and, as a result, we have increased the focus and efforts of our distributors and manufacturer representative organizations, or MROs, to more effectively generate sales leads and customer interest within the physician market. We have also continued our efforts to initiate several pilot programs in the retail market with the goal of developing sustainable models for rapid HCV testing in national and retail outlets. We have made good progress under this initiative with three (3) pilots expected to be initiated in May 2015. Due to the competitive market conditions for HCV therapies, we have broadened our initiative, that was initially focused on the long-haul trucking industry, to identify other employer groups that may offer opportunities to promote both the use of our HCV test and the AbbVie patient support program. We expect that additional employer opportunities will be identified in the second half of this year. Finally, we are looking for ways into areas not previously covered by the co-promotion agreement with AbbVie, particularly the public health market.

We remain committed to the HCV co-promotion agreement with AbbVie and intend to devote the focus and resources needed to maximize the chances of success for this important collaboration.

Current Consolidated Financial Results

During the three months ended March 31, 2015, our consolidated net revenues were \$27.1 million compared to \$23.5 million in the three months ended March 31, 2014. Net product revenues during the three months ended March 31,

2015 increased 1% when compared to the first three months of 2014, primarily due to higher sales of our molecular collection systems, OraQuick® HCV and Intercept® products. Other revenues for the first three months of 2015 were \$3.3 million and represent the ratable recognition of payments for exclusive co-promotion rights and certain services provided under our HCV co-promotion agreement with AbbVie. We did not record similar revenues during the first quarter of 2014.

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Our consolidated net income for the three months ended March 31, 2015 was \$113,000, or \$0.00 per share, compared to a net loss of \$5.6 million, or \$0.10 per share, for the three months ended March 31, 2014.

Cash used in operating activities for the three months ended March 31, 2015 was \$6.6 million, compared to \$7.7 million used during the three months ended March 31, 2014. As of March 31, 2015, we had \$89.5 million in cash and short-term investments compared to \$97.9 million at December 31, 2014.

Business Segments

We operate our business within two reportable segments: our OSUR business, which consists of the development, manufacture and sale of diagnostic products, specimen collection devices, and medical devices, 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, commercial and industrial entities, retail pharmacies, mass merchandisers and consumers over the internet. DNAG revenues result primarily from products sold into the commercial market, which consists of customers 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 March 31, 2015 compared to March 31, 2014****CONSOLIDATED NET REVENUES**

The table below shows the amounts of total net revenues (dollars in thousands) generated by each of our business segments for the three months ended March 31, 2015 and 2014.

	Three Months Ended March 31,				
	Dollars			Percentage of Total Net Revenues	
	2015	2014	Change	2015	2014
OSUR	\$ 17,048	\$ 17,778	(4)%	63%	76%
DNAG	6,717	5,759	17	25	24
Net product revenues	23,765	23,537	1	88	100
Other	3,323		NM*	12	
Net revenues	\$ 27,088	\$ 23,537	15%	100%	100%

* Calculation is not considered meaningful.

Consolidated net product revenues increased 1% to \$23.8 million in the first quarter of 2015 from \$23.5 million in the comparable period of 2014. Higher sales of our molecular collection systems, OraQuick® HCV and Intercept® products were partially offset by lower sales of our cryosurgical systems, professional OraQuick® HIV, and OraQuick® In-Home HIV products. Other revenues were \$3.3 million in the first quarter of 2015 and represent the recognition of revenues from exclusivity payments received under our HCV co-promotion agreement with AbbVie.

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Consolidated net revenues derived from products sold to customers outside the U.S. were \$6.7 million and \$6.1 million, or 25% and 26% of total net revenues, in the first quarters of 2015 and 2014, 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 a breakdown of total net revenues (dollars in thousands) generated by our OSUR segment.

Market	Three Months Ended March 31,				
	Dollars			Percentage of Total Net Revenues	
	2015	2014	% Change	2015	2014
Infectious disease testing	\$ 11,495	\$ 11,064	4%	57%	63%
Substance abuse testing	2,102	1,830	15	10	10
Cryosurgical systems	2,545	3,967	(36)	13	22
Insurance risk assessment	906	917	(1)	4	5
Net product revenues	17,048	17,778	(4)	84	100
Other	3,323		NM*	16	
Net revenues	\$ 20,371	\$ 17,778	15%	100%	100%

* Calculation is not considered meaningful.

Infectious Disease Testing Market

Sales to the infectious disease testing market increased 4% to \$11.5 million in the first quarter of 2015 from \$11.1 million in the first quarter of 2014 primarily due to higher sales of our OraQuick® HCV product in both domestic and international markets, higher sales of our professional OraQuick® HIV product in the international market and an increase in sales of our other infectious disease testing products. These increases in sales were partially offset by lower domestic sales of our professional OraQuick® HIV product and our OraQuick® In-Home HIV test.

The table below shows a breakdown of our total net OraQuick® revenues (dollars in thousands) during the first quarters of 2015 and 2014.

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Market	Three Months Ended March 31,		
	2015	2014	% Change
Domestic HIV	\$ 6,007	\$ 6,618	(9)%
International HIV	948	558	70
Domestic OTC HIV	1,561	1,953	(20)
Net HIV revenues	8,516	9,129	(7)
Domestic HCV	1,197	663	81
International HCV	972	896	8
Net HCV revenues	2,169	1,559	39
Net OraQuick® revenues	\$ 10,685	\$ 10,688	%

Domestic OraQuick® HIV sales decreased 9% to \$6.0 million for the three months ended March 31, 2015 from \$6.6 million for the three months ended March 31, 2014. This decrease was primarily the result of the migration of some customers to 4th generation automated HIV immunoassays performed in a laboratory, as recommended under testing guidelines issued by the CDC, price competition, and the timing of certain customer orders. We anticipate that future sales of our professional HIV product will continue to be negatively affected as a result of the CDC's new testing guidelines, changes in government funding, and continued price competition. International sales of our OraQuick® HIV test during the first quarter of 2015 increased 70% to \$948,000 from \$558,000, primarily due to higher sales in Asia and Africa, partially offset by a decline in sales in Europe.

Sales of our OraQuick® In-Home HIV test decreased 20% to \$1.6 million in the first quarter of 2015 from \$2.0 million in the first quarter of 2014. The decline in sales is primarily the result of our decision in the second half of 2014 to transition away from broad-based consumer advertising and focus our marketing and promotional efforts at the retail outlet level. Sales of our OraQuick® In-Home HIV test in the first quarters of 2015 and 2014 included approximately \$150,000 and \$183,000, respectively, of direct sales to public health customers.

Domestic OraQuick® HCV sales increased 81% to \$1.2 million in the first quarter of 2015 from \$663,000 in the first quarter of 2014, 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 8% to \$972,000 in the first quarter of 2015 from \$896,000 in the first quarter of 2014, largely due to higher sales into certain Asian markets as a result of regional expansion, partially offset by lower sales in Europe.

We believe our OraQuick® HCV product represents an opportunity for future sales growth, given the recent FDA approvals of several new drug therapies for treating HCV. We also expect that sales of our HCV product will be positively impacted as we implement awareness and testing programs under our agreement with AbbVie. However, demand for our HCV product, particularly in the public health marketplace, is somewhat 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. Sales to physicians can also be adversely affected by the level of reimbursement available from insurance providers and competition from laboratory-based HCV tests. The intensely competitive market for new HCV therapies and the decisions by insurance providers and payors to grant preferred or exclusive formulary status to one HCV therapy over another could adversely affect our initiatives under the HCV co-promotion agreement with AbbVie. These and other factors could limit the future growth of our HCV business.

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.

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Sales to the substance abuse testing market increased 15% to \$2.1 million in the first quarter of 2015 from \$1.8 million in the first quarter of 2014, primarily as a result of higher sales of our Intercept® drug testing system.

Domestic Intercept® sales for the first quarter of 2015 increased to \$1.5 million compared to \$1.3 million for the first quarter of 2014 largely due to the recovery of customers that were previously lost to competition and improved domestic employment conditions.

Cryosurgical Systems Market

Sales of our cryosurgical systems products (which includes both the physicians office and OTC markets) decreased 36% to \$2.5 million in the first quarter of 2015, compared to \$4.0 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 first quarters of 2015 and 2014.

Market	Three Months Ended March 31,		
	2015	2014	% Change
Domestic professional	\$ 661	\$ 1,542	(57)%
International professional	357	310	15
Domestic OTC	55		100
International OTC	1,472	2,115	(30)
Net cryosurgical systems revenues	\$ 2,545	\$ 3,967	(36)%

Sales of our Histofreezer® product to physicians offices in the United States decreased 57% to \$661,000 in the first quarter of 2015 from \$1.5 million in the first quarter of 2014 largely as a result of distributor consolidation and competition from new private label brands. International sales of Histofreezer® increased to \$357,000 in the first quarter of 2015, compared to \$310,000 in the same period of the prior year, primarily due to the recognition of sales from a backlog that was created in 2014 as a result of delivery problems and inventory shortages associated with the transition to a new manufacturer of our international Histofreezer® products. In addition, in 2014 our former contract manufacturer began promoting a competing product similar to Histofreezer® and this competing product has adversely affected, and is expected to continue to adversely affect, revenues generated from our cryosurgical systems business. In order to remain competitive with this new product offering, we have decreased the per unit sales price of our Histofreezer® product in certain international markets.

In the fourth quarter of 2014, we launched our wart removal product in the U.S. retail market through private labeling with a large pharmacy chain. Sales related to this product in the first quarter of 2015 were \$55,000.

Sales of our international OTC cryosurgical products during the first quarter of 2015 decreased 30% to \$1.5 million compared to \$2.1 million in the first quarter of 2014, largely due to lower sales to both our European distributor, Reckitt Benckiser, and our Latin American distributor, Genomma.

Current quarter sales to Reckitt Benckiser decreased to \$1.3 million, compared to \$1.4 million during the first quarter of 2014, primarily due to customer ordering patterns. Sales to Genomma decreased to \$133,000 in the first quarter of

2015 from \$709,000 in the first quarter of 2014, also due to ordering patterns and challenges faced by Genomma, including declining economic conditions in Argentina.

Insurance Risk Assessment Market

Sales to the insurance risk assessment market remained relatively flat in the first quarter of 2015 at \$906,000 compared to \$917,000 in the first quarter of 2014.

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Other revenues

Other revenues for the first three months of 2015 were \$3.3 million and represent the ratable recognition of exclusivity payments recorded under our HCV co-promotion agreement with AbbVie. We did not record similar revenues during the first quarter of 2014.

DNAG Segment

Molecular Collection Systems

Net molecular collection systems revenues, which primarily represent sales of our Oragene[®] product line, increased 17% to \$6.7 million in the first quarter of 2015 from \$5.8 million in the first quarter of 2014. Sales in the commercial market grew 32%, which was primarily due to increased orders from existing U.S. customers, as well as incremental revenues from new customers. Sales in the academic market decreased 7% largely due to customer ordering patterns.

CONSOLIDATED OPERATING RESULTS

Consolidated gross margin was 63% for the first quarter of 2015 compared to 59% for the first quarter of 2014. Gross mar