ORASURE TECHNOLOGIES INC
Form 10-Q
November 08, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2016.

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 No

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

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

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

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

Number of shares of Common Stock, par value $.000001 per share, outstanding as of November 3, 2016: 55,730,629 shares.

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PART I. FINANCIAL INFORMATION

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Item 1. FINANCIAL STATEMENTS

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(Unaudited)

(in thousands, except per share amounts)

	September 30, 2016	December 31, 2015
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 111,726	$ 94,094
Restricted cash	1,810	
Short-term investments	7,618	7,225
Accounts receivable, net of allowance for doubtful accounts of $633 and $798	15,471	19,265
Inventories	12,070	13,242
Prepaid expenses	1,364	1,533
Other current assets	660	1,355
Total current assets	150,719	136,714
PROPERTY AND EQUIPMENT, net	20,069	20,083
INTANGIBLE ASSETS, net	11,205	12,591
GOODWILL	19,243	18,250
OTHER ASSETS	2,322	1,683
	$ 203,558	$ 189,321
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 4,422	$ 5,087
Deferred revenue	7,911	9,735
Accrued expenses	9,618	10,412
Total current liabilities	21,951	25,234
OTHER LIABILITIES	2,289	1,768
DEFERRED INCOME TAXES	2,836	2,883
COMMITMENTS AND CONTINGENCIES (Note 7)		
STOCKHOLDERS EQUITY		
Preferred stock, par value $.000001, 25,000 shares authorized, none issued		

Common stock, par value $.000001, 120,000 shares authorized, 55,723 and 55,705 shares issued and outstanding		
Additional paid-in capital	347,274	345,253
Accumulated other comprehensive loss	(13,138)	(15,639)
Accumulated deficit	(157,654)	(170,178)
Total stockholders equity	176,482	159,436
	$ 203,558	$ 189,321

See accompanying notes to the consolidated financial statements.

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ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF INCOME

(Unaudited)

(in thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
NET REVENUES:				
Product	$ 25,460	$ 25,714	$ 78,286	$ 75,792
Other	6,791	4,147	14,413	11,545
	32,251	29,861	92,699	87,337
COST OF PRODUCTS SOLD	9,576	9,192	28,626	28,974
Gross profit	22,675	20,669	64,073	58,363
OPERATING EXPENSES:				
Research and development	3,196	2,525	8,547	8,961
Sales and marketing	6,428	9,677	22,531	26,465
General and administrative	6,907	6,931	19,803	18,971
	16,531	19,133	50,881	54,397
Operating income	6,144	1,536	13,192	3,966
OTHER INCOME (EXPENSE)	498	81	(34)	395
Income before income taxes	6,642	1,617	13,158	4,361
INCOME TAX EXPENSE	400	147	634	810
NET INCOME	$ 6,242	$ 1,470	$ 12,524	$ 3,551
EARNINGS PER SHARE:				
BASIC	$ 0.11	$ 0.03	$ 0.23	$ 0.06
DILUTED	$ 0.11	$ 0.03	$ 0.22	$ 0.06
SHARES USED IN COMPUTING EARNINGS PER SHARE:				
BASIC	55,653	56,482	55,549	56,427
DILUTED	56,530	56,692	56,273	56,900

See accompanying notes to the consolidated financial statements.

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ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(Unaudited)

(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	**2015**	**2016**	**2015**
NET INCOME	$ 6,242	$ 1,470	$ 12,524	$ 3,551
OTHER COMPREHENSIVE INCOME (LOSS)				
Currency translation adjustments	(729)	(2,858)	2,501	(6,036)
COMPREHENSIVE INCOME (LOSS)	$ 5,513	$ (1,388)	$ 15,025	$ (2,485)

See accompanying notes to the consolidated financial statements.

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ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(in thousands)

	Nine Months Ended September 30,	
	2016	**2015**
OPERATING ACTIVITIES:		
Net income	$ 12,524	$ 3,551
Adjustments to reconcile net income to net cash provided by operating activities:		
Stock-based compensation	4,438	4,543
Depreciation and amortization	4,212	4,259
Amortization of lease incentives	(60)	
Unrealized foreign currency loss	75	450
Deferred income taxes	(205)	198
Changes in assets and liabilities		
Restricted cash	(1,810)	
Accounts receivable	3,818	(1,572)
Inventories	1,236	633
Prepaid expenses and other assets	1,186	(614)
Accounts payable	(125)	(72)
Deferred revenue	(1,829)	5,269
Accrued expenses and other liabilities	(90)	(1,540)
Net cash provided by operating activities	23,370	15,105
INVESTING ACTIVITIES:		
Purchases of short-term investments	(22,966)	(19,411)
Proceeds from maturities of short-term investments	22,966	16,450
Purchases of property and equipment	(3,512)	(1,885)
Net cash used in investing activities	(3,512)	(4,846)
FINANCING ACTIVITIES:		
Payments for debt issue costs	(367)	
Proceeds from exercise of stock options	894	124
Repurchase of common stock	(3,311)	(883)
Net cash used in financing activities	(2,784)	(759)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	558	(1,690)
NET INCREASE IN CASH AND CASH EQUIVALENTS	17,632	7,810
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	94,094	92,867

CASH AND CASH EQUIVALENTS, END OF PERIOD	$	111,726	$	100,677
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:				
Cash paid for income taxes	$	812	$	230
Noncash investing activities (accrued property and equipment purchases)	$	241	$	76

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 devices used to collect, stabilize, transport and store samples of genetic material for molecular testing in the consumer genetic, clinical genetic, academic research, pharmacogenomic, personalized medicine, microbiome and animal genetic 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 m OraSure and its consolidated subsidiary, 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, 2015. Results of operations for the three and nine months ended September 30, 2016 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 September 30, 2016 and December 31, 2015 consisted of guaranteed investment certificates with amortized cost and fair value of $7,618 and $7,225, respectively.

Fair Value of Financial Instruments. As of September 30, 2016 and December 31, 2015, the carrying values of cash and cash equivalents, 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).

Included in cash and cash equivalents at September 30, 2016 and December 31, 2015, was $98,056 and $65,509 invested in money market funds. These funds are Level 1 instruments.

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 September 30, 2016 and December 31, 2015 was $1,888 and $1,324, 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 September 30, 2016 and December 31, 2015.

In February 2016, we purchased certificates of deposit (CD) from a commercial bank in the amount of $1,810. The CDs bear interest at an annual rate ranging from 0.17% to 0.25% and mature monthly through February 28, 2018. The carrying values of the CDs approximate their fair value. These CDs serve as collateral for certain standby letters of credit and are reported as restricted cash on the accompanying consolidated balance sheets. Also see Note 7 Commitments and Contingencies.

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

	September 30, 2016	December 31, 2015
Raw materials	$ 6,832	$ 7,895
Work in process	1,190	333

Finished goods		4,048		5,014
	$	12,070	$	13,242

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

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two to ten years. Building improvements are amortized over their estimated useful lives. When assets are sold, retired, or discarded, the related property amounts are relieved from the accounts, and any gain or loss is recorded in the consolidated statements of income. Accumulated depreciation of property and equipment as of September 30, 2016 and December 31, 2015 was $35,264 and $33,013, respectively.

Intangible Assets. Intangible assets consist of the following:

		September 30, 2016		
	Amortization Period (Years)	Gross	Accumulated Amortization	Net
Customer list	10	$ 9,544	$ (4,714)	$ 4,830
Patents and product rights	10	5,400	(3,696)	1,704
Acquired technology	7	7,413	(5,151)	2,262
Tradename	15	3,658	(1,249)	2,409
		$ 26,015	$ (14,810)	$ 11,205

		December 31, 2015		
	Amortization Period (Years)	Gross	Accumulated Amortization	Net
Customer list	10	$ 9,051	$ (3,818)	$ 5,233
Patents and product rights	10	5,400	(3,358)	2,042
Acquired technology	7	7,030	(4,172)	2,858
Tradename	15	3,469	(1,011)	2,458
		$ 24,950	$ (12,359)	$ 12,591

The change in intangibles from $12,591 as of December 31, 2015 to $11,205 as of September 30, 2016 is a result of $2,467 in amortization expense and $1,081 in foreign currency translation gains.

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 values 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 the respective carrying values.

We performed our last annual impairment assessment as of July 31, 2016 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 value. 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 September 30, 2016, we believe no indicators of impairment exist.

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The change in goodwill from $18,250 as of December 31, 2015 to $19,243 as of September 30, 2016 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 sales of our OraQuick® In-Home HIV test to the retail trade, 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.

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. The allowance for expected returns is an estimate established by management, based upon currently available information, and is adjusted to reflect known changes in the factors that impact this estimate. Other customer allowances for cooperative advertising, discounts, rebates, and chargebacks are contractual in nature. These allowances are recorded as a reduction of gross revenue when recognized in our consolidated statements of income.

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.

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

Under the terms of this agreement, we were eligible to receive up to $75,000 in aggregate payments. We were recognizing this revenue ratably on a monthly basis over the term of the agreement which was to terminate on December 31, 2019.

Effective June 30, 2016, we mutually agreed to an early termination of this agreement with AbbVie and it will now end on December 31, 2016. Following the termination of the agreement, AbbVie will be relieved of its co-promotion obligations, including its obligation to detail the OraQuick® HCV Rapid Test into physician offices, and will have no further financial obligations to us. We will no longer be obligated to compensate AbbVie for product detailing activities and will be free to pursue arrangements with other pharmaceutical companies to market and promote our OraQuick® HCV Rapid Antibody Test in the U.S. As a result of the shortened term, the remaining associated deferred revenue of $12,229 at June 30, 2016, is being recognized ratably as other revenue over the remaining six months of 2016 as there are no substantive on-going obligations remaining beyond December 31, 2016. During the third quarter and first nine months of 2016, $6,114 and $12,837, respectively, in exclusivity revenue was recognized and was recorded as other revenue in our consolidated statements of income.

On June 12, 2015, we were awarded a grant for up to $10,400 in total funding from the U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response s Biomedical Advanced

Research and Development Authority (BARDA) related to our OraQuick® Ebola Rapid Antigen test. The three-year, multi-phased grant includes an initial commitment of $1,800 and options for up to an additional $8,600 to fund certain clinical and regulatory activities. In September 2015, BARDA exercised an option to provide $7,200 in additional funding for the development of our OraQuick® Ebola Rapid Antigen test. Amounts related to this grant are recorded as other revenue in our consolidated statements of income as the activities are being performed and the related costs are incurred. During the third quarter and first nine months of 2016, $474 and $1,373, respectively, was recognized in connection with this grant.

In August 2016, we were awarded a contract for up to $16,600 in total funding from BARDA related to our rapid Zika test. The six-year, multi-phased contract includes an initial commitment of $7,000 and options for up to an

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additional $9,600 to fund the evaluation of additional product enhancements, and clinical and regulatory activities. Funding received under this contract is recorded as other revenue in our consolidated statement of operations as the activities are being performed. During the third quarter of 2016, $203 was recognized in connection with this grant.

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 income. 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 September 30, 2016 and December 31, 2015, the reserve for sales returns and allowances was $253 and $310, 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 September 30, 2016 and December 31, 2015 includes customer prepayments of $1,797 and $784, respectively. Deferred revenue as of September 30, 2016 and December 31, 2015 also includes $6,114 and $8,951, respectively, from AbbVie, which represents the excess of the payments received from AbbVie over the amounts earned and recognized ratably in our consolidated statements of income.

Customer and Vendor Concentrations. We had no significant concentrations in accounts receivable as of September 30, 2016 and December 31, 2015. One customer accounted for approximately 19% and 14% of our net revenues for the three and nine months ended September 30, 2016, respectively. The same customer accounted for approximately 11% and 12% of our net revenues for the three and nine months ended September 30, 2015, respectively.

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 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 Per Share. Basic earnings per share is computed by dividing net income by the weighted-average number of shares of common stock outstanding during the period. Diluted earnings per share is computed in a manner similar to basic earnings per share except that the weighted average number of shares outstanding is increased to include shares from the assumed vesting or exercise of dilutive securities, such as common stock options, unvested restricted stock, and performance stock units, unless the impact is antidilutive. The number of incremental shares is calculated by assuming that outstanding stock options were exercised and unvested restricted shares and performance stock units 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Net income	$ 6,242	$ 1,470	$ 12,524	$ 3,551
Weighted average shares of common stock outstanding:				
Basic	55,653	56,482	55,549	56,427
Dilutive effect of stock options and restricted stock	877	210	724	473
Diluted	56,530	56,692	56,273	56,900
Earnings per share:				
Basic	$ 0.11	$ 0.03	$ 0.23	$ 0.06
Diluted	$ 0.11	$ 0.03	$ 0.22	$ 0.06

For the three-month periods ended September 30, 2016 and 2015, outstanding common stock options and unvested restricted stock representing 2,130 and 6,231 shares, respectively, were excluded from the computation of diluted earnings per share as their inclusion would have been anti-dilutive. For the nine months ended September 30, 2016 and 2015, outstanding common stock options and unvested restricted stock representing 2,837 and 4,648 shares, respectively, were similarly excluded from the computation of diluted earnings 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 our consolidated statements of income in the period in which the change occurs. Net foreign exchange gains resulting from foreign currency transactions that are included in other income (expense) in our consolidated statements of income were $84 and $188 for the three months ended September 30, 2016 and 2015, respectively. Net foreign exchange gains (losses) were $(564) and $729 for the nine months ended September 30, 2016 and 2015, respectively.

Accumulated Other Comprehensive Income (Loss). We classify items of other comprehensive income (loss) by their nature and disclose the accumulated balance of other comprehensive income (loss) separately from accumulated deficit and additional paid-in capital in the stockholders equity section of our consolidated 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 $2,501 and $(6,036) currency translation adjustments recorded in the first nine months of 2016 and 2015, 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, 2017, with early adoption permitted. We are still evaluating the effects, if any, which adoption of this guidance will have on our consolidated financial statements.

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In July 2015, the FASB issued ASU 2015-11, *Simplifying the Measurement of Inventory*, which requires an entity that uses the first-in, first-out method for inventory measurement to report inventory cost at the lower of cost and net realizable value versus the current measurement principle of lower of cost or market. The ASU requires prospective adoption for inventory measurements for fiscal years beginning after December 15, 2016. Early adoption is permitted. We are evaluating the effect that ASU 2015-11 may have on our consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU 2016-02, *Leases*, which requires entities to begin recording assets and liabilities from leases on the balance sheet. The new guidance will also require significant additional disclosures about the amount, timing and uncertainty of cash flows from leases. The standard will be effective for the first interim period within annual reporting periods beginning after December 15, 2018, using a modified retrospective approach. Early adoption is permitted. We are evaluating the effect that ASU 2016-02 may have on our consolidated financial statements and related disclosures.

In March 2016, the FASB issued authoritative guidance under ASU 2016-09, *Compensation-Stock Compensation (Topic 718) Improvements to Employee Share-Based Payment Accounting*. ASU 2016-09 provides for simplification of several aspects of the accounting for share-based payment transactions, including income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. The Company is required to adopt this new authoritative guidance in the first quarter of fiscal 2018. Early adoption is permitted. The Company is currently evaluating the potential impact of adoption of this standard on its consolidated financial statements.

3. Accrued Expenses

	September 30, 2016	December 31, 2015
Payroll and related benefits	$ 5,547	$ 6,311
Professional Fees	1,370	1,014
Royalties	610	819
Other	2,091	2,268
	$ 9,618	$ 10,412

4. Credit Facility

On September 30, 2016, we entered into a credit agreement (the Credit Agreement) with Wells Fargo Bank, National Association. The Credit Agreement provides for revolving extensions of credit in an initial aggregate amount of up to $10,000 (inclusive of a letter of credit subfacility of $2,500), with an option to request, prior to the second anniversary of the closing date, that lenders, at their election, provide up to $5,000 of additional revolving commitments. Obligations under the Credit Agreement are secured by a first priority security interest in certain eligible accounts receivable, 65% of the equity of our subsidiary, DNAG, and certain related assets. There were no borrowings outstanding at September 30, 2016.

Borrowings under the Credit Agreement are subject to compliance with borrowing base limitations tied to eligibility of accounts receivable. Interest under the Credit Agreement is payable at the London Interbank Offered Rate for one,

two, three or six-month loans, as selected by the Company, plus 2.50% per year. The Credit Agreement will be subject to an unused line fee of 0.375% per year on the unused portion of the commitment under the Credit Agreement during the revolving period. The maturity date of the Credit Agreement is September 30, 2019.

In connection with the Credit Agreement, under certain circumstances, we must comply with a minimum fixed charge coverage ratio of 1.10 to 1.00, measured as of the last day of each fiscal month and for the twelve-fiscal month period ending on such date. As of September 30, 2016 we were in compliance with all applicable covenants in the Credit Agreement.

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5. Stockholders Equity

Stock-Based Awards

We grant stock-based awards under the OraSure Technologies, Inc. Stock Award Plan, as amended (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 and performance awards, we issue new shares rather than purchase shares on the open market.

Commencing in 2016, we have granted to certain executives performance-based restricted stock units (PSUs). Vesting of these PSUs is dependent upon achievement of performance-based metrics during a one-year or three-year period, from the date of grant. Assuming achievement of each performance-based metrics, the executive must also remain in our service for three years, commencing with the grant date. Performance during the one-year period will be based on a one-year earnings per share target. Upon achievement of the one-year target, the PSUs will then vest three years from grant date. Performance during the three-year period will be based on achievement of a three-year compound annual growth rate for consolidated product revenues. Upon achievement of the three-year target, the corresponding PSUs will vest in full. PSUs are converted into shares of our common stock once vested. Upon grant of the PSUs, the Company recognizes compensation expense related to these awards based on assumptions as to what percentage of each target will be achieved. The Company evaluates these target assumptions on a quarterly basis and adjusts compensation expense related to these awards, as appropriate.

Total compensation cost related to stock options for the nine months ended September 30, 2016 and 2015 was $2,033 and $2,557, respectively. Net cash proceeds from the exercise of stock options were $894 and $124 for the nine months ended September 30, 2016 and 2015, 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 $2,137 and $1,986 related to restricted shares was recognized during the nine months ended September 30, 2016 and 2015, respectively. In connection with the vesting of restricted shares and exercise of stock options during the nine months ended September 30, 2016 and 2015, we purchased and immediately retired 117 and 132 shares with aggregate values of $651 and $883, respectively, in satisfaction of minimum tax withholding and exercise obligations.

Compensation cost of $268 related to the PSUs was recognized during the nine months ended September 30, 2016.

Stock Repurchase Program

On August 5, 2008, our Board of Directors approved a share repurchase program pursuant to which we are permitted to acquire up to $25,000 of our outstanding common shares. During the nine months ended September 30, 2016, we purchased and retired 423 shares of common stock at an average price of $6.29 per share for a total cost of $2,660. No shares were purchased and retired during the nine months ended September 30, 2015, under this share repurchase program.

6. Income Taxes

During the three and nine months ended September 30, 2016, we recorded tax expense of $400 and $634, respectively. During the three and nine months ended September 30, 2015, we recorded tax expense of $147 and $810, respectively.

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The following table summarizes the components of income tax expense:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Current taxes	$ 561	$ 315	$ 839	$ 612
Deferred taxes	(161)	(168)	(205)	198
Total	$ 400	$ 147	$ 634	$ 810

Current taxes reflect taxes due to state and Canadian taxing authorities. 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 September 30, 2016 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. deferred tax asset. Management believes the full valuation allowance is still appropriate as of both September 30, 2016 and December 31, 2015 since the facts and circumstances necessitating the allowance have not changed. As a result, no U.S. federal or state deferred income tax expense or benefit was recorded for the three and nine-month periods ended September 30, 2016 and 2015.

7. 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, individually or in the aggregate, to have a material adverse effect on our future financial position or results of operations.

In July 2016, we established two standby letters of credit in the aggregate amount of $1,800, naming an international customer as the beneficiary. These letters of credit were required as a performance guarantee of our obligations under our contract with that customer and are collateralized by certificates of deposit maintained at a commercial bank.

8. 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 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, animal and livestock genetic testing, and microbiome 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 and inter-segment expenses have been eliminated.

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The following table summarizes operating segment information for the three and nine months ended September 30, 2016 and 2015, and asset information as of September 30, 2016 and December 31, 2015:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Net revenues:				
OSUR	$ 23,924	$ 22,532	$ 69,050	$ 65,189
DNAG	8,327	7,329	23,649	22,148
Total	$ 32,251	$ 29,861	$ 92,699	$ 87,337
Operating income (loss):				
OSUR	$ 4,571	$ 725	$ 9,098	$ (111)
DNAG	1,573	811	4,094	4,077
Total	$ 6,144	$ 1,536	$ 13,192	$ 3,966
Depreciation and amortization:				
OSUR	$ 688	$ 764	$ 2,003	$ 2,224
DNAG	746	646	2,209	2,035
Total	$ 1,434	$ 1,410	$ 4,212	$ 4,259
Capital expenditures:				
OSUR	$ 283	$ 536	$ 1,406	$ 1,102
DNAG	500	204	2,106	783
Total	$ 783	$ 740	$ 3,512	$ 1,885

	September 30, 2016	December 31, 2015
Total assets:		
OSUR	$ 146,836	$ 137,082
DNAG	56,722	52,239
Total	$ 203,558	$ 189,321

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 September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015

United States	$ 26,302	$ 24,207	$ 72,493	$ 69,695
Europe	2,171	2,738	9,006	10,051
Other regions	3,778	2,916	11,200	7,591
	$ 32,251	$ 29,861	$ 92,699	$ 87,337

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

	September 30, 2016	December 31, 2015
United States	$ 15,476	$ 15,660
Canada	4,575	4,415
Other regions	18	8
	$ 20,069	$ 20,083

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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; 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 levels 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 testing guidelines, algorithms or other recommendations by the Centers for Disease Control and Prevention (CDC) or other agencies; 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 meet financial covenants in credit agreements; 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, 2015, 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, 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 collection devices used to collect, stabilize, transport and store samples of genetic material for molecular testing in the consumer genetic, clinical genetic, academic research, pharmacogenomic, personalized medicine, microbiome and animal genetic 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.

Recent Developments

Rapid Zika Test

In August 2016, we were awarded a contract for up to $16.6 million in total funding from the U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response s Biomedical Advanced Research and Development Authority (BARDA) related to our rapid Zika test. The six-year, multi-phased contract includes an initial commitment of $7.0 million and options for up to an additional $9.6 million to fund the evaluation of additional product enhancements, and clinical and regulatory activities. Funding received under this contract is recorded as other revenue in our consolidated statement of operations as the activities are performed and the related costs are incurred.

Restructuring

During 2016, the Company updated its long-term business strategy and reaffirmed the Company s focus on its infectious disease testing and molecular collection systems businesses as the primary drivers of long-term growth and profitability. As part of this project, a restructuring plan was developed to better align resources in the United States and Canada. As a result of this restructuring, which was finalized and presented to our employees in the fourth quarter of 2016, we will accrue $1.4 million in restructuring charges which largely consist of workforce reduction costs, including severance and related benefits.

Current Consolidated Financial Results

During the nine months ended September 30, 2016, our consolidated net revenues were $92.7 million, compared to $87.3 million for the nine months ended September 30, 2015. Net product revenues during the nine months ended September 30, 2016 increased 3% when compared to the first nine months of 2015, primarily due to higher international sales of our professional OraQuick® HIV product and higher sales of our OraQuick® HCV, molecular collection systems and cryosurgical systems products, partially offset by lower domestic sales of our OraQuick® HIV product and the absence of sales of our OraQuick® Ebola product in the current period. Other revenues for the first nine months of 2016 were $14.4 million, of which $12.8 million represents the ratable recognition of payments for

exclusive co-promotion rights and certain services provided under our HCV co-promotion agreement with AbbVie and $1.6 million represents revenue recognized in connection with funding received from BARDA for our Ebola and Zika products.

Our consolidated net income for the nine months ended September 30, 2016 was $12.5 million, or $0.22 per share on a fully-diluted basis, compared to consolidated net income of $3.6 million, or $0.06 per share on a fully-diluted basis, for the nine months ended September 30, 2015.

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Cash provided by operating activities for the nine months ended September 30, 2016 was $23.4 million, compared to $15.1 million provided by operating activities during the nine months ended September 30, 2015. As of September 30, 2016, we had $121.2 million in cash (including restricted cash), cash equivalents, and short-term investments compared to $101.3 million at December 31, 2015.

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, transport, 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 from products sold into the commercial market, which consists of customers engaged in consumer genetics, clinical genetic testing, pharmacogenomics, personalized medicine, microbiome 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 September 30, 2016 compared to September 30, 2015

CONSOLIDATED NET REVENUES

The table below shows a breakdown of total net revenues (dollars in thousands) generated by each of our business segments for the three months ended September 30, 2016 and 2015.

	Three Months Ended September 30,				
	Dollars		%	Percentage of Total Net Revenues	
	2016	2015	Change	2016	2015
OSUR	$ 17,133	$ 18,385	(7)%	53 %	61 %
DNAG	8,327	7,329	14	26	25
Net product revenues	25,460	25,714	(1)	79	86
Other	6,791	4,147	64	21	14
Net revenues	$ 32,251	$ 29,861	8 %	100 %	100 %

Consolidated net product revenues decreased 1% to $25.5 million in the third quarter of 2016 from $25.7 million in the comparable period of 2015. The absence of sales of our OraQuick® Ebola rapid antigen test, lower domestic sales of our OraQuick® HCV and HIV products, and lower sales of our cryosurgical systems and risk assessment products during the three months ended September 30, 2016, as compared to the three months ended September 30, 2015, were partially offset by higher sales of our molecular collection systems products and increased international sales of our OraQuick® HIV and HCV products. Other revenues in the third quarter of 2016 increased 64% to $6.8 million

compared to $4.1 million during the third quarter of 2015, largely due to higher exclusivity revenue recognized under our HCV co-promotion agreement with AbbVie.

Consolidated net revenues derived from products sold to customers outside of the United States were $5.9 million and $5.6 million, or 18% and 19% of total net revenues, in the third quarters of 2016 and 2015, 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.

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Net Revenues by Segment

OSUR Segment

The table below shows a breakdown of total net revenues (dollars in thousands) generated by our OSUR segment.

	Three Months Ended September 30,				
	Dollars		%	Percentage of Total Net Revenues	
Market	2016	2015	Change	2016	2015
Infectious disease testing	$ 10,412	$ 11,297	(8)%	43 %	50 %
Risk assessment testing	3,481	3,630	(4)	15	16
Cryosurgical systems	3,240	3,458	(6)	14	16
Net product revenues	17,133	18,385	(7)	72	82
Other	6,791	4,147	64	28	18
Net revenues	$ 23,924	$ 22,532	6 %	100 %	100 %

Infectious Disease Testing Market

Sales to the infectious disease testing market decreased 8% to $10.4 million in the third quarter of 2016 from $11.3 million in the third quarter of 2015. The absence of sales of our OraQuick® Ebola rapid antigen test and lower domestic sales of our OraQuick® HIV and HCV tests during the three months ended September 30, 2016 contributed to the decline in infectious disease testing revenues. Third quarter 2015 revenues included $482,000 in sales of our OraQuick® Ebola rapid antigen test to the CDC for field testing in Africa. There were no similar sales of this product in the third quarter of 2016. The decreases in sales of our domestic HIV and HCV products in the third quarter of 2016 were partially offset by higher sales of our OraQuick® HIV and HCV products internationally.

The table below shows a breakdown of our total net OraQuick® HIV and HCV product revenues (dollars in thousands) during the third quarters of 2016 and 2015.

	Three Months Ended September 30,		
Market	2016	2015	% Change
Domestic HIV	$ 4,858	$ 5,548	(12)%
International HIV	1,110	450	147
Domestic OTC HIV	1,311	1,642	(20)
Net HIV revenues	7,279	7,640	(5)
Domestic HCV	1,529	1,914	(20)
International HCV	1,293	957	35
Net HCV revenues	2,822	2,871	(2)

Net OraQuick® HIV and HCV product revenues	$ 10,101	$ 10,511	(4)%

Domestic OraQuick® HIV sales decreased 12% to $4.9 million for the three months ended September 30, 2016 from $5.5 million for the three months ended September 30, 2015. This decrease was primarily the result of customer ordering patterns and continued price and product competition. We anticipate that future domestic sales of our professional HIV product

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will continue to be negatively affected as a result of CDC testing guidelines recommending the use of competing fourth generation automated HIV immunoassays performed in a laboratory, changes in government funding and continued product and price competition. International sales of our OraQuick® HIV test during the third quarter of 2016 rose 147% to $1.1 million from $450,000 in the third quarter of 2015. This increase was largely due to higher sales in Africa as a result of the timing of orders and the implementation of a new testing program.

Sales of our OraQuick® In-Home HIV test decreased 20% to $1.3 million in the third quarter of 2016 from $1.6 million in the third quarter of 2015. Over-the-counter sales declined as a result of a buildup of inventory at retailers early in the third quarter of 2015 in advance of a price increase implemented on August 1, 2015. In addition, consumer purchases were down due to reduced promotions during the third quarter of 2016.

Domestic OraQuick® HCV sales decreased 20% to $1.5 million in the third quarter of 2016 from $1.9 million in the third quarter of 2015, primarily due to customer ordering patterns and a reduction in funding of certain projects. International OraQuick® HCV sales increased 35% to $1.3 million in the third quarter of 2016 from $957,000 in the third quarter of 2015, largely due to the expansion of our business in Asia, higher sales to a multi-national humanitarian organization primarily resulting from the timing of order placement by this organization, and a new testing program in Africa. Sales to the multi-national humanitarian organization can be variable, are influenced by its worldwide field activities, and therefore are difficult to predict.

We believe our OraQuick® HCV product represents an opportunity for future sales growth given the FDA approval of several new drug therapies for treating HCV. However, demand for our HCV product, particularly in the public health marketplace, may be 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. 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.

Risk Assessment Market

Commencing in 2016, we have combined the former substance abuse testing market and insurance risk assessment market categories under a single category referred to as the risk assessment market. We combined revenues for these markets because they are similar in nature and testing modalities. Revenues for 2015 have been combined in a similar manner for presentation purposes.

Sales to the risk assessment market decreased 4% to $3.5 million in the third quarter of 2016 from $3.6 million in the third quarter of 2015, primarily as a result of a decline in sales of our Q.E.D® alcohol test and our Intercept® drug testing system in the workplace testing market, partially offset by higher sales of Intercept® in the criminal justice market.

Cryosurgical Systems Market

Sales of our cryosurgical systems products (which includes sales in both the physicians office and OTC markets) decreased 6% to $3.2 million in the third quarter of 2016 from $3.5 million in the third quarter of 2015.

The table below shows a breakdown of our total net cryosurgical systems revenues (dollars in thousands) generated in each market during the third quarters of 2016 and 2015.

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Market	Three Months Ended September 30, 2016	2015	% Change
Domestic professional	$ 1,456	$ 1,600	(9)%
International professional	162	258	(37)
Domestic OTC	339	137	147
International OTC	1,283	1,463	(12)
Net cryosurgical systems revenues	$ 3,240	$ 3,458	(6)%

Sales of our Histofreezer® product to physicians offices in the United States decreased 9% to $1.5 million in the third quarter of 2016 from $1.6 million in the third quarter of 2015, primarily due to distributor ordering patterns. International sales of Histofreezer® decreased to $162,000 in the third quarter of 2016 from $258,000 in the same period of the prior year largely due to lower sales into Asia, partially offset by higher sales into Europe.

Sales of our private-label wart removal product in the U.S. retail market increased to $339,000 in the third quarter of 2016 from $137,000 in the third quarter of 2015 due to the launch of private-label products in two additional large pharmacy chains earlier this year.

Sales of our international OTC cryosurgical products during the third quarter of 2016 decreased 12% to $1.3 million compared to $1.5 million in the third quarter of 2015, largely due to lower sales into Europe.

Other revenues

Other revenues in the third quarter of 2016 increased 64% to $6.8 million from $4.1 million in the third quarter of 2015.

AbbVie exclusivity revenues increased 80% to $6.1 million in the third quarter of 2016 from $3.4 million in the third quarter of 2015 due to the early termination of our co-promotion agreement with AbbVie which we agreed to as of June 30, 2016. The agreement will now end on December 31, 2016, and as a result of the shortened term, the remaining associated deferred revenues which existed as of June 30, 2016 are being recognized ratably as revenue over the remaining months of 2016. Following the termination of our HCV co-promotion agreement on December 31, 2016, AbbVie will have no further financial obligations to us. Funding from BARDA remained relatively consistent at $677,000 in the third quarter of 2016 compared to $750,000 in the third quarter of 2015.

DNAG Segment

Molecular Collection Systems

Net molecular collection systems revenues increased 14% to $8.3 million in the third quarter of 2016 from $7.3 million in the third quarter of 2015. Sales of our Oragene® product in the commercial market rose 22% in the third quarter of 2016 compared to the third quarter of 2015, primarily as a result of the timing of purchases by one of our larger U.S. customers. Sales of our Oragene® product in the academic market decreased 12% in the third quarter of 2016 compared to the third quarter of 2015, largely due to ordering patterns of existing customers partially offset by the shipment of product to support a study on autism which commenced in 2016. The higher revenues in the third quarter of 2016 also included $362,000 in sales of our microbiome product compared to $137,000 in the same period of 2015. We believe interest in our microbiome product offering continues to grow with both new and existing customers.

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CONSOLIDATED OPERATING RESULTS

Consolidated gross margin was 70% for the third quarter of 2016 compared to 69% for the third quarter of 2015. Gross margin for the third quarter of 2016 increased primarily due to higher AbbVie exclusivity revenues in the third quarter of 2016 compared to the same period of 2015, partially offset by a less favorable product mix.

Consolidated operating income for the third quarter of 2016 was $6.1 million, a $4.6 million improvement from $1.5 million of operating income reported in the third quarter of 2015. The operating income for the third quarter of 2016 benefited from the increased AbbVie exclusivity revenues and lower sales and marketing costs.

OPERATING INCOME BY SEGMENT

OSUR Segment

OSUR s gross margin was 71% in the third quarter of 2016 compared to 69% in the third quarter of 2015. OSUR s gross margin in the third quarter of 2016 was positively impacted by the increase in other revenues, partially offset by an unfavorable product mix related to higher international sales.

Research and development expenses increased 14% to $2.3 million in the third quarter of 2016 from $2.0 million in the third quarter of 2015, largely due to higher supply costs associated with the development of our Ebola and Zika products. Sales and marketing expenses decreased 40% to $4.7 million in the third quarter of 2016 from $7.7 million in the third quarter of 2015. This decrease was primarily the result of lower detailing and other expenses associated with our OraQuick® HCV co-promotion agreement with AbbVie. General and administrative expenses increased 10% to $5.5 million in the third quarter of 2016 from $5.0 million in the third quarter of 2015 due to increased staffing and consulting costs partially offset by a decline in legal expense.

All of the above contributed to OSUR s third quarter 2016 operating income of $4.6 million, which included non-cash charges of $688,000 for depreciation and amortization and $1.4 million for stock-based compensation.

DNAG Segment

DNAG s gross margin was 69% in the third quarter of 2016 compared to 71% in the third quarter of 2015. This decline was attributable to an increase in lower margin sales experienced in the third quarter of 2016 when compared to the third quarter of 2015.

Research and development expenses increased 71% to $924,000 in the third quarter of 2016 from $542,000 in the third quarter of 2015, largely due to additional costs associated with field studies required to achieve World Health Organization (WHO) endorsement of our OMNIgene® Sputum product for tuberculosis. Sales and marketing expenses decreased 10% to $1.8 million in the third quarter of 2016 from $1.9 million in the third quarter of 2015 due to a decline in the allowance for uncollectible accounts and lower commission costs. General and administrative expenses decreased 24% to $1.4 million in the third quarter of 2016 compared to $1.9 million in the third quarter of 2015 primarily due lower legal, staffing, and property maintenance costs.

All of the above contributed to DNAG s third quarter 2016 operating income of $1.6 million, which included non-cash charges of $746,000 for depreciation and amortization and $134,000 for stock-based compensation.

CONSOLIDATED INCOME TAXES

We continue to believe the full valuation allowance established in 2008 against OSUR s total U.S. deferred tax asset is appropriate as the facts and circumstances necessitating the allowance have not changed. For the three months ended September 30, 2016, state income tax expense of $200,000 was recorded compared to $0 in the three months ended September 30, 2015. Canadian income tax expense of $200,000 and $147,000 was recorded in the third quarters of 2016 and 2015, respectively.

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Nine months ended September 30, 2016 compared to September 30, 2015

CONSOLIDATED NET REVENUES

The table below shows a breakdown of total net revenues (dollars in thousands) generated by each of our business segments for the nine months ended September 30, 2016 and 2015.

	Nine Months Ended September 30,				
	Dollars		%	Percentage of Total Net Revenues	
	2016	2015	Change	2016	2015
OSUR	$ 54,637	$ 53,644	2%	59%	62%
DNAG	23,649	22,148	7	25	25
Net product revenues	78,286	75,792	3	84	87
Other	14,413	11,545	25	16	13
Net revenues	$ 92,699	$ 87,337	6%	100%	100%

Consolidated net product revenues increased 3% to $78.3 million in the first nine months of 2016 from $75.8 million in the comparable period of 2015. Higher international sales of our OraQuick® HIV and HCV products and higher sales of our molecular collection systems and cryosurgical systems products in the nine months ended September 30, 2016 were partially offset by lower domestic sales of our OraQuick® HIV product, lower sales of our risk assessment products, and the absence of sales of our OraQuick® Ebola Rapid Antigen test in the nine months ended September 30, 2016. Other revenues in the first nine months of 2016 increased 25% to $14.4 million from $11.5 million in the first nine months of 2015 largely due to higher exclusivity revenue recognized under our HCV co-promotion agreement with AbbVie.

Consolidated net revenues derived from products sold to customers outside of the United States were $20.2 million and $17.6 million, or 22% and 20% of total net revenues, during the nine months ended September 30, 2016 and 2015, 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.

	Nine Months Ended September 30,				
	Dollars		%	Percentage of Total Net Revenues	
Market	2016	2015	Change	2016	2015
Infectious disease testing	$ 34,729	$ 34,585	0%	50%	53%

Risk assessment testing	9,746	10,103	(4)	14	16
Cryosurgical systems	10,162	8,956	13	15	13
Net product revenues	54,637	53,644	2	79	82
Other	14,413	11,545	25	21	18
Net revenues	$ 69,050	$ 65,189	6%	100%	100%

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Infectious Disease Testing Market

Sales to the infectious disease testing market remained relatively consistent at $34.7 million in the first nine months of 2016 compared to $34.6 million in the first nine months of 2015. Increased sales of our OraQuick® HCV tests into the domestic and international markets and higher international sales of our OraQuick® HIV tests were partially offset by lower sales of our OraQuick® HIV test domestically and the absence of sales of our OraQuick® Ebola Rapid Antigen test during the nine months ended September 30, 2016. Revenues for the first nine months of 2015 included $1.2 million in sales of our OraQuick® Ebola rapid antigen test to the CDC for field testing in Africa. There were no similar sales of this product in 2016.

The table below shows a breakdown of our total net OraQuick® HIV and HCV product revenues (dollars in thousands) during the nine months ended September 30, 2016 and 2015.

	Nine Months Ended September 30,		
Market	**2016**	**2015**	**% Change**
Domestic HIV	$ 16,446	$ 18,147	(9)%
International HIV	3,934	1,995	97
Domestic OTC HIV	4,574	4,923	(7)
Net HIV revenues	24,954	25,065	0
Domestic HCV	5,218	4,803	9
International HCV	3,722	2,577	44
Net HCV revenues	8,940	7,380	21
Net OraQuick® revenues	$ 33,894	$ 32,445	4 %

Domestic OraQuick® HIV sales decreased 9% to $16.4 million for the nine months ended September 30, 2016 from $18.1 million for the nine months ended September 30, 2015. This decrease was primarily the result of the continued loss of sales to competing fourth generation automated HIV immunoassays performed in a laboratory, as recommended under testing guidelines issued by the CDC, the loss of sales to point-of-care HIV tests perceived to be more sensitive, and reduced program funding. We anticipate that future sales of our professional HIV product will continue to be negatively affected as a result of the CDC s testing guidelines, changes in government funding and continued product and price competition. International sales of our OraQuick® HIV test during the first nine months of 2016 increased 97% to $3.9 million from $2.0 million during the first nine months of 2015. This increase is largely due to the shipment of product in support of a new HIV self-testing program in Africa coupled with higher sales in Europe as a result of the addition of a new distributor in Russia, and increased sales in Asia due to a new military testing project.

Sales of our OraQuick® In-Home HIV test decreased 7% to $4.6 million for the first nine months of 2016 from $4.9 million for the first nine months of 2015. OTC sales declined primarily as a result of a reduction in promotions run in 2016 as compared to 2015.

Domestic OraQuick® HCV sales increased 9% to $5.2 million in the first nine months of 2016 from $4.8 million in the first nine months of 2015, primarily due to the expansion of existing HCV testing programs and the addition of new programs in the public health market. International OraQuick® HCV sales increased 44% to $3.7 million in the first nine months of 2016 from $2.6 million in the first nine months of 2015, largely due to the expansion of our business in Asia, higher sales to a multi-national humanitarian organization primarily resulting from the timing of order placement by this organization, and increased sales in Africa. Sales to the multi-national humanitarian organization can be variable, are influenced by its worldwide field activities, and therefore are difficult to predict.

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We believe our OraQuick® HCV product represents an opportunity for future sales growth given the FDA approval of several new drug therapies for treating HCV. However, demand for our HCV product, particularly in the public health marketplace, may be 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. 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.

Risk Assessment Market

Commencing in 2016, we have combined the former substance abuse testing market and insurance risk assessment market categories under a single category referred to as the risk assessment market. We combined revenues for these markets because they are similar in nature and testing modalities. Revenues for 2015 have been combined in a similar manner for presentation purposes.

Sales to the risk assessment market decreased 4% to $9.7 million for the nine months ended September 30, 2016 from $10.1 million for the nine months ended September 30, 2015, primarily as a result of a decline in sales of our OraSure® oral fluid collection device into the domestic life insurance market.

Cryosurgical Systems Market

Sales of our cryosurgical systems products (which includes sales in both the physicians office and OTC markets) increased 13% to $10.2 million in the first nine months of 2016, compared to $8.9 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 nine months ended September 30, 2016 and 2015.

	Nine Months Ended September 30,		
Market	**2016**	**2015**	**% Change**
Domestic professional	$ 4,155	$ 3,268	27 %
International professional	607	757	(20)
Domestic OTC	1,062	300	254
International OTC	4,338	4,631	(6)
Net cryosurgical systems revenues	$ 10,162	$ 8,956	13 %

Sales of our Histofreezer® product to physicians offices in the United States increased 27% to $4.2 million in the first nine months of 2016 from $3.3 million in the first nine months of 2015, primarily due to the recovery of business previously lost to competition from private label brands, as well the initiation of a distributor expansion strategy. International sales of Histofreezer® decreased 20% to $607,000 in the nine months ended September 30, 2016 from $757,000 in the same period of the prior year, primarily due to lower sales in Asia.

Sales of our private-label wart removal product in the U.S. retail market increased to $1.1 million in the first nine months of 2016 from $300,000 in the first nine months of 2015, due to the launch of private-label products in two additional large pharmacy chains earlier this year.

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Sales of our international OTC cryosurgical products during the first nine months of 2016 decreased 6% to $4.3 million compared to $4.6 million in the first nine months of 2015, largely due to lower sales into Europe partially offset by higher sales in Latin America.

Other revenues

Other revenues in the first nine months of 2016 increased 25% to $14.4 million from $11.5 million in the first nine months of 2015.

AbbVie exclusivity revenues increased 27% to $12.8 million in the first nine months of 2016 from $10.0 million in the first nine months of 2015 due to the early termination of our co-promotion agreement with AbbVie which we agreed to as of June 30, 2016. The agreement will now end on December 31, 2016, and as a result of the shortened term the remaining associated deferred revenues balances which existed as of June 30, 2016 are being recognized ratably into revenue over the remaining months of 2016. Following the termination of our HCV co-promotion agreement with AbbVie on December 31, 2016, AbbVie will have no further financial obligations to us. Funding from BARDA remained relatively unchanged at $1.6 million in the first nine-months of 2016 compared to $1.5 million in the first nine months of 2015.

DNAG Segment

Molecular Collection Systems

Net molecular collection systems revenues increased 7% to $23.6 million in the first nine months of 2016 from $22.1 million in the first nine months of 2015. Sales of our Oragene® product in the academic market rose 6% in the first nine months of 2016 compared to the first nine months of 2015, due to the shipment of product to support a study on the epidemiology of aging and a study on autism partially offset by the impact of ordering patterns by other customers. Sales of our Oragene® product in the commercial market increased 4% in the first nine months of 2016 compared to the first nine months of 2015, primarily as a result of the ordering patterns of one of our larger U.S. commercial customers and sales to new customers, partially offset by the loss of two U.S. customers that filed for bankruptcy protection. These customers contributed approximately $2.9 million in sales during the first nine months of 2015. The Company has no unreserved collection exposure related to these two customers. Sales in the first nine months of 2016 also included $742,000 in sales of our microbiome product compared to $258,000 in the same period of 2015. We believe interest in our microbiome product offering continues to grow with both new and existing customers.

CONSOLIDATED OPERATING RESULTS

Consolidated gross margin was 69% for the first nine months of 2016 compared to 67% for the first nine months of 2015. Gross margin for 2016 increased primarily due to lower scrap and spoilage expenses and higher AbbVie exclusivity revenues, partially offset by an unfavorable product mix.

Consolidated operating income for the first nine months of 2016 was $13.2 million, a $9.2 million increase from the $4.0 million of operating income reported in the first nine months of 2015. The current period operating income benefited from higher revenues, improved gross margins and lower sales and marketing and research and development costs, partially offset by higher general and administrative expenses.

OPERATING INCOME BY SEGMENT

OSUR Segment

OSUR s gross margin was 69% in the first nine months of 2016 compared to 65% in the first nine months of 2015. OSUR s gross margin in 2016 was positively impacted by lower scrap and spoilage costs and higher AbbVie exclusivity revenues.

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Research and development expenses decreased 9% to $6.4 million in the first nine months of 2016 from $7.0 million in the first nine months of 2015. During the first quarter of 2015, we conducted clinical studies related to the development of our fully-automated high-throughput drugs-of-abuse assays. In addition, we incurred certain program expenses related to the co-development agreement for these assays. These costs did not recur in 2016 and were partially offset by the additional costs associated with hiring our new Senior Vice President, Research and Development and Chief Science Officer and increased lab supply expenses associated with the development of our Zika and Ebola products. Sales and marketing expenses decreased 22% to $16.1 million in the first nine months of 2016 from $20.7 million in the first nine months of 2015. This decrease was primarily the result of lower detailing and other expenses associated with our OraQuick® HCV co-promotion agreement with AbbVie as well as lower staffing costs. General and administrative expenses increased 7% to $16.1 million in the first nine months of 2016 compared to $15.0 million in the first nine months of 2015 largely due to higher consulting and staffing expenses, partially offset by a decrease in legal costs.

All of the above contributed to OSUR s operating income of $9.1 million for the first nine months of 2016, which included non-cash charges of $2.0 million for depreciation and amortization and $4.0 million for stock-based compensation.

DNAG Segment

DNAG s gross margin was 70% in the first nine months of 2016 compared to 71% in the first nine months of 2015. This decline was attributable to an increase in lower margin sales experienced in the first nine months of 2016 when compared to the same period in 2015.

Research and development expenses increased 11% to $2.2 million in the first nine months of 2016 from $1.9 million in the first nine months of 2015 largely due to higher costs associated with field studies required to achieve WHO endorsement of our OMNIgene® Sputum product for tuberculosis. Sales and marketing expenses also increased 11% to $6.4 million in the first nine months of 2016 from $5.8 million in the first nine months of 2015 due to higher staffing costs and an increase in our allowance for uncollectible accounts. General and administrative expenses decreased 3% to $3.8 million in the first nine months of 2016 compared to $3.9 million in the first nine months of 2015 largely due to lower staffing and property costs, partially offset by an increase in legal expenses.

All of the above contributed to DNAG s operating income of $4.1 million for the first nine months of 2016, which included non-cash charges of $2.2 million for depreciation and amortization and $399,000 for stock-based compensation.

CONSOLIDATED INCOME TAXES

We continue to believe the full valuation allowance established in 2008 against OSUR s total U.S. deferred tax asset is appropriate as the facts and circumstances necessitating the allowance have not changed. For the nine months ended September 30, 2016, state income tax expense of $250,000 was recorded compared to $0 in the nine months ended September 30, 2015. Canadian income tax expense of $384,000 and $810,000 was recorded in the first nine months of 2016 and 2015, respectively.

Liquidity and Capital Resources

	September 30,	**December 31,**

	2016	2015
	(In thousands)	
Cash and cash equivalents	$ 111,726	$ 94,094
Short-term investments	7,618	7,225
Working capital	128,768	111,480

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Our cash, cash equivalents, and short-term investment balances increased to $119.3 million at September 30, 2016 from $101.3 million at December 31, 2015. Our working capital increased to $128.8 million at September 30, 2016 from $111.5 million at December 31, 2015.

During the first nine months of 2016, we generated $23.4 million in cash from operating activities. Our net income of $12.5 million benefitted from non-cash stock-based compensation expense of $4.4 million and depreciation and amortization expense of $4.2 million. Additional sources of cash included a decrease in accounts receivable of $3.8 million resulting from the collection of outstanding balances due at the end of 2015, a decrease in inventory balances of $1.2 million largely related to lower raw material costs, and a decrease in prepaid expenses and other assets of $1.2 million largely associated with the new Canadian office building lease. Uses of cash in operating activities during the period included an increase in our restricted cash balance of $1.8 million associated with the purchase of certificates of deposit to collateralize standby letters of credit, a decrease in deferred revenues of $1.8 million related to the ratable recognition into revenue of previously deferred exclusivity payments received from AbbVie, and a decrease in accounts payable.

Net cash used in investing activities was $3.5 million for the nine months ended September 30, 2016, which reflects $22.9 million used to purchase short-term investments and $3.5 million to acquire property and equipment, partially offset by $22.9 million in proceeds from the maturities of short-term investments.

Net cash used in financing activities was $2.8 million for the nine months ended September 30, 2016, which resulted from the use of $2.7 million to repurchase shares under our previously authorized stock repurchase plan, $651,000 used for the repurchase of common stock to satisfy withholding taxes related to the vesting of restricted shares, and $367,000 paid for debt issue costs associated with our new credit facility, partially offset by $894,000 in proceeds received from the exercise of stock options.

On September 30, 2016, we entered into a credit agreement (the Credit Agreement) with Wells Fargo Bank, National Association. The Credit Agreement provides for revolving extensions of credit in an initial aggregate amount of up to $10,000,000 (inclusive of a letter of credit subfacility of $2,500,000), with an option to request, prior to the second anniversary of the closing date, that lenders, at their election, provide up to $5,000,000 of additional revolving commitments. Obligations under the Credit Agreement are secured by a first priority security interest in certain eligible accounts receivable, 65% of the equity of our subsidiary, DNAG, and certain related assets. There were no borrowings outstanding at September 30, 2016.

Borrowings under the Credit Agreement are subject to compliance with borrowing base limitations tied to eligibility of accounts receivable. Interest under the Credit Agreement is payable at the London Interbank Offered Rate for one, two, three or six-month loans, as selected by the Company, plus 2.50% per annum. The Credit Agreement will be subject to an unused line fee of 0.375% per annum on the unused portion of the commitment under the Credit Agreement during the revolving period. The maturity date of the Credit Agreement is September 30, 2019.

In connection with the Credit Agreement, under certain circumstances, we must comply with a minimum fixed charge coverage ratio of 1.10 to 1.00, measured as of the last day of each fiscal month and for the twelve-fiscal month period ending on such date. As of September 30, 2016, we were in compliance with all applicable covenants under the Credit Agreement.

Our current cash and cash equivalents balance and available borrowing capacity is expected to be sufficient to fund our current operating and capital needs for the foreseeable future. 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 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.

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Summary of Contractual Obligations

A summary of our obligations to make future payments under contracts existing at December 31, 2015 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, 2015. As of September 30, 2016, except for our new Credit Agreement, 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 Annual Report on Form 10-K for the year ended December 31, 2015 filed with the SEC. During the first nine months of 2016, there were no material changes in our critical accounting policies.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

As of September 30, 2016, we did not have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. Sales denominated in foreign currencies comprised 5.1% of our total revenues for the nine months ended September 30, 2016. We do have foreign currency exchange risk related to our operating subsidiary in Canada. While the majority of this subsidiary s revenues are recorded in U.S. dollars, almost all of this subsidiary s operating expenses are denominated in Canadian dollars. Fluctuations in the exchange rate between the U.S. dollar and the Canadian dollar could affect year-to-year comparability of operating results and cash flows. Our Canadian subsidiary had net assets, subject to translation, of $61.4 million CDN ($46.8 million USD), which are included in the Company s consolidated balance sheet as of September 30, 2016. A 10% unfavorable change in the Canadian-to-U.S. dollar exchange rate would have decreased our comprehensive income by $4.7 million in the nine months ended September 30, 2016.

Item 4. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures. The Company s management, with the participation of the Company s Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company s

disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) as of September 30, 2016. Based on that evaluation, the Company s management, including such officers, concluded that the Company s disclosure controls and procedures were effective as of September 30, 2016 to provide reasonable assurance that material information required to be disclosed by the Company in the reports that it files or submits 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.

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(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 September 30, 2016 that has materially affected, or is reasonably likely to materially affect, the Company s internal control over financial reporting.

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PART II. OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

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, individually or in the aggregate, to have a material adverse effect on our future financial position or results of operations.

In May 2015, our subsidiary DNAG filed a complaint in the United States District Court for the District of Delaware against Ancestry.com DNA LLC (Ancestry) relating to the manufacture and sale by Ancestry of its oral fluid DNA collection device (the Ancestry Device). Ancestry previously purchased DNAG s patented oral fluid DNA collection devices. The complaint alleges that the manufacture and sale by Ancestry of the Ancestry Device infringes U.S. Patent No. 8,221,381 B2, which is owned by DNAG. In addition, the complaint alleges that Ancestry has breached the terms of agreements under which Ancestry previously purchased DNAG products. The complaint also includes an action to quiet title to the Ancestry Device and related patent applications. DNAG is requesting the court to grant injunctive relief and damages. Ancestry has filed counterclaims seeking a declaration of non-infringement, invalidity, and to quiet title to its patent applications. The case is currently in the discovery stage. DNAG amended its complaint to add Lanham Act claims against Ancestry, alleging that Ancestry falsely labeled the Ancestry Device as being Made in the USA.

On October 20, 2015, Ancestry filed with the United States Patent and Trademark Office (USPTO) a Petition for *Inter Partes* Review (IPR) of some, but not all, claims of U.S. Patent No. 8,221,381 B2. On April 8, 2016, the USPTO instituted an IPR of some, but not all of the claims raised in Ancestry s petition. A final decision from the USPTO is expected in April 2017. On June 3, 2016, Ancestry filed a second Petition for IPR of some, but not all, claims of U.S. Patent No. 8,221,381 B2. The USPTO has not yet decided whether to institute the second IPR.

In July 2015, DNAG filed a complaint in the United States District Court for the District of Delaware against Spectrum DNA, Spectrum Solutions L.L.C. and Spectrum Packaging L.L.C. (collectively Spectrum) relating to the manufacture and sale by Spectrum of an oral fluid DNA collection device (the Spectrum Device). We believe the Spectrum Device is the same as the Ancestry device mentioned above and that Spectrum is the manufacturer of the Ancestry Device for Ancestry. The complaint alleges that the manufacture and sale by Spectrum of the Spectrum Device infringes U.S. patent number 8,221,381 B-2, which is owned by DNAG. DNAG is requesting the court to grant injunctive relief and damages. Spectrum alleges that the Delaware District Court lacks jurisdiction over Spectrum. The Court is now considering a fully-briefed motion to dismiss for lack of personal jurisdiction.

On June 20, 2016, DNAG filed a complaint in the United States District Court for the Southern District of California against Spectrum relating to the manufacture and sale of the Spectrum Device. The complaint alleges that the manufacture and sale by Spectrum of the Spectrum Device infringes U.S. Patent No. 9,207,164, which is owned by DNAG. DNAG is requesting the court to grant injunctive relief and damages. On June 21, 2016, DNAG filed a motion for preliminary injunction. On July 21, 2016, Spectrum filed a motion to stay the case pending resolution by the PTO of an Petition for IPR of U.S. Patent No. 9,207,164, which was filed by Ancestry in July 2016. The USPTO has not yet decided whether to institute the IPR. On October 6, 2016, the Court issued an order denying DNAG s motion for preliminary injunction and on October 7, 2016, the Court issued an order staying the case pending resolution of the IPR of U.S. Patent No. 9,207,164.

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, 2015.

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Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS
None

Item 3. DEFAULTS UPON SENIOR SECURITIES
None

ITEM 4. MINE SAFETY DISCLOSURES
Not applicable

ITEM 5. OTHER INFORMATION
None

Item 6. EXHIBITS
Exhibits are listed on the Exhibit Index following the signature page of this Report.

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SIGNATURES

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

ORASURE TECHNOLOGIES, INC.

Date: November 8, 2016

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

Date: November 8, 2016

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

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EXHIBIT INDEX

Exhibit Number	Exhibit
10	Credit Agreement between Wells Fargo Bank, National Association, and OraSure Technologies, Inc. dated as of September 30, 2016.
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