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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 June 30, 2017.

OR

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

For the transition period from _____ to _____.

Commission File Number 001-16537

ORASURE TECHNOLOGIES, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**36-4370966**
(State or Other Jurisdiction of Incorporation or Organization)	**(IRS Employer Identification No.)**
220 East First Street, Bethlehem, Pennsylvania	**18015**
(Address of Principal Executive Offices)	**(Zip code)**

(610) 882-1820
(Registrant's Telephone Number, Including Area Code)

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

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

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

Large accelerated filer	☐		
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☐
Accelerated filer	☒	Emerging growth company	☐

If an emerging growth company, indicate by check mark if the Registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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 August 3, 2017: 59,459,438 shares.

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PART I. FINANCIAL INFORMATION

PART II. OTHER INFORMATION

Item 1. FINANCIAL STATEMENTS

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(Unaudited)
(in thousands, except per share amounts)

	June 30, 2017	December 31, 2016
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 104,872	$ 107,959
Restricted cash	1,831	1,831
Short-term investments	55,354	11,160
Accounts receivable, net of allowance for doubtful accounts of $637 and $484	26,731	19,827
Inventories	14,548	11,799
Prepaid expenses	1,336	1,722
Other current assets	1,027	2,143
Total current assets	205,699	156,441
PROPERTY AND EQUIPMENT, net	20,291	20,033
INTANGIBLE ASSETS, net	9,343	10,337
GOODWILL	19,482	18,793
OTHER ASSETS	3,536	2,331
	$ 258,351	$ 207,935
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 9,623	$ 4,633
Deferred revenue	1,477	1,388
Accrued expenses	12,092	11,314
Total current liabilities	23,192	17,335
OTHER LIABILITIES	3,538	2,304
DEFERRED INCOME TAXES	2,209	2,446
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, 59,330 and 56,001 shares issued and outstanding	—	—
Additional paid-in capital	373,964	350,528
Accumulated other comprehensive loss	(11,963)	(14,220)
Accumulated deficit	(132,589)	(150,458)
Total stockholders' equity	229,412	185,850
	$ 258,351	$ 207,935

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF INCOME
(Unaudited)
(in thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
NET REVENUES:				
Product	$ 39,132	$ 27,582	$ 70,614	$ 52,827
Other	1,044	3,777	2,108	7,621
	40,176	31,359	72,722	60,448
COST OF PRODUCTS SOLD	14,699	10,274	26,935	19,050
Gross profit	25,477	21,085	45,787	41,398
OPERATING EXPENSES:				
Research and development	3,338	2,985	6,308	5,351
Sales and marketing	7,502	7,397	14,379	16,103
General and administrative	7,750	6,354	14,842	12,896
Gain on litigation settlement	—	—	(12,500)	—
	18,590	16,736	23,029	34,350
Operating income	6,887	4,349	22,758	7,048
OTHER INCOME (EXPENSE)	96	(340)	563	(532)
Income before income taxes	6,983	4,009	23,321	6,516
INCOME TAX EXPENSE	1,555	173	5,452	234
NET INCOME	$ 5,428	$ 3,836	$ 17,869	$ 6,282
EARNINGS PER SHARE:				
BASIC	$ 0.09	$ 0.07	$ 0.31	$ 0.11
DILUTED	$ 0.09	$ 0.07	$ 0.30	$ 0.11
SHARES USED IN COMPUTING EARNINGS PER SHARE:				
BASIC	58,478	55,543	57,708	55,497
DILUTED	60,728	56,208	59,755	56,144

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(Unaudited)
(in thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
NET INCOME	$ 5,428	$ 3,836	$ 17,869	$ 6,282
OTHER COMPREHENSIVE INCOME (LOSS)				
Currency translation adjustments	1,862	363	2,312	3,230
Unrealized loss on marketable securities	(55)	—	(55)	—
COMPREHENSIVE INCOME	$ 7,235	$ 4,199	$ 20,126	$ 9,512

See accompanying notes to the consolidated financial statements.

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

	Six Months Ended June 30,	
	2017	2016
OPERATING ACTIVITIES:		
Net income	$ 17,869	$ 6,282
Adjustments to reconcile net income to net cash provided by operating activities:		
Stock-based compensation	3,631	2,942
Depreciation and amortization	2,891	2,738
Unrealized foreign currency loss	178	115
Deferred income taxes	(322)	(44)
Changes in assets and liabilities		
Accounts receivable	(6,923)	893
Inventories	(2,680)	1,949
Prepaid expenses and other assets	1,525	17
Accounts payable	4,739	(782)
Deferred revenue	83	4,083
Accrued expenses and other liabilities	713	(1,452)
Net cash provided by operating activities	21,704	16,741
INVESTING ACTIVITIES:		
Purchases of short-term investments	(62,233)	(15,335)
Proceeds from maturities and redemptions of short-term investments	18,585	15,335
Purchases of property and equipment	(1,567)	(2,729)
Net cash used in investing activities	(45,215)	(2,729)
FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	21,014	209
Repurchase of common stock	(1,209)	(3,311)
Net cash provided by (used in) financing activities	19,805	(3,102)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	619	697
NET (DECREASE) INCREASE IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH	(3,087)	11,607
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH, BEGINNING OF PERIOD	109,790	94,094
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH, END OF PERIOD	$ 106,703	$ 105,701
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for income taxes	$ 4,325	$ 556
Noncash investing activities (accrued property and equipment purchases)	$ 412	$ 287

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
Notes to the Consolidated Financial Statements
(Unaudited)
(in thousands, except per share amounts, unless otherwise indicated)

1. The Company

We develop, manufacture, market and sell 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, a rapid point-of-care HIV in-home test approved for use in the domestic consumer retail or over-the-counter ("OTC") market and a rapid point-of-care HIV self-test used in certain international markets. 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" mean 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, 2016. Results of operations for the three and six months ended June 30, 2017 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, accruals, and performance- based compensation expense, 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 and corporate bonds 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.

The following is a summary of our available-for-sale securities at June 30, 2017 and December 31, 2016:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
June 30, 2017				
Guaranteed investment certificates	$ 19,281	$ —	$ —	$ 19,281
Corporate bonds	36,128	—	(55)	36,073
Total available-for-sale securities	$ 55,409	$ —	$ (55)	$ 55,354
December 31, 2016				
Guaranteed investment certificates	$ 11,160	$ —	$ —	$ 11,160
Total available-for-sale securities	$ 11,160	$ —	$ —	$ 11,160
At June 30, 2017 maturities of our available-for-sale securities were as follows:				
Less than one year	$ 55,409	$ —	$ (55)	$ 55,354

Fair Value of Financial Instruments. As of June 30, 2017 and December 31, 2016, the carrying values of cash and cash equivalents, restricted cash, 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).

All of our available-for-sale securities are measured as Level 1 instruments as of June 30, 2017 and December 31, 2016.

Included in cash and cash equivalents at June 30, 2017 and December 31, 2016, was $60,987 and $83,704 invested in government money market funds. These funds hold investments in government securities and are measured as 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 June 30, 2017 and December 31, 2016 was $3,220 and $1,980, 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.

In 2017, we purchased certificates of deposit (“CDs”) from a commercial bank. The CDs bear interest at rates ranging from 0.68% to 0.84% 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 and net realizable value determined on a first-in, first-out basis and are comprised of the following:

	June 30, 2017	December 31, 2016
Raw materials	$ 5,410	$ 5,399
Work in process	1,305	1,034
Finished goods	7,833	5,366
	$ 14,548	$ 11,799

Property and Equipment. Property and equipment are stated at cost. Additions or improvements are capitalized, while repairs and maintenance are charged to expense. Depreciation and amortization are provided using the straight-line method over the estimated useful lives of the related assets. Buildings are depreciated over twenty to forty years, while computer equipment, machinery and equipment, and furniture and fixtures are depreciated over two to ten years. Building improvements are amortized over their estimated useful lives. When assets are sold, 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 June 30, 2017 and December 31, 2016 was $37,709 and $36,067, respectively.

Intangible Assets. Intangible assets consist of a customer list, patents and product rights, acquired technology and tradenames. Patents and product rights consist of costs associated with the acquisition of patents, licenses, and product distribution rights. Intangible assets are amortized using the straight-line method over their estimated useful lives of seven to fifteen years. Accumulated amortization of intangible assets as of June 30, 2017 and December 31, 2016 was $16,928 and $15,197, respectively. The change in intangibles from $10,337 as of December 31, 2016 to $9,343 as of June 30, 2017 is a result of $1,295 in amortization expense and $301 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 carrying value of a reporting unit is greater than its fair value, then we would be required to recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value, provided the impairment charge does not exceed the total amount of goodwill allocated to the reporting unit.

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 June 30, 2017, we believe no indicators of impairment exist.

The change in goodwill from $18,793 as of December 31, 2016 to $19,482 as of June 30, 2017 is a result of foreign currency translation gain.

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 are at contractual rates and 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.

In June 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. On June 30, 2016, we mutually agreed to terminate our agreement with AbbVie effective December 31, 2016. Following the termination of the agreement, AbbVie was relieved of its co-promotion obligations, including its obligation to detail the OraQuick® HCV Rapid Test into physician offices, and has no further financial obligations to us. We are no longer obligated to compensate AbbVie for product detailing activities and are free to pursue arrangements with other pharmaceutical companies to market and promote our OraQuick® HCV Rapid Antibody Test in the U.S. Accordingly, during the second quarter and first six months of 2017 we did not record any revenue from this co-promotion agreement. During the second quarter and first six months of 2016, $3,360 and $6,722, respectively, of exclusivity revenue was recognized and 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 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 second quarter and first six months of 2017, $454 and $874, respectively, was recognized in connection with this grant. During the second quarter and first six months of 2016, $417 and $899 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 additional $9,600 to fund the evaluation of additional product enhancements, and clinical and regulatory activities. In May 2017, BARDA exercised an option to provide $2,600 in additional funding for our rapid Zika test. Funding received under this contract is recorded as other revenue in our consolidated statements of income as the activities are being performed and the related costs are incurred. During the second quarter and first six months of 2017, $590 and $1,234, respectively, 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 June 30, 2017 and December 31, 2016, the reserve for sales returns and allowances was $183 and $217, 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 June 30, 2017 and December 31, 2016 was comprised of customer prepayments of $1,477 and $1,388, respectively.

Customer and Vendor Concentrations. One of our customers accounted for 17% and 15% of our accounts receivable as of June 30, 2017 and December 31, 2016, respectively. Another customer accounted for 16% of our accounts receivable as of June 30, 2017. One of our customers accounted for approximately 20% and 15% of our net consolidated revenues for the three and six months ended June 30, 2017, respectively. Another customer accounted for 10% of our net consolidated revenues for the three months ended June 30, 2017. For the three and six months ended June 30, 2016, one of our customers accounted for approximately 11% of our net consolidated revenues, 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 or 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Net income	$ 5,428	$ 3,836	$17,869	$ 6,282
Weighted average shares of common stock outstanding:				
Basic	58,478	55,543	57,708	55,497
Dilutive effect of stock options, restricted stock, and performance units	2,250	665	2,047	647
Diluted	60,728	56,208	59,755	56,144
Earnings per share:				
Basic	$ 0.09	$ 0.07	$ 0.31	$ 0.11
Diluted	$ 0.09	$ 0.07	$ 0.30	$ 0.11

For the three-month periods ended June 30, 2017 and 2016, outstanding common stock options, unvested restricted stock, and unvested performance units representing 40 and 2,459 shares, respectively, were excluded from the computation of diluted earnings per share as their inclusion would have been anti-dilutive. For the six months ended June 30, 2017 and 2016, outstanding common stock options, unvested restricted stock and unvested performance units representing 353 and 3,191 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 losses resulting from foreign currency transactions that are included in other income (expense) in our consolidated statements of income were $418 and $302 for the three months ended June 30, 2017 and 2016, respectively. Net foreign exchange losses were $618 and $648 for the six months ended June 30, 2017 and 2016, 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 $2,312 and $3,230 currency translation adjustments recorded in the first six months of 2017 and 2016, respectively, are largely the result of the translation of our Canadian operation's balance sheets into U.S. dollars. Other comprehensive income at June 30, 2017 also includes net unrealized losses on marketable securities of $55.

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, at which point we plan to adopt the standard.

The FASB allows two adoption methods under ASU 2014-09. We plan to adopt the standard using the "modified retrospective method." Under that method, we will apply the rules to all contracts existing as of January 1, 2018, recognizing in beginning retained earnings an adjustment for the cumulative effective of the change and providing additional disclosures comparing results to previous accounting standards.

Upon initial evaluation, we believe the key changes in the standard that impact our revenue recognition relate to the allocation of the transaction price to performance obligations related to our device and lab services for drug testing. This revenue stream amounts to less than 1% of total consolidated revenues. We will continue to evaluate the impact that the adoption of ASU 2014-09 will have on our consolidated financial statements and related disclosures, but do not anticipate the adoption will have a material impact on our financial results.

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. We adopted ASU 2015-11 on January 1, 2017. The adoption of this standard did not have a material impact 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. We adopted ASU 2016-09 on January 1, 2017. Since we have a full valuation allowance against our U.S. net deferred tax assets, the adoption of this standard for recognition of tax effects of deductions for employee share awards in excess of compensation costs ("windfall") did not have a material impact on our consolidated financial statements and related disclosures. See Note 6 – Income Taxes, for additional information. Should our full valuation allowance be reversed in future periods, the adoption of this new guidance will introduce more volatility in the calculation of our effective tax rate, depending on the Company's share price at exercise or vesting of share-based awards as compared to grant date. The other provisions of ASU 2016-09 did not have a material impact on our consolidated financial statements and related disclosures.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*, which provides guidance related to cash flows presentation and is effective for annual reporting periods beginning after December 15, 2017, subject to early adoption. The majority of the guidance in ASU 2016-15 is consistent with our current cash flow classifications and we do not expect the adoption of this standard will have a material impact on our consolidated financial statements.

In January 2017, the FASB issued ASU 2017-04, *Intangibles-Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment*, which requires an entity to no longer perform a hypothetical purchase price allocation to measure goodwill impairment. Instead, impairment will be measured using the difference between the carrying amount and the fair value of the reporting unit. This update will be effective for annual and interim periods in fiscal years beginning after December 15, 2019. Early adoption is permitted. We adopted ASU 2017-04 in the second quarter of 2017. The adoption of this standard did not have a material impact on our consolidated financial statements and related disclosures.

3. Accrued Expenses

	June 30, 2017	December 31, 2016
Payroll and related benefits	$ 6,877	$ 7,685
Income taxes payable (receivable)	1,463	(39)
Professional fees	804	982
Royalties	761	715
Other	2,187	1,971
	$ 12,092	$ 11,314

4. Credit Facility

On September 30, 2016, we entered into a credit agreement (the "Credit Agreement") with a commercial bank. 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 the lender, at its 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 under the Credit Agreement at June 30, 2017 and December 31, 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 is 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 June 30, 2017 and December 31, 2016, we were in compliance with all applicable covenants in the Credit Agreement.

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. We recognize compensation expense related to performance-based restricted stock units based on assumptions as to what percentage of each performance target will be achieved. We evaluate these target assumptions on a quarterly basis and adjust compensation expense related to these awards, as appropriate. To satisfy the exercise of options or to issue restricted stock, or redeem performance-based restricted stock units, we issue new shares rather than purchase shares on the open market.

Total compensation cost related to stock options for the six months ended June 30, 2017 and 2016 was $1,007 and $1,387, respectively. Net cash proceeds from the exercise of stock options were $21,014 and $209 for the six months ended June 30, 2017 and 2016, respectively. As a result of the Company's net operating loss carryforward position, no actual income tax benefit was recognized in the consolidated statements of income from stock option exercises during these periods.

Compensation cost of $1,355 and $1,401 related to restricted shares was recognized during the six months ended June 30, 2017 and 2016, respectively. In connection with the vesting of restricted shares and options during the six months ended June 30, 2017 and 2016, we purchased and immediately retired 120 and 117 shares with aggregate values of $1,209 and $651, respectively, in satisfaction of minimum tax withholding obligations.

Commencing in 2016, we 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 metric, the executive must also remain in our service for three years from the grant date. Performance during the one-year period will be based on a one-year earnings per share target. If the one-year target is achieved, 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. If the three-year target is achieved, the corresponding PSUs will then vest three years from grant date. PSUs are converted into shares of our common stock once vested. Upon grant of the PSUs, we recognize compensation expense related to these awards based on assumptions as to what percentage of each target will be achieved. The Company evaluates these assumptions on a quarterly basis and adjusts compensation expense related to these awards, as appropriate. Compensation cost of $1,269 and $154 related to PSUs was recognized during the six months ended June 30, 2017 and 2016, respectively.

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. No shares were purchased and retired during the six months ended June 30, 2017. During the six months ended June 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 under this share purchase agreement.

6. Income Taxes

During the three and six months ended June 30, 2017, we recorded tax expense of $1,555 and $5,452, respectively. During the three and six months ended June 30, 2016, we recorded tax expense of $173 and $234, respectively.

Tax expense reflects taxes due to state and Canadian taxing authorities and the tax effects of temporary differences between the basis of assets and liabilities recognized for financial reporting and tax purposes, and net operating loss and tax credit carryforwards. The significant components of our total deferred tax liability as of June 30, 2017 relate to the tax effects of the basis difference between the intangible assets acquired in the DNAG acquisition for financial reporting and tax purposes. Tax expense in the first six months of 2017 reflects the additional Canadian taxes due as a result of the $12,500 gain from the settlement of our patent infringement and breach of contract litigation against Ancestry.com DNA LLC and its contract manufacturer.

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 June 30, 2017 and December 31, 2016 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 six-month periods ended June 30, 2017 and 2016.

The new accounting guidance under ASU 2016-09 allows for the recognition of excess tax benefits regardless of whether the deduction reduces taxes payable. On January 1, 2017, we recorded a cumulative-effect adjustment to retained earnings of $3,391 to recognize the increase in our net operating loss carryforwards from the cumulative excess tax benefits not recognized in periods prior to January 1, 2017. A corresponding $3,391 increase to our valuation allowance associated with this tax benefit was also recorded to retained earnings thereby resulting in a net impact to retained earnings of $0.

7. Commitments and Contingencies

Standby Letters of Credit

In 2016, we established four standby letters of credit in the aggregate amount of $1,831, naming international customers as the beneficiaries. These letters of credit were required as a performance guarantee of our obligations under our product supply contracts with those customers and are collateralized by certificates of deposit maintained at a commercial bank.

Litigation

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

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 and 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, microbiome, and animal genetic testing. DNAG products are also sold into the academic research market, which consists of research laboratories, universities and hospitals.

We organized our operating segments according to the nature of the products included in those segments. The accounting policies of the segments are the same as those described in the summary of significant accounting policies (see Note 2). We evaluate performance of our operating segments based on revenue and operating income.

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.

The following table summarizes operating segment information for the three and six months ended June 30, 2017 and 2016, and asset information as of June 30, 2017 and December 31, 2016:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Net revenues:				
OSUR	$ 24,119	$ 22,926	$ 45,958	$ 45,125
DNAG	16,057	8,433	26,764	15,323
Total	$ 40,176	$ 31,359	$ 72,722	$ 60,448
Operating income:				
OSUR	$ 438	$ 2,919	$ 218	$ 4,526
DNAG	6,449	1,430	22,540	2,522
Total	$ 6,887	$ 4,349	$ 22,758	$ 7,048
Depreciation and amortization:				
OSUR	$ 678	$ 661	$ 1,334	$ 1,315
DNAG	793	727	1,557	1,423
Total	$ 1,471	$ 1,388	$ 2,891	$ 2,738
Capital expenditures:				
OSUR	$ 553	$ 661	$ 1,337	$ 1,123
DNAG	136	460	230	1,606
Total	$ 689	$ 1,121	$ 1,567	$ 2,729

	June 30, 2017	December 31, 2016
Total assets:		
OSUR	$ 178,693	$ 151,719
DNAG	79,658	56,216
Total	$ 258,351	$ 207,935

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
United States	$ 28,954	$ 24,021	$ 49,808	$ 46,191
Europe	2,436	2,957	5,561	6,836
Other regions	8,786	4,381	17,353	7,421
	$ 40,176	$ 31,359	$ 72,722	$ 60,448

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

	June 30, 2017	December 31, 2016
United States	$ 15,966	$ 15,737
Canada	4,317	4,286
Other regions	8	10
	$ 20,291	$ 20,033

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 U.S. Food and Drug Administration ("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; ability to meet increased demand for our products; impact of increased reliance on U.S. government contracts; 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 the Company to achieve its financial and strategic objectives and continue to increase its revenues, including the ability to expand international sales; 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 the Company'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, 2016, 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.

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, a rapid point-of-care HIV test approved for use in the domestic consumer retail or over-the-counter (“OTC”) market and a rapid point-of-care HIV self-test used in certain international markets. 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

Gates Foundation

In June 2017, we entered into a charitable support agreement with the Bill & Melinda Gates Foundation (“Gates Foundation”) that will enable us to offer our OraQuick® HIV self-test at an affordable price in 50 developing countries in Africa and Asia with funding from the Gates Foundation. The funding will consist of support payments tied to the volume of product we sell and reimbursement of certain related costs. The agreement has a four-year term and will enable non-governmental organizations in the eligible countries that receive funding from government or public sector agencies and donors to access our HIV self-test at reduced pricing. The funding from the Gates Foundation will be in an aggregate amount not to exceed $20.0 million over the four-year term or $6.0 million each year of the agreement.

WHO Prequalification

In July 2017, our OraQuick® HIV self-test was prequalified by the World Health Organization (“WHO”). WHO prequalification aims to ensure that diagnostic tests for high burden diseases meet global standards of quality, safety, and efficacy, in order to optimize use of health resources and improve health outcomes. WHO prequalification enables governmental organizations implementing HIV self-test pilots and programs to access international funding to purchase our test.

Self-Testing Project in Africa

In July 2017, our OraQuick® HIV self-test was selected by UNITAID and Population Services International (“PSI”) for use in Phase II of the HIV Self-Testing in Africa (“STAR”) project. Phase II of the project will begin in the fourth quarter of 2017 and continue over a two-year period. Approximately 4 million HIV self-tests are expected to be deployed in Phase II. We believe that we will supply the vast majority of these tests. The OraQuick® HIV self-test has been used in Phase I of the STAR Project, which represented the largest evaluation of HIV self-testing to date. Under Phase I of the project, 750,000 OraQuick® HIV self-tests will have been distributed when this phase is completed.

Current Consolidated Financial Results

During the six months ended June 30, 2017, our consolidated net revenues were $72.7 million, compared to $60.4 million for the six months ended June 30, 2016. Net product revenues during the six months ended June 30, 2017 increased 34% when compared to the first half of 2016, primarily due to higher sales of our molecular and OraQuick® HCV products and higher international sales of our OraQuick® HIV self-test, partially offset by lower domestic sales of our professional OraQuick® HIV product and lower sales of our cryosurgical products. Other revenues for the first six months of 2017 were $2.1 million compared to $7.6 million in the same period of 2016. Other revenues in the first six months of 2017 represent revenue recognized in connection with funding received 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") for our Ebola and Zika products. Other revenues in the first six months of 2016 included $899,000 of BARDA funding and $6.7 million of exclusivity revenues recognized under our HCV co-promotion agreement with AbbVie, which terminated effective December 31, 2016.

Our consolidated net income for the six months ended June 30, 2017 was $17.9 million, or $0.30 per share on a fully-diluted basis, compared to consolidated net income of $6.3 million, or $0.11 per share on a fully-diluted basis, for the six months ended June 30, 2016. Results for the current six month period include a pre-tax gain of $12.5 million associated with the settlement of our litigation against Ancestry.com DNA LLC and its contract manufacturer in the first quarter of 2017.

Cash provided by operating activities for the six months ended June 30, 2017 was $21.7 million and included the $12.5 million litigation settlement noted above. Cash provided by operating activities during the six months ended June 30, 2016 was $16.7 million. As of June 30, 2017, we had $162.1 million in cash (including restricted cash), cash equivalents, and short-term investments, compared to $120.9 million at December 31, 2016.

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 primarily 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 June 30, 2017 compared to June 30, 2016

CONSOLIDATED NET REVENUES

The table below shows a breakdown of total consolidated net revenues (dollars in thousands) generated by each of our business segments for the three months ended June 30, 2017 and 2016.

	Three Months Ended June 30,				
	Dollars		%	Percentage of Total Net Revenues	
	2017	2016	Change	2017	2016
OSUR	$23,075	$19,149	21%	57%	61%
DNAG	16,057	8,433	90	40	27
Net product revenues	39,132	27,582	42	97	88
Other	1,044	3,777	(72)	3	12
Net revenues	$40,176	$31,359	28%	100%	100%

Consolidated net product revenues increased 42% to $39.1 million in the second quarter of 2017 from $27.6 million in the comparable period of 2016. Higher sales of our molecular and OraQuick® HCV products were partially offset by lower domestic sales of our professional OraQuick® HIV product. In the second quarter of 2017, we recognized $1.0 million in other revenues in connection with funding from BARDA related to our Ebola and Zika products. Other revenues in the second quarter of 2016 were $3.8 million and included $3.4 million in exclusivity payments received under our HCV co-promotion agreement with AbbVie and $417,000 in BARDA funding. Our co-promotion agreement with AbbVie was terminated effective as of December 31, 2016 and no further revenues under this agreement will be recognized.

Consolidated net revenues derived from products sold to customers outside of the United States were $11.2 million and $7.3 million, or 28% and 23% of total net revenues, in the second quarters of 2017 and 2016, 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 consolidated 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.

	Three Months Ended June 30,				
	Dollars		%	Percentage of Total Net Revenues	
Market	2017	2016	Change	2017	2016
Infectious disease testing	$16,663	$12,949	29%	70%	57%
Risk assessment testing	3,238	3,159	3	13	14
Cryosurgical	3,174	3,041	4	13	13
Net product revenues	23,075	19,149	21	96	84
Other	1,044	3,777	(72)	4	16
Net revenues	$24,119	$22,926	5%	100%	100%

Infectious Disease Testing Market

Sales to the infectious disease testing market increased 29% to $16.7 million in the second quarter of 2017 from $12.9 million in the second quarter of 2016. This increase resulted from higher sales of our OraQuick® HCV product, partially offset by a decline in domestic sales of our professional OraQuick® HIV product.

The table below shows a breakdown of our total net OraQuick® HIV and HCV product revenues (dollars in thousands) during the second quarters of 2017 and 2016.

Market	Three Months Ended June 30, 2017	2016	% Change
Domestic HIV	$ 4,965	$ 5,886	(16)%
International HIV	2,025	1,969	3
Domestic OTC HIV	1,894	1,739	9
Net HIV revenues	8,884	9,594	(7)
Domestic HCV	2,382	1,788	33
International HCV	5,261	1,428	268
Net HCV revenues	7,643	3,216	138
Net OraQuick® HIV and HCV product revenues	$16,527	$12,810	29%

Domestic OraQuick® HIV sales decreased 16% to $5.0 million for the three months ended June 30, 2017 from $5.9 million for the three months ended June 30, 2016. 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 will continue to be negatively affected as a result of the Centers for Disease Control and Prevention (“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 second quarter of 2017 remained relatively consistent at $2.0 million compared to $1.9 million in the second quarter of 2016.

Sales of our OraQuick® In-Home HIV test during the second quarter of 2017 increased 9% to $1.9 million from $1.7 million in the second quarter of 2016 as a result of additional shelf placement in certain retail pharmacies and increased sales to public health customers.

Domestic OraQuick® HCV sales increased 33% to $2.4 million in the second quarter of 2017 from $1.8 million in the second quarter of 2016 primarily due to customer ordering patterns and an increase in the average size of customer orders. International OraQuick® HCV sales increased 268% to $5.3 million in the second quarter of 2017 from $1.4 million in the second quarter of 2016, largely due to continued product shipments to a foreign government to support a nationwide HCV testing and treatment program.

Risk Assessment Market

Sales to the risk assessment market remained relatively consistent at $3.2 million in the second quarter of 2017 compared to $3.1 million in the second quarter of 2016.

Cryosurgical Market

Sales of our cryosurgical products (which includes sales in both the physicians’ office and OTC markets) increased 4% to $3.2 million in the second quarter of 2017 from $3.0 million in the second quarter of 2016.

The table below shows a breakdown of our total net cryosurgical revenues (dollars in thousands) generated in each market during the second quarters of 2017 and 2016.

Market	Three Months Ended June 30, 2017	2016	% Change
Domestic professional	$1,445	$1,145	26%
International professional	243	211	15
Domestic OTC	347	345	1
International OTC	1,139	1,340	(15)
Net cryosurgical revenues	$3,174	$3,041	4%

Sales of our Histofreezer® product to physicians' offices in the United States increased 26% to $1.4 million in the second quarter of 2017 from $1.1 million in the second quarter of 2016, primarily due to the continued recovery of business previously lost to competition. International sales of Histofreezer® increased to $243,000 in the second quarter of 2017 from $211,000 in the same period of the prior year largely due to higher sales into Asia.

Sales of our private-label wart removal product in the U.S. retail market remained consistent at $347,000 in the second quarter of 2017 compared to $345,000 in the second quarter of 2016.

Sales of our international OTC cryosurgical products during the second quarter of 2017 decreased 15% to $1.1 million compared to $1.3 million in the second quarter of 2016, largely due to lower sales into Europe.

Other revenues

Other revenues in the second quarter of 2017 decreased 72% to $1.0 million from $3.8 million in the second quarter of 2016. Other revenues in the second quarter of 2016 included $3.4 million of AbbVie exclusivity revenues. There are no similar revenues in the second quarter of 2017 due to the termination of our HCV co-promotion agreement with AbbVie on December 31, 2016. Revenue from BARDA funding increased to $1.0 million in the second quarter of 2017 compared to $417,000 in the second quarter of 2016, largely due to the inclusion of funding related to our rapid Zika test.

DNAG Segment

Molecular Market

Net molecular revenues increased 90% to $16.1 million in the second quarter of 2017 from $8.4 million in the second quarter of 2016. Sales of our Oragene® product in the commercial market rose 122% in the second quarter of 2017 compared to the second quarter of 2016, largely as a result of higher customer demand, primarily in the consumer genetics market. Sales of our Oragene® product in the academic market increased 2% in the second quarter of 2017 compared to the second quarter of 2016 largely due to customer ordering patterns. The higher revenues in the second quarter of 2017 also included $843,000 in sales of our microbiome product compared to $218,000 in the same period of 2016. We believe interest in our microbiome product offering continues to grow with both new and existing customers.

CONSOLIDATED OPERATING RESULTS

Consolidated gross margin was 63% for the second quarter of 2017 compared to 67% for the second quarter of 2016. Gross margin in the second quarter of 2017 was negatively impacted by the absence of exclusivity revenues under our HCV co-promotion agreement with AbbVie.

Consolidated operating income for the second quarter of 2017 was $6.9 million, a $2.5 million improvement from $4.3 million of operating income reported in the second quarter of 2016. The operating income for the second quarter of 2017 benefited from higher product revenues in the current period as compared to last year, partially offset by an increase in staffing costs Company-wide.

OPERATING INCOME BY SEGMENT

OSUR Segment

OSUR's gross margin was 62% in the second quarter of 2017 compared to 67% in the second quarter of 2016. OSUR's gross margin in the second quarter of 2017 was negatively impacted by the absence of exclusivity revenues under our HCV co-promotion agreement with AbbVie ($3.4 million was recorded in the second quarter of 2016 and none in 2017), partially offset by the benefit of increased product revenues in the quarter.

Research and development expenses increased 12% to $2.6 million in the second quarter of 2017 from $2.3 million in the second quarter of 2016, largely due to higher supply costs associated with the development of our Ebola and Zika products. Sales and marketing expenses increased 4% to $5.2 million in the second quarter of 2017 from $5.0 million in the second quarter of 2016 largely due to increased external commissions to be paid to our international distributors and increased staffing costs. General and administrative expenses increased 34% to $6.8 million in the second quarter of 2017 from $5.1 million in the second quarter of 2016 due to higher staffing costs which includes an increase in accrued bonuses as a result of Company performance.

All of the above contributed to OSUR's second quarter 2017 operating income of $438,000, which included non-cash charges of $678,000 for depreciation and amortization and $1.9 million for stock-based compensation.

DNAG Segment

DNAG's gross margin was 65% in the second quarter of 2017 compared to 68% in the second quarter of 2016. This decline was attributable to an increase in lower margin product sales in the second quarter of 2017 compared to the second quarter of 2016.

Research and development expenses increased 13% to $722,000 in the second quarter of 2017 from $639,000 in the second quarter of 2016, largely due to higher staffing costs. Sales and marketing expenses decreased 3% to $2.3 million in the second quarter of 2017 from $2.4 million in the second quarter of 2016 due to a reduction in our allowance for uncollectible accounts partially offset by higher staffing costs. General and administrative expenses decreased 25% to $949,000 in the second quarter of 2017 compared to $1.3 million in the second quarter of 2016 primarily due to lower legal costs partially offset by increased staffing expenses.

All of the above contributed to DNAG's second quarter 2017 operating income of $6.4 million, which included non-cash charges of $793,000 for depreciation and amortization and $164,000 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 June 30, 2017, no state income tax expense was recorded as compared to $50,000 in the three months ended June 30, 2016. Canadian income tax expense of $1.6 million and $123,000 was recorded in the second quarters of 2017 and 2016, respectively.

Six months ended June 30, 2017 compared to June 30, 2016

CONSOLIDATED NET REVENUES

The table below shows a breakdown of total consolidated net revenues (dollars in thousands) generated by each of our business segments for the six months ended June 30, 2017 and 2016.

	Six Months Ended June 30,				
	Dollars		%	Percentage of Total Net Revenues	
	2017	2016	Change	2017	2016
OSUR	$43,850	$37,504	17%	60%	62%
DNAG	26,764	15,323	75	37	25
Net product revenues	70,614	52,827	34	97	87
Other	2,108	7,621	(72)	3	13
Net revenues	$72,722	$60,448	20%	100%	100%

Consolidated net product revenues increased 34% to $70.6 million in the first half of 2017 from $52.8 million in the comparable period of 2016. Higher sales of our molecular and OraQuick® HCV products and higher international sales of our OraQuick® HIV self-test were partially offset by lower domestic sales of our professional OraQuick® HIV product and lower sales of our cryosurgical products. In the first half of 2017, we recognized $2.1 million as other revenues in connection with funding from BARDA related to our Ebola and Zika products. Other revenues in the first half of 2016 were $7.6 million and included $6.7 million in exclusivity payments received under our HCV co-promotion agreement with AbbVie and $899,000 in BARDA funding. Our co-promotion agreement with AbbVie was terminated effective as of December 31, 2016 and no further revenues under this agreement will be recognized.

Consolidated net revenues derived from products sold to customers outside of the United States were $22.9 million and $14.3 million, or 32% and 24% of total net revenues, during the six months ended June 30, 2017 and 2016, 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 consolidated 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.

	Six Months Ended June 30,				
	Dollars		%	Percentage of Total Net Revenues	
Market	2017	2016	Change	2017	2016
Infectious disease testing	$31,245	$24,317	28%	67%	54%
Risk assessment testing	6,368	6,265	2	14	14
Cryosurgical systems	6,237	6,922	(10)	14	15
Net product revenues	43,850	37,504	17	95	83
Other	2,108	7,621	(72)	5	17
Net revenues	$45,958	$45,125	2%	100%	100%

Infectious Disease Testing Market

Sales to the infectious disease testing market increased 28% to $31.2 million in the first half of 2017 from $24.3 million in the first half of 2016. This increase resulted from higher sales of our OraQuick® HCV product and higher international sales of our OraQuick® HIV self-test partially offset by a decline in domestic sales of our professional OraQuick® HIV product.

The table below shows a breakdown of our total net OraQuick® HIV and HCV product revenues (dollars in thousands) during the six months ended June 30, 2017 and 2016.

	Six Months Ended June 30,		
Market	2017	2016	% Change
Domestic HIV	$ 8,779	$11,588	(24)%
International HIV	4,669	2,824	65
Domestic OTC HIV	3,436	3,262	5
Net HIV revenues	16,884	17,674	(4)
Domestic HCV	4,091	3,689	11
International HCV	9,664	2,430	298
Net HCV revenues	13,755	6,119	125
Net OraQuick® revenues	$30,639	$23,793	29%

Domestic OraQuick® HIV sales decreased 24% to $8.8 million for the six months ended June 30, 2017 from $11.6 million for the six months ended June 30, 2016. This decrease was primarily the result of continued price and product competition and customer ordering patterns. We anticipate that future domestic sales of our professional HIV product will continue to be negatively affected as a result of the Centers for Disease Control and Prevention (“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 products during the first half of 2017 rose 65% to $4.7 million from $2.8 million in the first half of 2016. This increase was largely due to the continued shipment of product in support of a HIV self-testing program in Africa and higher sales into the Middle East.

Sales of our OraQuick® In-Home HIV test during the first half of 2017 of $3.4 million increased 5% compared to $3.3 million in the first half of 2016.

Domestic OraQuick® HCV sales increased 11% to $4.1 million in the first half of 2017 from $3.7 million in the first half of 2016 primarily due to customer ordering patterns and an increase in the average size of customer orders. International OraQuick® HCV sales increased 298% to $9.7 million in the first half of 2017 from $2.4 million in the first half of 2016, largely due to continued product shipments to a foreign government to support a nationwide HCV testing and treatment program and increased sales in Africa.

Risk Assessment Market

Sales to the risk assessment market remained relatively consistent at $6.4 million in the first half of 2017 compared to $6.3 million in the first half of 2016.

Cryosurgical Market

Sales of our cryosurgical products (which includes sales in both the physicians’ office and OTC markets) decreased 10% to $6.2 million in the first half of 2017 from $6.9 million in the first half of 2016.

The table below shows a breakdown of our total net cryosurgical revenues (dollars in thousands) generated in each market during the six months ended June 30, 2017 and 2016.

	Six Months Ended June 30,		
Market	2017	2016	% Change
Domestic professional	$2,941	$2,699	9%
International professional	373	446	(16)
Domestic OTC	632	723	(13)
International OTC	2,291	3,054	(25)
Net cryosurgical systems revenues	$6,237	$6,922	(10)%

Sales of our Histofreezer® product to physicians' offices in the United States increased 9% to $2.9 million in the first half of 2017 from $2.7 million in the first half of 2016, primarily due to the continued recovery of business previously lost to competition partially offset by the impact of distributor ordering patterns. International sales of our Histofreezer® product decreased to $373,000 in the first half of 2017 from $446,000 in the same period of the prior year largely due to lower sales into Europe.

Sales of our private-label wart removal product in the U.S. retail market decreased to $632,000 in the first half of 2017 from $723,000 in the first half of 2016. Sales volume in the first half of 2016 was higher as a result of initial stocking orders for a new large pharmacy customer during that period.

Sales of our international OTC cryosurgical products during the first half of 2017 decreased 25% to $2.3 million compared to $3.1 million in the first half of 2016, largely due to lower sales into Europe and Latin America.

Other revenues

Other revenues in the first half of 2017 decreased 72% to $2.1 million from $7.6 million in the first half of 2016.
Other revenues in the first half of 2016 included AbbVie exclusivity revenues of $6.7 million. There are no similar revenues in 2017 due to the termination of our HCV co-promotion agreement with AbbVie on December 31, 2016. Revenues related to funding from BARDA increased to $2.1 million in the first half of 2017 compared to $899,000 in the first half of 2016.

DNAG Segment

Molecular Market

Net molecular revenues increased 75% to $26.8 million in the first half of 2017 from $15.3 million in the first half of 2016. Sales of our Oragene® product in the commercial market rose 121% in the first half of 2017 compared to the first half of 2016, largely as a result of higher customer demand, primarily in the consumer genetics market. Sales of our Oragene® product in the academic market decreased 11% in the first half of 2017 compared to the first half of 2016 largely due to ordering patterns of existing customers. The higher revenues in the first half of 2017 also included $1.6 million in sales of our microbiome product compared to $381,000 in the same period of 2016. We believe interest in our microbiome product offering continues to grow with both new and existing customers.

CONSOLIDATED OPERATING RESULTS

Consolidated gross margin was 63% for the first half of 2017 compared to 68% for the first half of 2016. Gross margin in the first half of 2017 was negatively impacted by the absence of exclusivity revenues under our HCV co-promotion agreement with AbbVie, an increase in lower margin product sales, and an increase in scrap and spoilage costs.

Consolidated operating income for the first half of 2017 was $22.7 million, a $15.7 million improvement from $7.0 million of operating income reported in the first half of 2016. The operating income for the first half of 2017 benefited from the Ancestry litigation settlement gain, increased product revenues, and lower sales and marketing costs, partially offset by higher research and development and general and administrative expenses.

OPERATING INCOME BY SEGMENT

OSUR Segment

OSUR's gross margin was 61% in the first half of 2017 compared to 68% in the first half of 2016. OSUR's gross margin in the first half of 2017 was negatively impacted primarily by the absence of exclusivity revenues under our HCV co-promotion agreement with AbbVie ($6.7 million was recorded in the first half of 2016 and none was recorded in 2017).

Research and development expenses increased 22% to $5.0 million in the first half of 2017 from $4.1 million in the first half of 2016, largely due to higher supply costs associated with the development of our Ebola and Zika products and increased staffing expenses. Sales and marketing expenses decreased 14% to $9.8 million in the first half of 2017 from $11.4 million in the same period of 2016. This decrease was primarily the result of the termination of our OraQuick® HCV co-promotion agreement with AbbVie on December 31, 2016 and lower staffing costs. General and administrative expenses increased 24% to $13.1 million in the first half of 2017 from $10.5 million in the first half of 2016 due to increased staffing costs, which includes an increase in accrued bonuses as a result of Company performance.

All of the above contributed to OSUR's operating income of $218,000 in the first half of 2017, which included non-cash charges of $1.3 million for depreciation and amortization and $3.4 million for stock-based compensation.

DNAG Segment

DNAG's gross margin was 66% in the first half of 2017 compared to 70% in the first half of 2016. This decline was attributable to an increase in lower margin sales in the first half of 2017 compared to the first half of 2016.

Research and development expenses remained consistent at $1.3 million in both the first six months of 2017 and the first six months of 2016. Sales and marketing expenses decreased 2% to $4.5 million in the first half of 2017 from $4.6 million in the first half of 2016 due to a reduction in our allowance for uncollectible accounts partially offset by higher staffing costs. General and administrative expenses decreased 24% to $1.8 million in the first half of 2017 compared to $2.3 million in the first half of 2016 primarily due to lower legal costs partially offset by increased staffing expenses. Operating expenses in the first half of 2017 were offset by the $12.5 million pre-tax gain associated with the settlement of our litigation with Ancestry.com DNA, LLC and its contract manufacturer.

All of the above contributed to DNAG's operating income of $22.5 million in the first half of 2017, which included non-cash charges of $1.6 million for depreciation and amortization and $260,000 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 six months ended June 30, 2017, state income tax expense of $31,000 was recorded compared to $50,000 in the six months ended June 30, 2016. Canadian income tax expense of $5.4 million and $184,000 was recorded in the first half of 2017 and 2016, respectively. Taxes in the first half of 2017 included the additional taxes due as a result of the $12.5 million Ancestry litigation settlement payment.

Liquidity and Capital Resources

	June 30, 2017	December 31, 2016
	(In thousands)	
Cash, cash equivalents and restricted cash	$106,703	$ 109,790
Short-term investments	55,354	11,160
Working capital	182,507	139,106

Our cash, cash equivalents, restricted cash and short-term investment balances increased to $162.1 million at June 30, 2017 from $120.9 million at December 31, 2016. Our working capital increased to $182.5 million at June 30, 2017 from $139.1 million at December 31, 2016.

During the first half of 2017, we generated $21.7 million in cash from operating activities. Our net income of $17.9 million benefitted from non-cash stock-based compensation expense of $3.6 million and depreciation and amortization expense of $2.9 million, partially offset by a net reduction of other non-cash charges of $144,000. Additional sources of cash included an increase in accounts payable of $4.7 million largely due to inventory purchases that were invoiced at the end of the quarter, and a decrease in prepaid and other assets of $1.5 million largely due to the receipt of $1.4 million as payment of a claim from one of our raw material suppliers. This settlement was recorded as a receivable at December 31, 2016. Uses of cash in operating activities during the period include an increase in accounts receivable of $6.9 million largely resulting from the increase in orders placed near the end of the current quarter, an increase in inventory balances of $2.7 million required to meet expected demand, and a decrease in accrued expenses and other liabilities of $713,000 associated with payment of our 2016 management incentive bonuses partially offset by an increase in our Canadian income taxes payable.

Net cash used in investing activities was $45.2 million for the six months ended June 30, 2017, which reflects $62.2 million used to purchase short-term investments and $1.6 million to acquire property and equipment partially offset by $18.6 million in proceeds from the maturities of short-term investments.

Net cash provided by financing activities was $19.8 million for the six months ended June 30, 2017, which resulted from $21.0 million in proceeds received from the exercise of stock options partially offset by $1.2 million used for the repurchase of common stock to satisfy withholding taxes related to the vesting of restricted shares.

On September 30, 2016, we entered into a credit agreement (the “Credit Agreement”) with a commercial bank. The Credit Agreement provides for revolving extensions of credit in an initial aggregate amount of up to $10.0 million (inclusive of a letter of credit subfacility of $2.5 million), with an option to request, prior to the second anniversary of the closing date, that lenders, at their election, provide up to $5.0 million 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 June 30, 2017 or December 31, 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 June 30, 2017 and December 31, 2016, we were in compliance with all applicable covenants under the Credit Agreement.

Our current cash and cash equivalents balance and available borrowing capacity are 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 any future litigation, the magnitude of capital expenditures, changes in existing and potential relationships with business partners, the timing and cost of obtaining regulatory approvals, the timing and cost of future stock purchases, the costs involved in obtaining and enforcing patents, proprietary rights and any necessary licenses, the cost and timing of expansion of sales and marketing activities, market acceptance of new products, competing technological and market developments, the impact of the current economic environment and other factors.

Summary of Contractual Obligations

A summary of our obligations to make future payments under contracts existing at December 31, 2016 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, 2016. As of June 30, 2017, 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, 2016 filed with the SEC. During the first six months of 2017, there were no material changes in our critical accounting policies.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

As of June 30, 2017, 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 six months ended June 30, 2017. 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 $83.4 million CDN ($64.3 million USD), which are included in the Company's consolidated balance sheet as of June 30, 2017. A 10% unfavorable change in the Canadian-to-U.S. dollar exchange rate would have decreased our comprehensive income by $6.4 million in the six months ended June 30, 2017.

Item 4. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures. The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) as of June 30, 2017. Based on that evaluation, the Company's management, including such officers, concluded that the Company's disclosure controls and procedures were effective as of June 30, 2017 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 Securities and Exchange Commission.

(b) Changes in Internal Control Over Financial Reporting. There was no change in the Company's internal control over financial reporting that occurred during the three months ended June 30, 2017 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

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.

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, 2016.

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

Period	Total number of shares purchased	Average price paid per Share	Total number of shares purchased as part of publicly announced plans or programs	Maximum number (or approximate dollar value) of shares that may yet be repurchased under the plans or programs (2, 3)
April 1, 2017 - April 30, 2017	2,335 (1)	$ 12.39	N/A	$ 11,984,720
May 1, 2017 - May 31, 2017	21,753 (1)	15.13	N/A	11,984,720
June 1, 2017 - June 30, 2017	—	—	—	11,984,720
	24,088		**—**	

(1) Pursuant to the OraSure Technologies, Inc. Stock Award Plan, and in connection with the vesting of restricted shares, these shares were retired to satisfy minimum tax withholdings.

(2) On August 5, 2008, our Board of Directors approved a share repurchase program pursuant to which we are permitted to acquire up to $25.0 million of outstanding shares. This share repurchase program may be discontinued at any time.

(3) This column represents the amount that remains available under the $25.0 million repurchase plan, as of the period indicated. We have made no commitment to purchase any shares under this plan.

Item 3. DEFAULTS UPON SENIOR SECURITIES

None

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable

ITEM 5. OTHER INFORMATION

In light of the results of the advisory vote on the frequency of say-on-pay votes at our Annual Meeting of Stockholders held on May 16, 2017, our Board of Directors determined that the Company will continue to hold an advisory say-on-pay vote each year. The Board of Directors will re-evaluate this determination no later than the next stockholder vote on the frequency of say-on-pay votes.

Item 6. EXHIBITS

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

SIGNATURES

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

ORASURE TECHNOLOGIES, INC.

/s/ Ronald H. Spair

Date: August 9, 2017

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

/s/ Mark L. Kuna

Date: August 9, 2017

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

EXHIBIT INDEX

Exhibit Number	Exhibit
10.1	Employment Agreement, dated as of January 7, 2008, as amended, between DNA Genotek, Inc. and Brian Smith.*
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

* Management contract or compensatory plan or arrangement.

AMENDING AGREEMENT

THIS AMENDING AGREEMENT made as of June 10, 2016.

B E T W E E N:

DNA Genotek Inc.

(the "**Company**")

-and-

Brian Smith

(the "**Executive**" or "**you**")

WHEREAS the Company and the Executive are parties to an employment agreement dated January 7, 2008, as amended by an amending agreement dated July 25, 2011 (collectively, the "**Employment Agreement**");

AND WHEREAS the parties desire to enter into this Amending Agreement in order to implement a change in executive's position and compensation.

NOW, THEREFORE, in consideration of the promises and mutual covenants herein, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

ARTICLE 1
INTERPRETATION

Section 1.1 Incorporation of Employment Agreement.

This Amending Agreement is supplemental to and shall be read in conjunction with the Employment Agreement, and the Employment Agreement and this Amending Agreement shall have effect so far as practicable as if all the provisions thereof and hereof were contained in one document.

Section 1.2 Effect on the Employment Agreement.

Except as specifically amended in the Amending Agreement, the Employment Agreement and its terms and conditions shall remain in full force and effect and are hereby ratified and confirmed.

ARTICLE 2
EFFECTIVE DATE OF AMENDMENTS

Section 2.1 Effective Date of the Amendments.

The amendments contained in this Amending Agreement shall become effective as of June 10, 2016 and shall remain in effect until otherwise agreed to in writing by the parties or upon the termination of the Executive's employment for any reason, whichever occurs first.

ARTICLE 3
AMENDMENTS TO THE EMPLOYMENT AGREEMENT

Section 3.1 Amendment to Schedule A – Section 1

Section 1 shall be deleted in its entirety and replaced with:

1. **Duties**

a. ***Position***. You will hold the position of Senior Vice President and General Manager, Molecular Collection Systems and will report directly to the President and Chief Executive Officer ("CEO") of the Company's parent, OraSure Technologies, Inc. ("OraSure"). You agree that you will not, during the time that you are employed by the Company, perform work or services for any competitor of the Company or its affiliates, or otherwise breach the provisions of the Agreement.

b. ***Duties and Obligations***. Your initial duties shall consist of duties for the Company comparable to those that would be performed by a General Manager of a company in a similar industry and at a comparable state of development as the Company. In particular, your duties shall include:

- Setting strategic direction for the Company;
- Setting and achieving financial targets;
- Managing the executive and management teams;
- Allocating resources to achieve business objectives; and
- Maintaining a culture and environment to attract and retain resources in support of the Company's business plans.

The President and CEO of OraSure may, at any time, require you to perform other duties that are consistent with your skill and experience and/or the position of Senior Vice President and General Manager, Molecular Collection Systems, or meet group or individual milestones or objectives that are consistent with any other milestones or objectives set by OraSure which are required to be achieved by the Company.

Section 3.2. Amendment to Schedule A – Section 2

Section 2 shall be deleted in its entirety and replaced with:

2. **Compensation**

a. ***Base Salary***. Subject to the terms of this Agreement, as of June 10, 2016, you are entitled to receive the aggregate gross bi-weekly salary of $11,538.46 CND ($300,000 CND annualized), less all applicable deductions, payable in twenty-six (26) bi-weekly installments in accordance with the Company's established pay periods.

b. ***Equity Awards***. You will be eligible to participate, on an annual basis, in the OraSure Long Term Incentive Policy or similar equity incentive plan maintained by OraSure (the "LTIP") pursuant to which annual equity grants may be made by OraSure to executives of OraSure and its affiliates under the OraSure Stock Award Plan as in effect from time to time ("Annual Awards"). Your participation in the LTIP shall begin with performance during the 2016 calendar year and you will be eligible to receive an Annual Award, subject to the requisite approval of OraSure's Board of Directors (or the Compensation Committee thereof), with a target value of 100% of your Base Salary consistent with targets for officers at the level of executive vice president under the LTIP. Each Annual Award shall have vesting and other terms consistent with the terms of equity awards provided by OraSure to other executives under the LTIP with your level of responsibilities.

c. ***Benefits***. You shall be entitled to participate in all benefits plans, funds or arrangements that are available to employees of the Company as they become available.

*d. **Incentives***. You will be eligible for annual cash incentive bonus awards, on an annual basis, under the OraSure Management Incentive Plan or similar incentive cash bonus plan maintained by OraSure (the "MIP") pursuant to which annual incentive cash bonuses may be paid by OraSure to executives of OraSure and its affiliates, as in effect from time to time ("Annual Bonus Awards"). Your participation in the MIP shall begin with the performance during the 2016 calendar year and you will be eligible to receive an annual bonus award, subject to the requisite approval of OraSure's Board of Directors (or the compensation committee thereof), with a target value of 40% of your base salary, consistent with the targets for officers at the level of executive vice president under the MIP. Each Annual Bonus Award shall have terms consistent with the terms of annual incentive bonus awards provided by OraSure to other executives with your level of responsibilities.

Section 3.3 Amendment to Schedule A – Section 5

Section 5 shall be deleted in its entirety and replaced with:

For purposes of Article II, Section (d) of the Agreement, the amount shall be the greater of (i) a payment of twelve (12) months of your then Base Salary to be paid in the form of salary continuation in accordance with the Company's regular payroll practices or (ii) such minimum amounts relating to termination pay and severance pay as may be required by the *Employment Standards Act, 2000*, as may be amended from time to time (the "**Notice Period**"). Subject to the approval of the insurer, the Company shall also continue your group insurance benefits for the length of the Notice Period.

To the extent bonuses are paid under the OraSure MIP for the year of your termination, you will be entitled to receive a payment under the terms of said MIP, prorated for the period of time you were employed prior to the date of termination under this Section 5. To the extent bonus payments are made, your pro-rated bonus will be made at the same time bonuses are paid to all participants in said MIP, and the Company and you agree in advance that your individual performance factor will be set at a Meets Expectations or Target level for the purposes of calculating any pro-rated bonus that is owing according to the terms of this Section 5.

You acknowledge that the amounts indicated in this Section 5 are inclusive of any amounts owing to pursuant to the *Employment Standards Act, 2000*, as may be amended from time to time and not in addition to such amounts. You agree that except as set out in this Agreement, no further amounts will be payable to you whether pursuant to statute, common law or otherwise in respect of the termination of your employment without Cause.

Section 3.4 Amendment to Schedule A – New Section 6

The following new Section 6 is hereby added:

6. **Indemnification**

The Company agrees that if you are made a party (or is threatened to be made a party to) any action, suit, or proceeding, whether civil, criminal, administrative, or investigative (a "Proceeding"), by reason of your service (including past service) as an officer, director, employee, agent, or the like of the Company, or is or was serving at the request of the Company as an officer, director, employee, agent, or the like of another entity, including, without limitation, as a fiduciary of an employee benefit plan sponsored or established by the Company (any such service for a subsidiary, affiliate, joint venture or other entity in which the Company has an ownership or other financial interest, or as a fiduciary of any employee benefit plan sponsored by the Company or any such other entity, shall be presumed to be at the request of the Company), whether or not the basis of such Proceeding is an act or omission alleged to have occurred while you were acting in an official capacity as a director, officer, employee, agent, or the like, then you shall be indemnified and held harmless by the Company to the fullest extent authorized by applicable law (including for all reasonable attorneys' fees and costs incurred by you), and such indemnification shall continue even if you have ceased to be a director, officer, employee, agent, or the like of the Company for any reason.

ARTICLE 4
MISCELLANEOUS

Section 4.1 Independent Legal Advice.

The Executive acknowledges, having been given sufficient opportunity to seek independent legal advice concerning the meaning and legal effect of this Amending Agreement. The Executive acknowledges that he understands the nature and consequences of this Amending Agreement.

Section 4.2 Counterparts.

This Amending Agreement may be executed in any number of counterparts and all such counterparts taken together shall be deemed to constitute one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have executed this Amending Agreement as of the date first specified above.

/s/ Linda Saad Smith
Witness

/s/ Brian Smith
Brian Smith

DNA Genotek Inc.

By: */s/ Douglas A. Michels*
Douglas A. Michels
Chief Executive Officer

AMENDING AGREEMENT

THIS AMENDING AGREEMENT made as of July , 2011.

B E T W E E N:

DNA Genotek Inc.

(the "**Company**")

-and-

Brian Smith

(the "**Executive**" or "**you**")

WHEREAS the Company and the Executive are parties to an employment agreement dated January 7, 2008 (the "**Employment Agreement**");

AND WHEREAS the Company is entering into a Support Agreement dated July , 2011 with OraSure Technologies, Inc. ("**OraSure**") and certain other parties, which provides for the purchase of all of the outstanding capital stock of the Company by OraSure (the "**Transaction**");

AND WHEREAS conditional upon the closing of the Transaction, OraSure intends to grant to the Executive an option to purchase shares of OraSure's common stock and to make additional equity grants to Executive on an annual basis pursuant to OraSure's long term incentive plan (the "**Equity Grant**");

NOW, THEREFORE, in consideration of the promises and mutual covenants herein, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

ARTICLE 1
INTERPRETATION

Section 1.1 Incorporation of Employment Agreement.

This Amending Agreement is supplemental to and shall be read in conjunction with the Employment Agreement, and the Employment Agreement and this Amending Agreement shall have effect so far as practicable as if all the provisions thereof and hereof were contained in one document.

Section 1.2 Effect on the Employment Agreement.

Except as specifically amended in the Amending Agreement, the Employment Agreement and its terms and conditions shall remain in full force and effect and are hereby ratified and confirmed.

ARTICLE 2
EFFECTIVE DATE OF AMENDMENTS

Section 2.1 Effective Date of the Amendments.

The amendments contained in this Amending Agreement shall become effective on the closing of the Transaction and shall remain in effect until otherwise agreed to in writing by the parties or upon the termination of the Executive's employment for any reason, whichever occurs first.

ARTICLE 3
AMENDMENTS TO THE EMPLOYMENT AGREEMENT

Section 3.1 Amendment to Article III

(1) Article III is hereby deleted and substituted with the following:

III. Restrictive Covenants and Confidentiality Agreements

(a) Non-Competition

Both during your employment and for a period of twelve months after the termination of your employment with the Company, for any reason, you will not, directly or indirectly, on your own behalf or on behalf of any other person, engage in, represent in any way, or be connected with, any business that manufactures, produces, offers, sells, distributes, develops, produces, markets or licenses any product or service which directly or indirectly competes with the Company Business within the Territory, whether your engagement shall be as an officer, director, owner (other than ownership of less than 1% of the outstanding securities of any class of securities then listed on a stock exchange in North America), employee, partner, joint-venture, consultant, agent, affiliate or other participant.

(b) Non-Solicitation

Both during your employment with the Company and for twelve months after the termination of your employment with the Company, for any reason, you will not without the written consent of the Company:

(a) directly or indirectly induce or attempt to induce any Customer or Prospective Customer of the Company, to cease doing business in whole or in part with the Company or any of its affiliates or solicit the business of any Customer or Prospective Customer of the Company for a purpose which is competitive with the Company Business; or

(b) directly or indirectly solicit, or attempt to solicit, employ, interfere with, or endeavour to cause any employee of the Company to leave his or her employment.

For the purposes of this Agreement, the following definitions shall apply:

"**Company Business**" means the development, production, marketing and sale of nucleic acid (DNA and RNA) sample collection, stabilization and preparation products, and any other business or operations conducted by the Company, including with respect to any intellectual property owned by the Company.

"**Customer**" means any person who, in the twelve months preceding the date of the termination of your employment hereunder for any reason, has purchased from the Company any product or services produced, sold, licensed, or distributed by the Company in respect of the Company Business.

"**Prospective Customer**" means (i) any person solicited by you on behalf of the Company or its affiliates for any purpose relating to the Company Business at any time during the twelve (12) month period immediately preceding the date of the termination of your employment, for any reason; and (ii) any person solicited by the Company or its affiliates, with your knowledge, for any purpose relating to the Company Business at any time during the twelve month period immediately preceding the date of the termination of your employment.

"**Territory**" means North America and Europe.

You hereby agree to sign the Confidentiality and Proprietary Information Agreement and Conflict of Interest Policy.

Section 3.2 Amendment to Article V

You hereby acknowledge that the sentence "The only claims not covered by this section shall be claims for benefits under applicable workers' compensation laws or employment insurances or claims under the non-competition and non-solicitation clauses of this Agreement" shall be deleted in its entirety and replace with the following:

The only claims not covered by this section shall be claims for benefits under applicable workers' compensation laws or employment insurances or claims for relief which cannot otherwise be granted in Arbitration. You recognize and expressly acknowledge that the Company would be subject to irreparable harm should any of the provisions of the Restrictive Covenants be infringed, or should any of your obligations thereunder be breached by you, and that damages alone will be an inadequate remedy for any breach or violation thereof and that the Company, in addition to all other remedies, shall be entitled as a matter of right to equitable relief, including temporary or permanent injunction to restrain such breach.

Section 3.3 Amendment to Schedule A – Section 2(b)

Section 2(b) shall be deleted in its entirety and replaced with:

b. Equity Awards. Conditional upon the requisite approval of the Board of Directors (or the Compensation Committee thereof) of OraSure, you will receive an option to purchase an aggregate of 20,000 common shares of OraSure subject to the terms of the OraSure Stock Award Plan and the grant agreement entered into between you and OraSure (the "Initial Award"). The Initial Award shall occur as soon as practicable following, and shall be subject to, the completion of the closing of the Transaction. You will also be eligible to participate, on an annual basis, in the OraSure Long Term Incentive Plan or similar equity incentive plan maintained by OraSure (the "LTIP") pursuant to which annual equity grants may be made by OraSure to executives of OraSure and its affiliates under the OraSure Stock Award Plan as in effect from time to time ("Annual Awards"). Your participation in the LTIP shall begin with performance during the 2011 calendar year and you will be eligible to receive an Annual Award, subject to the requisite approval of OraSure's Board of Directors (or the Compensation Committee thereof), with a target value of 20% of your Base Salary, prorated to reflect the period during 2011 following the closing of the Transaction. The Initial Award and each Annual Award shall have vesting and other terms consistent with the terms of equity awards provided by OraSure to other executives with your level of responsibilities.

Section 3.4 Amendment to Schedule A – Section 3(d)

Section 3(d) shall be deleted in its entirety and replaced with:

d. Cash Incentive Compensation. You will be eligible for a cash incentive bonus equivalent to 100% of your Base Salary subject to the achievement of the performance targets set in accordance with the Company's plan as in effect from time to time.

Section 3.1 Amendment to Schedule A – Section 5

Section 5 shall be deleted in its entirety and replaced with:

For purposes of Article II, Section (d) of the Agreement, the amount shall the greater of (i) a payment of six (6) months of your then Base Salary to be paid in the form of salary continuation in accordance with the Company's regular payroll practices or (ii) such minimum amounts relating to termination pay and severance pay as may be required by the *Employment Standards Act, 2000*, as may be amended from time to time (the "**Notice Period**"). Subject to the approval of the insurer, the Company shall also continue your group insurance benefits for the length of the Notice Period.

You acknowledge that the amounts indicated in this Section 5 are inclusive of any amounts owing to pursuant to the *Employment Standards Act, 2000*, as may be amended from time to time and not in addition to such amounts. You agree that except as set out in this Agreement, no further amounts will be payable to you whether pursuant to statute, common law or otherwise in respect of the termination of your employment without Cause.

ARTICLE 4
MISCELLANEOUS

Section 4.1 Independent Legal Advice.

The Executive acknowledges, having been given sufficient opportunity to seek independent legal advice concerning the meaning and legal effect of this Amending Agreement. The Executive acknowledges that he understands the nature and consequences of this Amending Agreement.

Section 4.2 Counterparts.

This Amending Agreement may be executed in any number of counterparts and all such counterparts taken together shall be deemed to constitute one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have executed this Amending Agreement as of the date first specified above.

/s/ Linda Saad Smith
Witness

/s/ Brian Smith
Brian Smith

DNA Genotek Inc.

By: */s/ Patrick Walsh*

EMPLOYMENT AGREEMENT

Dated as of **January 7, 2008**

Brian Smith
108 Goodman Drive
Kanata, Ontario

Dear Brian:

This employment agreement between you and DNA Genotek Inc. (the "**Company**") having its principal place of business at 29 Camelot Drive, Ottawa, Ontario, Canada, is effective on and from **January 7, 2008** (the "**Effective Date**"). References in this document to "Agreement" are deemed to include the terms of Schedule A attached hereto. All dollar amounts specified in this document are Canadian dollars.

I. **Remuneration**

This will confirm that you and the Company have negotiated and agreed upon the terms and conditions for your employment, as set out in "Schedule A" of this Agreement.

II. **Termination**

You and the Company understand and agree that employment under this Agreement may be terminated under the following conditions:

(a) by you for any reason, if you give at least four (4) weeks of notice to the Company (the Company may waive this notice, in whole or in part);

(b) by you for Good Reason (as defined below) by providing written notice to the Company, in which case you shall be entitled to receive the payments referred to in paragraph (d) below as if the Company had terminated your employment without cause;

(c) by the Company, without notice or payment in lieu of notice for "cause", which, for the purposes of this Agreement shall be defined as:

(i) the commission of act or omission involving (A) material dishonesty or (B) fraud with respect to the Company or any of its subsidiaries or any of their customers or suppliers,

(ii) substantial and repeated failure to perform your duties as reasonably directed by the Company's CEO,

(iii) gross negligence or willful misconduct with respect to the Company or any of its subsidiaries, or

(iv) conduct tending to bring the Company or any of its subsidiaries into substantial public disgrace or disrepute; or

(d) by the Company without cause, at its sole discretion and for any reason, on giving you an amount equal to the amount set out in Schedule "A" attached hereto.

A resignation for "Good Reason" will occur if you terminate your employment within thirty (30) days of the occurrence of any of the following events without your prior written consent: (i) any material reduction in your salary and bonus as specified herein; (ii) a material amendment to your duties as outlined herein, including any transfer to any position other than the position described in Schedule "A" unless such transfer is clearly consistent with a promotion; or (iii) any required relocation beyond a fifty (50) kilometer radius from the Company's head office at the date hereof or as the same shall change from time to time.

On any termination or resignation of your employment you will be entitled to be paid (i) all accrued but unpaid salary up to and including the final date of active service for the Company; (ii) any earned but unpaid commissions up to and including the final date of active service for the Company; (iii) salary equivalent to the salary you would have earned during the period of all accrued but unused vacation up to the final date of active service; and (iv) all properly documented but unpaid expenses incurred by you prior to the final date of active service for which documentation is filed with the Company not later than fourteen (14) days after the final date of active service.

To the extent permitted pursuant to the relevant benefit plans, on a resignation for Good Reason or a termination without cause you will also be entitled to continuation of all benefits for which you are eligible for the period calculated in accordance with paragraph (d) above.

III. **Covenants**

While employed by the Company and for a period of one (1) year after your employment by the Company is concluded, you hereby agree not to (i) induce or attempt to induce or directly or indirectly to participate in the inducement of, any employee, independent contractor or consultant of the Company to breach that employee's contract of employment with the Company (provided that a general solicitation to the public by you hereto that is responded to by employees, independent contractors or consultants of the Company shall not be construed to be a breach of this Agreement), (ii) directly or indirectly to solicit, attempt to solicit, canvass or interfere with any person that is or was a customer or supplier of the Company in a manner or for a purpose which is directly competitive to the Business of the Company (as that term is defined in the DNA Genotek Inc. Confidentiality and Proprietary Information Agreement, nor (iii) be directly or indirectly engaged, concerned or interested in any capacity including providing technical, commercial or professional advice, in any business which is in competition with the Company other than as a holder of not more than three percent of the issued shares or securities of any companies which are listed or traded on any recognized stock exchange or market.

As a condition of employment with the Company, you agree to sign the Company's Confidentiality and Proprietary Information Agreement and Conflict of Interest Policy.

IV. **Representation and Warranty**

You hereby represent and warrant to the Company that you are not party to any written or oral agreement with any third party that would restrict your ability to enter into this Agreement or the Confidentiality and Proprietary Information Agreement or to perform your obligations hereunder or thereunder and that you will not, by joining the Company, breach any non-disclosure, proprietary rights, non-competition, non-solicitation or other covenant in favour of any third party.

V. **Arbitration**

Except for claims described below, any and all disputes between the Company and you which arise out of (i) your employment, (ii) the termination of your employment, or (iii) the validity, interpretation or enforcement of the terms of this Agreement, shall be resolved exclusively through final and binding arbitration. This shall include, without limitation, disputes relating to this Agreement, any disputes relating to your employment by the Company, or the termination thereof, claims for breach of contract or breach of the covenant of good faith and fair dealing, and any claims of discrimination or other claims under any federal, provincial, state or local law or regulation now in existence or hereinafter enacted and as amended from time to time concerning in any way the subject matter of your employment with the Company or its termination.

The only claims not covered by this section shall be claims for benefits under applicable workers' compensation laws or employment insurance laws or claims under the non-competition and non-solicitation clauses of this Agreement.

Binding arbitration shall be conducted in Ottawa, Ontario in accordance with the rules and regulations of the *Arbitration Act, 1991* (Ontario) as amended. Unless the arbitrator or arbitrators shall order otherwise, the successful party in any arbitration shall be entitled to have the other party reimburse it for its costs associated with such arbitration and cover the cost of the arbitrator or arbitrators. You understand and agree that such arbitration shall be final and in the stead of any civil litigation, and that the arbitrator's or arbitrators' decision shall be final and binding to the fullest extent permitted by law and enforceable by any court having competent jurisdiction thereof.

VI. **Miscellaneous**

This Agreement, as well as the Confidentiality and Proprietary Information Agreement and Conflict of Interest Policy, contains the entire understanding between you and the Company relating to your employment and the additional matters provided for therein. This Agreement may be amended or altered only in writing signed by you and the Company. This Agreement shall be construed and interpreted in accordance with the laws of the Province of Ontario. Each provision of this Agreement is severable from the others, and if any provision hereof shall be to any extent unenforceable, it and the other provisions shall continue to be enforceable to the full extent allowable, as if such offending provision had not been a part of this Agreement.

VII. **Independent Legal Advice**

You acknowledge that you have had an opportunity to obtain independent financial and/or legal advice before signing this Agreement and agree either that such advice has been obtained or that you do not wish to seek or obtain such independent advice. You acknowledge that you have read this Agreement and fully understand the nature and effect of it and the terms contained herein and that the said terms are fair and reasonable and correctly set out your understanding and intention.

All written notices provided for under this Agreement may be given by personal delivery or by registered mail addressed to you at the address above and to the Board of Directors of the Company.

DNA GENOTEK INC.

Per: */s/ Ian Curry*
Ian Curry
President & CEO

I have read, understood and accept the terms and conditions of employment as stated in this Agreement.

/s/ Brian Smith
Brian Smith

SCHEDULE “A”

Unless otherwise defined in this Schedule “A”, capitalized terms shall have the same meanings as in the main body of the Agreement.

1. **Duties**

a. ***Position***. You will hold the position of Vice President of Sales. In this position, you shall report directly to the President & CEO. You agree that you will not, during the time that you are employed by the Company, perform work or services for any competitor of the Company or its subsidiaries, or otherwise breach the provisions of the Agreement.

b. ***Duties and Obligations***. Your initial duties shall consist of duties for the Company comparable to those that would be performed by a Vice President of Sales of a company in a similar industry and at a comparable stage of development as the Company. In particular, your duties shall include:

(i) Providing leadership through participation in establishing the Company’s goals, and through communicating the Company’s goals and objectives to members of the sales team and other employees, and

(ii) Providing appropriate incentives, structure, and management discipline to drive the Company’s sales team to achieve agreed-upon goals, particularly with respect to the Company’s revenue growth and continued profitability, and

(iii) Providing human resources management expertise for the Company’s sales team and provide development and training to members of the team, and

(iv) Providing strategic direction to the Company.

The CEO of the Company may, at any time, require you to perform other duties that are consistent with your skill and experience and/or the position of Vice President of Sales, or meet group or individual milestones or objectives that are consistent with any other milestones or objectives set by the Board of Directors of the Company which are required to be achieved by the Company.

2. **Compensation**

a. ***Base Salary***. Subject to the terms of this Agreement, as of January 7, 2008, you are entitled to receive the aggregate gross bi-weekly salary of $4,807.70 ($125,000.00 annualized), less all applicable deductions, payable in twenty six (26) bi-weekly installments in accordance with the Company’s established pay periods. Your first pay period with DNA Genotek will be January 11, 2008.

b. ***Stock Options***. You will be granted 443,637 options to purchase Class A Common shares from the Company under the terms of its current Employee Stock Option Plan. Any and all option grants are conditional upon obtaining the required approval of the Board of Directors of the Company, and will be effective as of the Effective Date of this Agreement. Notwithstanding the terms of the Company’s stock option plan, all options granted to you that would normally vest in the following 12 month period shall immediately vest and become exercisable by you upon the happening of any of the following events: (a) the entering into by the Company of any agreement involving any distribution of treasury common shares of the Company or any securities convertible into treasury common shares of the Company to the public pursuant to a prospectus or equivalent document registered or filed with applicable regulatory authorities; or (b) the sale of a controlling interest in the business of the Company (whether by way of shares, assets, merger, reorganization or otherwise) to a third party.

c. ***Benefits***. You shall be entitled to participate in all benefits plans, funds or arrangements that are available to employees of the Company as they become available.

d. ***Incentives***. The Company and you agree to create an incentive compensation structure ("Commission") for the full fiscal year of 2008 to provide a target incentive compensation of $120,000. You understand that this incentive compensation structure will be back- end weighted more towards high growth revenue and/or gross margin targets compared to 2007 Company performance.

3. **Vacation**

You shall be entitled to 20 days paid vacation on an annual basis to be taken at such time or times as are mutually acceptable to you and the Company. In addition, you shall be entitled to 9 days of statutory holidays annually. Unused vacation days remaining at the end of each fiscal year of the Company may be carried forward to a maximum of 20 days unless the Company, in its sole discretion, provides you with a payment in lieu of such unused vacation equal to the base salary you would have earned during the period of such unused vacation. At the end of each fiscal year, any unused vacation in excess of 20 days will be paid in lieu of such unused vacation equal to the base salary you would have earned during the period of such unused vacation.

4. **Expenses**

The Company agrees to promptly reimburse you at cost for all reasonable out-of-pocket expenses for expenses related to your work for the Company upon the delivery of detailed receipts for such expenses.

5. **Termination**

For purposes of Section II(d) of the Agreement, the amount shall equal three (3) months of your then current base salary. Entitlement to Commission ends the final active day of employment and is based only on recognized revenue to that date.

DNA GENOTEK INC.
CONFIDENTIALITY AND PROPRIETARY INFORMATION AGREEMENT

In consideration of employment or engagement as an employee, independent contractor or consultant (as the case may be) with DNA Genotek Inc. (the "Company"), the undersigned (the "Participant") agrees and covenants as follows:

Engagement with the Company as an employee, independent contractor or consultant (as the case may be) ("Engagement") will give the Participant access to proprietary and confidential information belonging to the Company, its customers, it suppliers and others (the proprietary and confidential information is collectively referred to in this Agreement as "Confidential Information"). Confidential Information includes but is not limited to customer lists, marketing plans, proposals, contracts, technical and/or financial information, databases, software, and know-how. All Confidential information remains the confidential and proprietary information of the Company. The Participant acknowledges and agrees that the "Business of the Company" relates to "the research, development, delivery and commercialization of products and services relating to improved methods for preserving, purifying and analyzing DNA" or such other business as is determined by the Board of Directors of the Company from time to time.

The Participant may in the course of the Participant's Engagement with the Company conceive, develop or contribute to material or information related to the Business of the Company, including, without limitation, software, technical documentation, ideas, inventions (whether or not patentable), hardware, know-how, marketing plans, designs, techniques, documentation, records, regardless of the form or media, if any, on which such is stored (referred to in this Agreement as "Proprietary Property"). The Company shall exclusively own all Proprietary Property which the Participant conceives, develops or contributes to in the course of the Participant's Engagement with the Company and all intellectual and industrial property and other rights of any kind in or relating to the Proprietary Property, including but not limited to all copyright, patent, trade secret and trade-mark rights in or relating to the Proprietary Property. Material or information conceived, developed or contributed to by the Participant outside work shall also be Proprietary Property and be governed by this Agreement if such material or information relates to the Business of the Company. The Participant shall keep full and accurate records accessible at all times to the Company relating to all Proprietary Property and shall promptly disclose and deliver to the Company all Proprietary Property.

The Participant shall, both during and after the Participant's Engagement with the Company, keep all Confidential Information, Proprietary Property and Company's Property confidential and shall not use any of it except for the purpose of carrying out authorized activities on behalf of the Company. The Participant may, however, use or disclose Confidential Information which:

(i) is or becomes public other than through a breach of this Agreement;

(ii) is known to the Participant prior to the date of this Agreement and with respect to which the Participant does not have any obligation of confidentiality; or

(iii) is required to be disclosed by law, whether under an order of a court or government tribunal or other legal process, provided that Participant informs the Company of such requirement in sufficient time to allow the Company to avoid such disclosure by the Participant.

The Participant shall return or destroy, as directed by the Company, Confidential Information, Proprietary Property and Company Property to the Company upon request by the Company at any time. The Participant shall certify, by way of affidavit or statutory declaration that all such Confidential Information, Proprietary Information or Company Property has been returned or destroyed, as applicable.

The Participant covenants and agrees not to make any unauthorized use whatsoever of or to bring onto the Company's premises for the purpose of making any unauthorized use whatsoever of any trade secrets, Confidential Information or Proprietary Property of any third party, including without limitation any trade-marks or copyrighted materials, during the course of the Participant's Engagement with the Company.

At the reasonable request and at the sole expense of the Company, the Participant shall do all reasonable acts necessary and sign all reasonable documentation necessary in order to ensure the Company's ownership of the Proprietary Property, the Company Property and all intellectual and industrial property rights and other rights in the same, including but not limited to providing to the Company written assignments of all rights to the Company and any other documents required to enable the Company to document rights to and/or register patents, copyrights, trade-marks, industrial designs and such other protections as the Company considers advisable anywhere in the world.

The Participant hereby irrevocably and unconditionally waives all moral rights the Participant may now or in the future have in any Proprietary Property or any Company Property.

The parties hereto agree that the character, duration and geographical scope of this Agreement are reasonable and necessary in light of the circumstances as they exist on the effective date of this Agreement. If any restriction set forth herein is found by court of competent jurisdiction to be invalid or unreasonable, then the Participant agrees, and hereby submits, to the geographic scope as shall be deemed reasonable and necessary to assure the Company of the intended benefit hereof.

The Participant agrees that the Participant will, if requested from time to time by the Company, execute such further reasonable agreements as to confidentiality and proprietary rights as the Company's customers or suppliers reasonably requires to protect confidential information or proprietary property. Without limiting the generality of the foregoing, the Participant agrees to execute, and be bound by, the attached Conflict of Interest Policy.

Regardless of any changes in position, salary or otherwise, including, without limitation, termination of the Participant's Engagement with the Company, unless otherwise stipulated pursuant to the terms hereof, the Participant will continue to be subject to each of the terms and conditions of this Agreement and any other(s) executed pursuant to the preceding paragraph.

The Participant agrees that the Participant's sole and exclusive remedy for any breach of this Agreement by the Company will be limited to monetary damages and that the Participant will not make any claim in respect of any rights to or interest in any Confidential Information or Proprietary Property.

IN WITNESS WHEREOF the Company and the Participant have caused this Agreement to be executed as of the 7 day of Jan, 2008.

DNA Genotek INC.

Per: */s/ Ian Curry*
Print
Name: Ian Curry

PARTICIPANT

Signature */s/ Brian Smith*
Print Name: Brian Smith

WITNESS TO PARTICIPANT

Signature */s/ Linda Saad Smith*
Print Name: Linda Saad Smith

DNA GENOTEK
CONFLICT OF INTEREST POLICY

Policy

Employees, independent contractors and consultants ("Participants") of DNA Genotek Inc. (the "Company") and any subsidiary of the Company shall refrain from activities which conflict with the interests of the Company during the course of their engagement with the Company as employees, independent contractors or consultants.

Implementation

Every Participant will at all times be conscious of the interests of the Company and will:

(a) not appropriate or convert the Company's property, tangible or intangible, including trade secrets, confidential information and other proprietary information;

(b) not offer bribes or accept corrupt payments or other like illegal or unethical considerations;

(c) not accept gifts or gratuities that cannot be reciprocated in the ordinary course of business;

(d) not disparage the Company or the Company's products, services or personnel;

(e) not influence, in a manner unfavorable to the Company, negotiations or transactions between the Company and its suppliers, contractors, customers and others, because of a personal, commercial or financial interest in the outcome of the negotiations or transactions;

(f) execute, respect and not act in breach of, directly or indirectly, the Company's Confidentiality and Proprietary Information Agreement.

The above examples are merely illustrations of sources of possible conflicts. It is anticipated that the activities of Participants will comply with both the letter and the spirit of this policy.

Objective

The objective of this policy is to establish basic rules of conduct for all the Company's Participants in order to ensure that the business of the Company is conducted with a high level of integrity and that the likelihood of conflicts of interest between the Company and its Participants is minimal.

Brian Smith	*/s/ Brian Smith*	Jan 7/2008
Participant Name (*please print*)	Participant Signature	Date
Linda Saad Smith	*/s/ Linda Saad Smith*	Jan. 7/2008
Witness Name (*please print*)	Witness Signature	Date

Exhibit 31.1

Certification

I, Douglas A. Michels, certify that:

1. I have reviewed this report on Form 10-Q of OraSure Technologies, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d –15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within the entity, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 9, 2017

/s/ Douglas A. Michels
Douglas A. Michels
President and Chief Executive Officer
(*Principal Executive Officer*)

Exhibit 31.2

Certification

I, Ronald H. Spair, certify that:

1. I have reviewed this report on Form 10-Q of OraSure Technologies, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d –15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within the entity, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 9, 2017

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

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. §1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of OraSure Technologies, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Douglas A. Michels, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Douglas A. Michels

Douglas A. Michels
President and Chief Executive Officer

August 9, 2017

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. §1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of OraSure Technologies, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ronald H. Spair, Chief Operating Officer and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Ronald H. Spair

Ronald H. Spair
Chief Operating Officer and Chief Financial Officer

August 9, 2017