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, 2018.

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	☒	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☐
		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, 2018: 61,173,523 shares.

PART I. FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

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

	June 30, 2018	December 31, 2017
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 71,047	$ 71,029
Restricted cash	22	1,840
Short-term investments	74,269	83,028
Accounts receivable, net of allowance for doubtful accounts of $301 and $471	31,648	42,521
Inventories	20,599	19,343
Prepaid expenses	1,519	1,658
Other current assets	3,118	2,486
Total current assets	202,222	221,905
PROPERTY AND EQUIPMENT, net	23,946	21,372
INTANGIBLE ASSETS, net	6,622	8,223
GOODWILL	19,231	20,083
LONG TERM INVESTMENTS	35,828	20,690
OTHER ASSETS	4,513	3,928
	$ 292,362	$ 296,201
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 9,659	$ 10,228
Deferred revenue	1,621	1,314
Accrued expenses	9,837	20,695
Total current liabilities	21,117	32,237
OTHER LIABILITIES	4,474	3,932
DEFERRED INCOME TAXES	1,600	1,951
COMMITMENTS AND CONTINGENCIES (Note 8)		
STOCKHOLDERS' EQUITY		
Preferred stock, par value $.000001, 25,000 shares authorized, none issued	—	—
Common stock, par value $.000001, 120,000 shares authorized, 61,174 and 60,662 shares issued and outstanding	—	—
Additional paid-in capital	397,218	387,931
Accumulated other comprehensive loss	(14,464)	(10,340)
Accumulated deficit	(117,583)	(119,510)
Total stockholders' equity	265,171	258,081
	$ 292,362	$ 296,201

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,	
	2018	2017	2018	2017
NET REVENUES:				
Product	$ 38,818	$ 39,132	$ 77,136	$ 70,614
Other	4,807	1,044	8,476	2,108
	43,625	40,176	85,612	72,722
COST OF PRODUCTS SOLD	17,730	14,699	35,250	26,935
Gross profit	25,895	25,477	50,362	45,787
OPERATING EXPENSES:				
Research and development	4,261	3,338	8,336	6,308
Sales and marketing	7,429	7,502	14,928	14,379
General and administrative	8,647	7,750	22,038	14,842
Gain on litigation settlement	-	-	—	(12,500)
	20,337	18,590	45,302	23,029
Operating income	5,558	6,887	5,060	22,758
OTHER INCOME	736	96	1,148	563
Income before income taxes	6,294	6,983	6,208	23,321
INCOME TAX EXPENSE	2,173	1,555	4,206	5,452
NET INCOME	$ 4,121	$ 5,428	$ 2,002	$ 17,869
EARNINGS PER SHARE:				
BASIC	$ 0.07	$ 0.09	$ 0.03	$ 0.31
DILUTED	$ 0.07	$ 0.09	$ 0.03	$ 0.30
SHARES USED IN COMPUTING EARNINGS PER SHARE:				
BASIC	61,100	58,478	60,983	57,708
DILUTED	62,244	60,728	62,379	59,755

See accompanying notes to the consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
NET INCOME	$ 4,121	$ 5,428	$ 2,002	$ 17,869
OTHER COMPREHENSIVE INCOME (LOSS)				
Currency translation adjustments	(1,652)	1,862	(3,806)	2,312
Unrealized gain (loss) on marketable securities	194	(55)	(318)	(55)
COMPREHENSIVE INCOME (LOSS)	$ 2,663	$ 7,235	$ (2,122)	$ 20,126

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,	
	2018	**2017**
OPERATING ACTIVITIES:		
Net income	$ 2,002	$ 17,869
Adjustments to reconcile net income to net cash provided by operating activities:		
Stock-based compensation	11,262	3,631
Depreciation and amortization	3,746	2,891
Unrealized foreign currency (gain) loss	(255)	178
Deferred income taxes	(272)	(322)
Changes in assets and liabilities		
Accounts receivable	10,166	(6,923)
Inventories	(1,429)	(2,680)
Prepaid expenses and other assets	289	1,525
Accounts payable	(193)	4,739
Deferred revenue	253	83
Accrued expenses and other liabilities	(11,641)	713
Net cash provided by operating activities	13,928	21,704
INVESTING ACTIVITIES:		
Purchases of investments	(93,917)	(62,233)
Proceeds from maturities and redemptions of investments	85,926	18,585
Purchases of property and equipment	(4,484)	(1,567)
Net cash (used in) investing activities	(12,475)	(45,215)
FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	1,201	21,014
Repurchase of common stock	(3,171)	(1,209)
Net cash (used in) provided by financing activities	(1,970)	19,805
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	(1,283)	619
NET (DECREASE) IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH	(1,800)	(3,087)
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH, BEGINNING OF PERIOD	72,869	109,790
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH, END OF PERIOD	$ 71,069	$ 106,703
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for income taxes	$ 11,159	$ 4,325
Noncash investing activities (accrued property and equipment purchases)	$ 665	$ 412
Noncash unrealized losses on marketable securities	$ (318)	$ —

See accompanying notes to the consolidated financial statements.

1. The Company

Our business is comprised of two segments: our "OSUR" business consists of the development, manufacture, marketing and sale of oral fluid 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 molecular collections systems or "DNAG" business consists of the manufacture and sale of specimen collection kits that are used to collect, stabilize, transport and store samples of genetic material for molecular testing in the consumer genetic, clinical genetic, academic research, pharmacogenomics, personalized medicine, microbiome and animal genetics markets.

Our OSUR diagnostic products include tests that are performed on a rapid basis at the point of care and tests that are processed in a laboratory. These products are sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, distributors, government agencies, physicians' offices, and commercial and industrial entities. We also manufacture and sell medical devices used for the removal of benign skin lesions by cryosurgery or freezing. These cryosurgical products are sold in both professional and over-the-counter ("OTC") markets in North America, Europe, Central and South America, and Australia.

Our "DNAG" or molecular collection systems business is operated by our subsidiary, DNA Genotek Inc., a company based in Ottawa, Canada. DNAG's Oragene® DNA sample collection kit provides an all-in-one system for the collection, stabilization, transportation and storage of DNA from human saliva. We also sell research use only sample collection products into the microbiome and tuberculosis markets and we offer our customers a suite of genomics and microbiome services called "GenoFIND™", which range from package customization and study design optimization to extraction, analysis and reporting services. We serve customers worldwide, including many leading research universities and hospitals.

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, 2017. Results of operations for the three and six months ended June 30, 2018 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 accruals, taxes, 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. 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.

Investments. We consider all 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 as of June 30, 2018 and December 31, 2017:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
June 30, 2018				
Guaranteed investment certificates	$ 23,982	$ —	$ —	$ 23,982
Corporate bonds	86,986	—	(871)	86,115
Total available-for-sale securities	$ 110,968	$ —	$ (871)	$ 110,097
December 31, 2017				
Guaranteed investment certificates	$ 22,261	$ —	$ —	$ 22,261
Corporate bonds	82,010	—	(553)	81,457
Total available-for-sale securities	$ 104,271	$ —	$ (553)	$ 103,718
At June 30, 2018, maturities of our available-for-sale securities were as follows:				
Less than one year	$ 74,736	$ —	$ (467)	$ 74,269
Greater than one year	$ 36,232	$ —	$ (404)	$ 35,828

Fair Value of Financial Instruments. As of June 30, 2018 and December 31, 2017, 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, 2018 and December 31, 2017.

Included in cash and cash equivalents at June 30, 2018 and December 31, 2017, was $32,915 and $40,760 invested in government money market funds and certificates of deposit. Both 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, 2018 and December 31, 2017 was $5,010 and $3,514, 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 2018, we purchased a certificate of deposit (“CD”) from a commercial bank as collateral for a standby letter of credit. The CD bears an interest rate of 1.68% and matures on August 20, 2018. The carrying value of the CD approximates its fair value and is reported as restricted cash on the accompanying consolidated balance sheets. Also see Note 8 – Commitments and Contingencies.

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

	June 30, 2018	December 31, 2017
Raw materials	$ 11,677	$ 10,299
Work in process	284	199
Finished goods	8,638	8,845
	$ 20,599	$ 19,343

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 operations. Accumulated depreciation of property and equipment as of June 30, 2018 and December 31, 2017 was $41,037 and $39,379, 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, 2018 and December 31, 2017 was $19,380 and $18,692, respectively. The change in intangibles from $8,223 as of December 31, 2017 to $6,622 as of June 30, 2018 is a result of $1,324 in amortization expense and $277 in foreign currency translation.

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, 2017 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, 2018, we believe no indicators of impairment exist.

The decrease in goodwill from $20,083 as of December 31, 2017 to $19,231 as of June 30, 2018 is a result of foreign currency translation.

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 incremental 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,	
	2018	2017	2018	2017
Net income	$ 4,121	$ 5,428	$ 2,002	$ 17,869
Weighted-average shares of common stock outstanding:				
Basic	61,100	58,478	60,983	57,708
Dilutive effect of stock options, restricted stock, and performance stock units	1,144	2,250	1,396	2,047
Diluted	62,244	60,728	62,379	59,755
Earnings per share:				
Basic	$ 0.07	$ 0.09	$ 0.03	$ 0.31
Diluted	$ 0.07	$ 0.09	$ 0.03	$ 0.30

For the three months ended June 30, 2018 and 2017, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 210 and 40 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, 2018 and 2017, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 205 and 353 shares, respectively, were similarly excluded from the computation of diluted earnings per share.

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

Transaction gains and losses resulting from exchange rate changes on transactions denominated in currencies other than functional currency are included in our consolidated statements of income in the period in which the change occurs. Net foreign exchange gains (losses) resulting from foreign currency transactions that are included in other income (expense) in our consolidated statements of operations were $91 and ($418) for the three months ended June 30, 2018 and 2017, respectively. Net foreign exchange gains (losses) were $345 and ($618) for the six months ended June 30, 2018 and 2017, 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 loss separately from accumulated deficit and additional paid-in capital in the stockholders' equity section of our consolidated balance sheets.

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. Accumulated other comprehensive loss at June 30, 2018 consists of $13,593 of currency translation adjustments and $871 of net unrealized losses on marketable securities, which represents the fair market value adjustment for our investment portfolio. Accumulated other comprehensive loss at December 31, 2017 consists of $9,787 of currency translation adjustments and $553 of net unrealized losses on marketable securities.

Recent Accounting Pronouncements. 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 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. We adopted ASU 2016-15 on January 1, 2018 and this standard did not have a material impact on our consolidated financial statements.

In March 2017, the FASB issued ASU 2017-08, *Receivables-Nonrefundable Fees and Other Costs (Subtopic 310-20): Premium Amortization on Purchased Callable Debt Securities*, which shortens the premium amortization period for purchased non-contingently callable debt securities. Shortening the amortization period is generally expected to more closely align the interest income recognition with the expectations incorporated in the market pricing of the underlying securities. This ASU is effective for annual and interim periods in fiscal years beginning after December 15, 2018. Early adoption is permitted. We adopted ASU 2017-08 on January 1, 2018 and this standard did not have a material impact on our consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting*, to provide clarity to which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. This update will be effective for annual periods and interim periods in fiscal years beginning after December 15, 2017 with early adoption permitted. We adopted ASU 2017-09 on January 1, 2018 and this standard did not have a material impact on our consolidated financial statements.

3. Revenues

Adoption of New Revenue Recognition Standard

In January 2018, we adopted ASU 2014-09, *Revenue from Contracts with Customers* using the modified retrospective method applied to contracts existing as of January 1, 2018. Results for reporting periods beginning after January 1, 2018 are presented under the new guidance, while prior period amounts are not adjusted and continue to be reported in accordance with previous guidance.

Upon adoption, we recorded a reduction of $75 to the opening balance of accumulated deficit as of January 1, 2018. This adjustment is related to the change in revenue recognition associated with our drug testing kit sales. Sales of our drug testing kits include two performance obligations:

sales of the device and laboratory services. Under this new accounting standard, we adjusted the allocation of the transaction price to the performance obligations and the estimate of unexercised rights ("breakage") associated with the contracts. Prior to the adoption of the new guidance, we used the residual value method to allocate the transaction prices. With the adoption of ASU 2014-09, we allocated transition prices based upon the stand-alone selling price, or fair value method. This change in methodology also impacted our estimated breakage amount.

The following table summarizes the impact of the new revenue standard adjustment on our opening balance sheet:

	Balance at December 31, 2017	New Revenue Standard Adjustment	Balance at January 1, 2018
LIABILITIES AND STOCKHOLDERS' EQUITY			
CURRENT LIABILITIES:			
Deferred revenue	1,314	75	1,389
STOCKHOLDERS' EQUITY			
Accumulated deficit	(119,510)	(75)	(119,585)

The adoption of this new standard had an immaterial impact on our reported total revenues and operating income, as compared to what would have been reported under the prior standard. We expect the impact of adoption in future periods to continue to be immaterial. Our accounting policies under the new standard were applied prospectively and are noted below.

Revenue Policies

Product sales. Revenue from product sales is recognized upon transfer of control of a product to a customer, generally upon delivery, based on an amount that reflects the consideration we are entitled to, net of allowances for any discounts or rebates.

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 operations.

We record shipping and handling charges billed to our customers as product revenue and the related expense as cost of products sold.

Arrangements with multiple-performance obligations. In arrangements involving more than one performance obligation, each required performance obligation is evaluated to determine whether it qualifies as a distinct performance obligation based on whether (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available and (ii) the good or services is separately identifiable from other promises in the contract. The consideration under the arrangement is then allocated to each separate distinct performance obligation based on their respective relative stand-alone selling price. The estimated selling price of each deliverable reflects our best estimate of what the selling price would be if the deliverable was regularly sold by us on a stand-alone basis or using an adjusted market assessment approach if selling price on a stand-alone basis is not available. The consideration allocated to each distinct performance obligation is recognized as revenue when control is transferred for the related goods or services.

Other revenues. Other revenues consist primarily of royalty income, funding of research and development efforts and cost reimbursements under a charitable support agreement. Royalties from licensees are based on third-party sales of licensed products and are recorded when the related third-party product sale occurs. Funding and charitable support reimbursements are recorded as the activities are being performed in accordance with the respective agreements.

As part of our litigation settlement agreement with Ancestry.com DNA LLC ("Ancestry") and its contract manufacturer, we granted Ancestry a royalty-bearing, non-exclusive, worldwide license to certain patents and patent applications related to the collection of DNA in human saliva. The license granted to Ancestry is limited to saliva DNA collection kits sold or used as part of Ancestry's genetic testing service offerings and does not cover the sale or use of collection kits outside of Ancestry's business. During the three and six months ended June 30, 2018, we recorded $2,092 and $3,694, respectively, in royalty income under this agreement.

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, which expires in October 2018, included 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 and July 2017, BARDA exercised options to provide $7,200 and $1,330, respectively, in additional funding for our OraQuick® Ebola test. Amounts related to this grant are recorded as other revenue in our consolidated statements of operations as the activities are being performed and the related costs are incurred. During the three and six months ended June 30, 2018, $962 and $1,799, respectively, were recognized in connection with this grant. During the three and six months ended June 30, 2017, $454 and $874, respectively, were 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 operations as the activities are being performed and the related costs are incurred. During the three and six months ended June 30, 2018, $958 and $1,659, respectively, were recognized as other revenue in connection with this grant. During the three and six months ended June 30, 2017, $590 and $1,234, respectively, were recognized in connection with this grant.

In June 2017, we entered into a four-year Charitable Support Agreement with the Bill & Melinda Gates Foundation ("Gates Foundation") that allows us to offer our OraQuick® HIV self-test at an affordable price in 50 developing countries with funding from the Gates Foundation. The funding consists of support payments tied to volume of product sold by us and reimbursement of certain related costs. The funding from the Gates Foundation will be in an aggregate amount not to exceed $20,000 over the four-year term or $6,000 each year of the agreement. Funding received under this agreement in the form of support payments for product purchases is recorded as a component of product revenue. During the three and six months ended June 30, 2018, $1,709 and $2,732, respectively, of support payments were recognized in product revenue in connection with this agreement. Funding received in the form of reimbursement of certain related costs is recorded as other revenue in our consolidated statements of operations. During the three and six months ended June 30, 2018, $795 and $1,324, respectively, were recognized in other revenue for reimbursement of certain related costs. No funding was received during the three and six months ended June 30, 2017.

Deferred Revenue. We record deferred revenue when funds are received prior to the recognition of the associated revenue. Deferred revenue as of June 30, 2018 and December 31, 2017 includes customer prepayments of $1,263 and $1,045, respectively. Deferred revenue as of June 30, 2018 and December 31, 2017 also includes $358 and $269, respectively, associated with a long-term contract that has variable pricing based on volume. The average price over the life of the contract was determined and revenue is recognized at that rate.

Financing and Payment. Our payment terms vary by the type and location of our customer and products or services offered. Payment terms differ by jurisdiction and customer but payment is generally required in a term ranging from 30 to 120 days from date of shipment or satisfaction of the performance obligation.

For certain products or services and customer types, we may require payment before the products are delivered or services are rendered to the customer.

Practical expedients and exemptions. Taxes assessed by governmental authorities, such as sales or value-added taxes, are excluded from product revenues.

Other than for sales of our OraQuick® In-Home HIV test to the retail trade, we do not grant product return rights to our customers except for warranty returns. Historically, returns arising from warranty issues have been infrequent and immaterial. Accordingly, we expense warranty returns as incurred.

We do not grant return rights to our customers for any product, except for our OraQuick® In-Home HIV test. Accordingly, we have recorded an estimate of expected returns as a reduction of gross OraQuick® In-Home HIV product revenues in our consolidated statements of operations. This estimate reflects our historical sales experience to retailers and consumers, as well as other retail factors, and is reviewed regularly to ensure that it reflects potential product returns. As of June 30, 2018 and December 31, 2017, the reserve for sales returns and allowances was $197 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.

Sales commissions are expensed when incurred if the amortization period is one year or less. These costs are recorded in sales and marketing expense in the consolidated statements of operations. If the amortization period exceeds one year, we defer the cost of the commission and expense it over the life of the related sales contract.

Revenues by product. The following table represents total net revenues by product line:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
OraQuick®	$ 15,791	$ 16,530	$ 28,796	$ 30,639
Oragene®	15,368	15,215	32,456	25,154
Intercept®	2,154	2,239	4,069	4,166
Histofreezer®	1,973	2,570	4,327	5,250
Other products	3,532	2,578	7,488	5,405
Net product revenues	38,818	39,132	77,136	70,614
Royalty income	2,092	-	3,694	-
BARDA funding	1,920	1,044	3,458	2,108
Charitable support reimbursement	795	-	1,324	-
Other revenues	4,807	1,044	8,476	2,108
Net revenues	$ 43,625	$ 40,176	$ 85,612	$ 72,722

Revenues by geographic area. 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,	
	2018	2017	2018	2017
United States	$ 31,991	$ 28,954	$ 62,977	$ 49,808
Europe	2,308	2,436	5,205	5,561
Other regions	9,326	8,786	17,430	17,353
	$ 43,625	$ 40,176	$ 85,612	$ 72,722

Customer and Vendor Concentrations. One of our customers accounted for 18% and 37% of our accounts receivable as of June 30, 2018 and December 31, 2017, respectively. The same customer accounted for approximately 18% and 21% of our net consolidated revenues for the three and six months ended June 30, 2018 and 20% and 15% of our net consolidated revenues for the three and six months ended June 30, 2017. Another customer accounted for 10% of our net consolidated revenues for the three months ended June 30, 2017.

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.

4. Accrued Expenses

	June 30, 2018	December 31, 2017
Payroll and related benefits	$ 4,949	$ 9,265
Income taxes payable	—	6,469
Professional fees	1,211	1,064
Royalties	1,054	845
Other	2,623	3,052
	$ 9,837	$ 20,695

5. Credit Facility

On September 30, 2016, we entered into a credit agreement (the “Credit Agreement”) with a commercial bank. The Credit Agreement, as amended on December 20, 2017, 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 facility at June 30, 2018 and December 31, 2017.

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, 2018 and December 31, 2017, we were in compliance with all applicable covenants in the Credit Agreement.

6. 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, 2018 and 2017 was $1,375 and $1,007, respectively. Net cash proceeds from the exercise of stock options were $1,201 and $21,014 for the six months ended June 30, 2018 and 2017, respectively. As a result of our net operating loss carryforward position, no actual income tax benefit was realized from stock option exercises during these periods.

Compensation cost of $5,045 and $1,355 related to restricted shares was recognized during the six months ended June 30, 2018 and 2017, respectively. In connection with the vesting of restricted shares during the six months ended June 30, 2018 and 2017, we purchased and immediately retired 163 and 120 shares with aggregate values of $3,171 and $1,209, respectively, in satisfaction of minimum tax withholding obligations.

We grant performance-based restricted stock units ("PSUs") to certain executives. 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 is based on a one-year earnings per share or income before income taxes 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 target assumptions on a quarterly basis and adjusts compensation expense related to these awards, as appropriate.

Compensation cost of $4,842 and $1,269 related to PSUs was recognized during the six months ended June 30, 2018 and 2017, respectively.

Modification of Grants

Stock compensation costs for the three and six months ended June 30, 2018 include the additional expense associated with modifications of existing grants held by our retiring President and Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"). These additional costs were $2,188 and $8,039 during the three and six months ended June 30, 2018, 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, 2018 and 2017.

7. Income Taxes

During the three and six months ended June 30, 2018, we recorded tax expense of $2,173 and $4,206, respectively. During the three and six months ended June 30, 2017, we recorded tax expense of $1,555 and $5,452, respectively.

Tax expense reflects taxes due to 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. Tax expense in the first six months of 2017 also includes 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.

The significant components of our total deferred tax liability as of June 30, 2018 and December 31, 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.

In 2008, we established a full valuation allowance against our U.S. deferred tax asset. Management believes the full valuation allowance is still appropriate at both June 30, 2018 and December 31, 2017 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, 2018 and 2017.

On December 22, 2017, the U.S. enacted the Tax Cuts and Jobs Act ("Tax Act") that instituted fundamental changes to the taxation on multinational corporations. Provisions of the Tax Act, which was effective January 1, 2018, include a permanent reduction in the corporate tax rate to 21% and a one-time transition tax imposed on a U.S. shareholder's historical undistributed earnings of foreign affiliates. Given that the U.S. entity has a full valuation allowance against its deferred tax assets and is generating net operating losses ("NOLs"), these tax provisions do not impact our financial results.

The Tax Act also imposes a U.S. tax on global intangible low taxed income ("GILTI") that is earned by certain foreign affiliates owned by a U.S. shareholder effective in 2018. GILTI is generally intended to impose tax on the earnings of a foreign corporation that are deemed to exceed a certain threshold return relative to the underlying tangible property. Although we are subject to GILTI, the computation of GILTI is still subject to interpretation and additional clarifying guidance is expected. Tax law ordering rules require that NOLs be utilized first to offset any GILTI tax liability before the use of any other tax attributes. We have sufficient NOLs to offset our projected 2018 GILTI income inclusion.

As a result of the complex impact of the Tax Act, the SEC provided guidance under Staff Accounting Bulletin No. 118 ("SAB 118") that allows the Company to record provisional amounts as of December 31, 2017 for the impact of the Tax Act, provided that the provisional amounts can be reasonably determined and with the requirement that the final accounting be completed in a period not to exceed one year from the date of enactment. During the three and six months ended June 30, 2018, there were no adjustments made to the provisional amounts that were recorded under SAB 118 as of December 31, 2017 and these amounts remain provisional at June 30, 2018.

8. Commitments and Contingencies

Standby Letters of Credit

We issued a standby letter of credit in the amount of $22, naming an international customer as the beneficiary. This letter of credit was required as a performance guarantee of our obligations under our product supply contract with this customer and is collateralized by a certificate of deposit maintained at a commercial bank. The standby letter of credit is recorded in restricted cash in the accompanying consolidated balance sheets.

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.

9. Transition Costs

In January 2018, we announced the retirement of our President and CEO and our CFO and Chief Operating Officer. Stephen S. Tang, Ph.D., who served as Chairman of the Board of Directors (the "Board"), was appointed as the Company's new President and CEO, effective as of April 1, 2018. Dr. Tang replaced Douglas A. Michels, who retired as President and CEO, and as a member of the Board, on March 31, 2018. In addition, Roberto Cuca was appointed as the Company's new CFO, effective June 8, 2018. Mr. Cuca replaced Ronald H. Spair, our former CFO and Chief Operating Officer, who retired on that same date. Charges associated with these transitions were $2,188 and $8,628 during the three and six months ended June 30, 2018, respectively. These charges primarily reflect non-cash charges associated with modifications to existing stock grants held by the retiring executives and expenses associated with the onboarding of the Company's new President and CEO.

10. Business Segment Information

Our business is comprised of two segments: our "OSUR" business consists of the development, manufacture, marketing and sale of oral fluid 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 molecular collections systems or "DNAG" business consists of the manufacture and sale of specimen collection kits that are used to collect, stabilize, transport and store samples of genetic material for molecular testing in the consumer genetic, clinical genetic, academic research, pharmacogenomics, personalized medicine, microbiome and animal genetics markets.

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, 2018 and 2017, and asset information as of June 30, 2018 and December 31, 2017:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Net revenues:				
OSUR	$ 24,341	$ 24,119	$ 46,365	$ 45,958
DNAG	19,284	16,057	39,247	26,764
Total	$ 43,625	$ 40,176	$ 85,612	$ 72,722
Operating income (loss):				
OSUR	$ (2,922)	$ 438	$ (11,821)	$ 218
DNAG	8,480	6,449	16,881	22,540
Total	$ 5,558	$ 6,887	$ 5,060	$ 22,758
Depreciation and amortization:				
OSUR	$ 993	$ 678	$ 2,004	$ 1,334
DNAG	885	793	1,742	1,557
Total	$ 1,878	$ 1,471	$ 3,746	$ 2,891
Capital expenditures:				
OSUR	$ 1,358	$ 553	$ 2,774	$ 1,337
DNAG	1,229	136	1,710	230
Total	$ 2,587	$ 689	$ 4,484	$ 1,567

	June 30, 2018	December 31, 2017
Total assets:		
OSUR	$ 188,426	$ 192,352
DNAG	103,936	103,849
Total	$ 292,362	$ 296,201

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

	June 30, 2018	December 31, 2017
United States	$ 17,720	$ 16,160
Canada	6,080	5,083
Other regions	146	129
	$ 23,946	$ 21,372

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 significant customer concentration in the genomics business; 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, 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; ability to successfully renew contracts or enter into new contracts with existing customers; 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, 2017, 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 and Business Segments

Our business is comprised of two segments: our "OSUR" business consists of the development, manufacture, marketing and sale of oral fluid 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 molecular collections systems or "DNAG" business consists of the manufacture and sale of specimen collection kits that are used to collect, stabilize, transport and store samples of genetic material for molecular testing in the consumer genetic, clinical genetic, academic research, pharmacogenomics, personalized medicine, microbiome and animal genetics markets.

Our OSUR diagnostic products include tests that are performed on a rapid basis at the point of care and tests that are processed in a laboratory. These products are sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, distributors, government agencies, physicians' offices, and commercial and industrial entities. We also

manufacture and sell medical devices used for the removal of benign skin lesions by cryosurgery or freezing. These cryosurgical products are sold in both professional and over-the-counter ("OTC") markets in North America, Europe, Central and South America, and Australia.

Our DNAG or molecular collection systems business is operated by our subsidiary, DNA Genotek Inc. ("DNAG"), a company based in Ottawa, Canada. DNAG's Oragene® DNA sample collection kit provides an all-in-one system for the collection, stabilization, transportation and storage of DNA from human saliva. We also sell research use only sample collection products into the microbiome and tuberculosis markets and we offer our customers a suite of genomics and microbiome services called "GenoFIND™", which range from package customization and study design optimization to extraction, analysis and reporting services. We serve customers worldwide, including many leading research universities and hospitals.

Current Consolidated Financial Results

During the six months ended June 30, 2018, our consolidated net revenues were $85.6 million, compared to $72.7 million for the six months ended June 30, 2017. Net product revenues during the six months ended June 30, 2018 increased 9% when compared to the first half of 2017, primarily due to higher sales of our molecular collection systems products and increased international sales of our OraQuick® HIV Self-Test. Partially offsetting these increases were lower sales of our OraQuick® HCV and cryosurgical systems products and lower domestic sales of our professional OraQuick® HIV product. Other revenues for the first six months of 2018 were $8.5 million compared to $2.1 million in the same period of 2017. Other revenues in the first half of 2018 consisted of royalty income of $3.7 million, 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") related to our Ebola and Zika products of $3.5 million and reimbursement of certain costs under our charitable support agreement with the Bill & Melinda Gates Foundation ("Gates Foundation") of $1.3 million. Other revenues in the first six months of 2017 consisted of $2.1 million of BARDA funding.

Our consolidated net income for the six months ended June 30, 2018 was $2.0 million, or $0.03 per share on a fully-diluted basis, compared to consolidated net income of $17.9 million, or $0.30 per share on a fully-diluted basis for the six months ended June 30, 2017. Results in the first half of 2018 included $8.6 million of management transition costs associated with the retirement of the Company's Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO") and Chief Operating Officer and the appointment of their successors, which approximates $0.14 per share. Results for the first quarter of 2017 included a gain of $12.5 million associated with the settlement of our litigation against Ancestry.com DNA LLC and its contract manufacturer in that period, which approximates $0.16 per share on a fully-diluted after-tax basis.

Cash provided by operating activities for the six months ended June 30, 2018 was $13.9 million. Cash provided by operating activities during the six months ended June 30, 2017 was $21.7 million and included the $12.5 million litigation settlement noted above. As of June 30, 2018, we had $181.2 million in cash (including restricted cash), cash equivalents, and available-for-sale securities, compared to $176.6 million at December 31, 2017.

Results of Operations

Three months ended June 30, 2018 compared to June 30, 2017

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, 2018 and 2017.

	Three Months Ended June 30,				
	Dollars			Percentage of Total Net Revenues	
	2018	2017	% Change	2018	2017
OSUR	$ 21,626	$ 23,075	(6) %	50 %	57 %
DNAG	17,192	16,057	7	39	40
Net product revenues	38,818	39,132	(1)	89	97
Other	4,807	1,044	360	11	3
Net revenues	$ 43,625	$ 40,176	9 %	100 %	100 %

Consolidated net product revenues decreased 1% to $38.8 million in the second quarter of 2018 from $39.1 million in the comparable period of 2017. Lower sales of our OraQuick® HCV and cryosurgical systems products and lower domestic sales of our professional OraQuick® HIV test were partially offset by higher international sales of our OraQuick® HIV Self-Test and higher sales of our molecular collection systems products. Other revenues for the second quarter of 2018 were $4.8 million compared to $1.0 million in the same period of 2017. Other revenues in the second quarter of 2018 included $2.1 million in royalty income earned under a litigation settlement agreement, $1.9 million in funding from BARDA related to our Ebola and Zika products and $795,000 in reimbursement of certain costs under our charitable support agreement with the Gates Foundation. Other revenues in the second quarter of 2017 consisted entirely of BARDA funding.

Consolidated net revenues derived from products sold to customers outside of the United States were $11.6 million and $11.2 million, or 27% and 28% of total net revenues, in the second quarters of 2018 and 2017, 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 during the second quarters of 2018 and 2017.

	Three Months Ended June 30,				
	Dollars			Percentage of Total Net Revenues	
Market	2018	2017	% Change	2018	2017
Infectious disease testing	$ 15,919	$ 16,663	(4) %	65 %	70 %
Risk assessment testing	3,315	3,238	2	14	13
Cryosurgical systems	2,392	3,174	(25)	10	13
Net product revenues	21,626	23,075	(6)	89	96
Other	2,715	1,044	160	11	4
Net revenues	$ 24,341	$ 24,119	1 %	100 %	100 %

Infectious Disease Testing Market

Sales to the infectious disease testing market decreased 4% to $15.9 million in the second quarter of 2018 from $16.7 million in the second quarter of 2017. This decrease resulted from lower sales of our OraQuick® HCV product and lower domestic sales of our professional OraQuick® HIV product, partially offset by higher international sales of our OraQuick® HIV Self-Test.

The table below shows a breakdown of our total net OraQuick® HIV and HCV product revenues (dollars in thousands) during the second quarters of 2018 and 2017.

	Three Months Ended June 30,		
Market	2018	2017	% Change
Domestic HIV	$ 3,881	$ 4,965	(22) %
International HIV	7,397	2,025	265
Domestic OTC HIV	1,308	1,894	(31)
Net HIV revenues	12,586	8,884	42
Domestic HCV	1,730	2,382	(27)
International HCV	1,473	5,261	(72)
Net HCV revenues	3,203	7,643	(58)
Net OraQuick® revenues	$ 15,789	$ 16,527	(4) %

Domestic OraQuick® HIV sales decreased 22% to $3.9 million for the three months ended June 30, 2018 from $5.0 million for the three months ended June 30, 2017. This decrease was primarily the result of competition from point-of-care HIV tests perceived to be more sensitive than our product, competition from fourth generation automated HIV immunoassays performed in a laboratory, and customer ordering patterns.

International sales of our OraQuick® HIV test during the second quarter of 2018 rose 265% to $7.4 million for the three months ended June 30, 2018 from $2.0 million for the three months ended June 30, 2017. This increase was largely due to higher sales of our OraQuick® HIV Self-Test into Africa. Funding under the charitable support agreement with the Gates Foundation began in the third quarter of 2017 and product revenues in the second quarter of 2018 included approximately $1.7 million of support payments under that agreement.

Sales of our OraQuick® In-Home HIV test decreased 31% to $1.3 million in the second quarter of 2018 from $1.9 million in the second quarter of 2017. Sales of this test benefitted in the second quarter of 2017 from higher inventory purchases by certain retail pharmacies in anticipation of additional shelf placements which began in that same quarter. Sales in the second quarter of 2018 are more reflective of normalized sales activity.

Domestic OraQuick® HCV sales decreased 27% to $1.7 million in the second quarter of 2018 from $2.4 million in the second quarter of 2017 primarily due to the non-renewal or delay of grant funding and a large NGO customer discontinuing its testing program. International OraQuick® HCV sales decreased 72% to $1.5 million in the second quarter of 2018 from $5.3 million in the second quarter of 2017, due to the non-renewal of a supply contract with a foreign government in support of a countrywide HCV eradication program and the loss of a multi-national humanitarian organization customer that switched to a competitive product due to pricing. These decreases were partially offset by higher sales into Asia and Africa as a result of new programs or studies instituted in those geographies.

Risk Assessment Market

Sales to the risk assessment market slightly increased to $3.3 million in the second quarter of 2018 compared to $3.2 million in the second quarter of 2017.

Cryosurgical Market

Sales of our cryosurgical products decreased 25% to $2.4 million in the second quarter of 2018 from $3.2 million in the second quarter of 2017.

The table below shows a breakdown of our total net cryosurgical revenues (dollars in thousands) generated in each market during the second quarters of 2018 and 2017.

	Three Months Ended June 30,		
Market	2018	2017	% Change
Domestic professional	$ 1,068	$ 1,445	(26) %
International professional	264	243	9
Domestic OTC	295	347	(15)
International OTC	765	1,139	(33)
Net cryosurgical systems revenues	$ 2,392	$ 3,174	(25) %

Second quarter 2018 sales of our domestic Histofreezer® product sold to physicians' offices decreased 26% to $1.1 million from $1.4 million in the second quarter of 2017, primarily due to the timing of orders placed by our distributors and competitive losses from lower-priced products that have entered the market as result of the expiration of the patents associated with our cryosurgical technology.

Sales of our international OTC cryosurgical products during the second quarter of 2018 decreased 33% to $765,000 compared to $1.1 million in the second quarter of 2017 primarily due to lower sales in Latin America.

Other revenues

Other revenues in the second quarter of 2018 increased 360% to $4.8 million from $1.0 million in the second quarter of 2017. The table below shows a breakdown of our other revenues (dollars in thousands) recorded during the second quarters of 2018 and 2017.

	Three Months Ended June 30,		
	2018	2017	% Change
Royalty income	$ 2,092	$ -	N/A
BARDA funding	1,920	1,044	84 %
Charitable support reimbursement	795	-	N/A
Other revenues	$ 4,807	$ 1,044	360 %

Other revenues in the second quarter of 2018 included $2.1 million of royalty income earned under a litigation settlement agreement. The settlement agreement was entered into in 2017 and required royalty payments beginning in the first quarter of 2018. There were no revenues of this nature in the second quarter of 2017. Revenue from BARDA funding increased to $1.9 million in the second quarter of 2018 compared to $1.0 million in the second quarter of 2017 as a result of increased efforts related to our Ebola and Zika products. Other revenues in the second quarter of 2018 also included $795,000 in reimbursement of certain costs under our charitable support agreement with the Gates Foundation, which are separate from the above-referenced support payments received under this agreement. Reimbursement of these costs began in the third quarter of 2017 and, as such, there was no comparable revenue in the second quarter of 2017.

DNAG Segment

Molecular Market

	Three Months Ended June 30,		
Market	2018	2017	% Change
Commercial genomics	$ 12,263	$ 12,815	(4) %
Academic genomics	3,105	2,399	29
Microbiome	1,824	843	116
Net molecular collection systems revenues	$ 17,192	$ 16,057	7 %

Net molecular collection systems revenues increased 7% to $17.2 million in the second quarter of 2018 from $16.1 million in the second quarter of 2017. Sales in the commercial market declined 4% in the second quarter of 2018 compared to the second quarter of 2017, largely as a result of the loss of a customer that switched to a different extraction technology. This decrease was partially offset by increased sales to other commercial customers as a result of the timing of orders placed, increased demand, and a new purchase order from a customer in the animal genomics market. Sales into the academic market increased 29% in the second quarter of 2018 compared to the second quarter of 2017 largely due to increased

shipments to support a study on autism, coupled with customer ordering patterns. Revenues in the second quarter of 2018 also included $1.8 million in sales of our microbiome products which represents a 116% increase over the $843,000 in microbiome revenues generated in the same period of 2017, as interest in our microbiome product offerings continues to grow with both new and existing customers.

CONSOLIDATED OPERATING RESULTS

Consolidated gross profit percentage (gross margin) was 59% for the second quarter of 2018 compared to 63% for the second quarter of 2017. Gross profit percentage in the second quarter of 2018 was negatively impacted by an increase in lower profit percentage sales partially offset by the increase in other revenues which have a gross profit percentage of 100%.

Consolidated operating income for the second quarter of 2018 was $5.6 million, a $1.3 million decline from the $6.9 million of operating income reported in the second quarter of 2017. Our results for the second quarter of 2018 were negatively impacted by the increase in lower profit percentage sales, the inclusion of $2.2 million of transition costs associated with executive management changes, and increased spending in research and development. These increases were partially offset by a decrease in Company-wide staffing costs largely due to a bonus accrual adjustment for performance in the second quarter of 2017 that did not repeat in the second quarter of 2018.

OPERATING INCOME (LOSS) BY SEGMENT

OSUR Segment

OSUR's gross profit percentage was 55% in the second quarter of 2018 compared to 62% in the second quarter of 2017. OSUR's gross profit percentage in the second quarter of 2018 was negatively impacted by an increase in lower profit percentage revenues as a result of higher international sales partially offset by the increase in BARDA funding and cost reimbursement from the Gates Foundation.

Research and development expenses increased 32% to $3.5 million in the second quarter of 2018 from $2.6 million in the second quarter of 2017, largely due to increased spending on our Ebola and Zika products and higher staffing costs. Sales and marketing expenses decreased 3% to $5.0 million in the second quarter of 2018 from $5.2 million in the second quarter of 2017 largely due to lower staffing costs. General and administrative expenses increased 16% to $7.9 million in the second quarter of 2018 from $6.8 million in the second quarter of 2017 as a result of the inclusion of $2.2 million of transition costs associated with executive management changes, partially offset by lower staffing costs which largely consisted of a bonus accrual adjustment for performance in the second quarter of 2017 that did not repeat in the second quarter of 2018.

All of the above contributed to OSUR's second quarter 2018 operating loss of $2.9 million, which included non-cash charges of $1.0 million for depreciation and amortization and $3.6 million for stock-based compensation.

DNAG Segment

DNAG's gross profit percentage was 64% in the second quarter of 2018 compared to 65% in the second quarter of 2017. This decline was attributable to an increase in lower profit percentage sales in the second quarter of 2018 compared to the second quarter of 2017, partially offset by the royalty income recorded in the second quarter of 2018. No royalty income was recorded in the second quarter of 2017.

Research and development expenses increased 11% to $803,000 in the second quarter of 2018 from $722,000 in the second quarter of 2017 due to increased staffing costs as a result of higher headcount. Sales and marketing expenses rose 3% to $2.4 million in the second quarter of 2018 from $2.3 million in the second quarter of 2017 due to higher staffing costs associated with increased headcount and an increase in commission expense. General and administrative expenses decreased 23% to $726,000 in the second quarter of 2018 compared to $949,000 in the second quarter of 2017 primarily due to lower staffing expense.

All of the above contributed to DNAG's second quarter 2018 operating income of $8.5 million, which included non-cash charges of $885,000 for depreciation and amortization and $138,000 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, 2018 and 2017, no state income tax expense was recorded. Canadian income tax expense of $2.2 million and $1.6 million was recorded in the second quarters of 2018 and 2017, respectively. The increase in income tax expense is directly related to the increase in income before taxes generated by DNAG. On December 22, 2017, the United States enacted the Tax Cuts and Jobs Act ("Tax Act") that instituted fundamental changes to the taxation on multinational corporations. The impact of the Tax Act on our financial results is not material given that OSUR has a full valuation allowance against its total U.S. deferred tax assets and due to the net operating losses ("NOLs") and tax credits that are being generated by the U.S. entity.

Results of Operations

Six months ended June 30, 2018 compared to June 30, 2017

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, 2018 and 2017.

	Six Months Ended June 30,				
	Dollars			Percentage of Total Net Revenues	
	2018	2017	% Change	2018	2017
OSUR	$ 41,583	$ 43,850	(5) %	48 %	60 %
DNAG	35,553	26,764	33	42	37
Net product revenues	77,136	70,614	9	90	97
Other	8,476	2,108	302	10	3
Net revenues	$ 85,612	$ 72,722	18 %	100 %	100 %

Consolidated net product revenues increased 9% to $77.1 million in the first half of 2018 from $70.6 million in the same period of 2017. Higher sales of our molecular collection systems products and higher international sales of our OraQuick® HIV Self-Test were partially offset by lower sales of our OraQuick® HCV product, lower domestic sales of our professional OraQuick® HIV test and lower sales of our cryosurgical systems products. Other revenues in the first half of 2018 were $8.5 million compared to $2.1 million in the same period of 2017. Other revenues in the first six months of 2018 included $3.7 million in royalty income earned under a litigation settlement agreement, $3.5 million in funding from BARDA related to our Ebola and Zika products and $1.3 million in reimbursement of certain costs under our charitable support agreement with the Gates Foundation. Other revenues in the first half of 2017 consisted entirely of BARDA funding.

Consolidated net revenues derived from products sold to customers outside of the United States were $22.6 million and $22.9 million, or 26% and 32% of total net revenues, during the six months ended June 30, 2018 and 2017, 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 for the six months ended June 30, 2018 and 2017.

Infectious Disease Testing Market

	Six Months Ended June 30,				
	Dollars			Percentage of Total Net Revenues	
Market	2018	2017	% Change	2018	2017
Infectious disease testing	$ 30,090	$ 31,245	(4) %	65 %	67 %
Risk assessment testing	6,316	6,368	(1)	14	14
Cryosurgical systems	5,177	6,237	(17)	11	14
Net product revenues	41,583	43,850	(5)	90	95
Other	4,782	2,108	127	10	5
Net revenues	$ 46,365	$ 45,958	1 %	100 %	100 %

Sales to the infectious disease testing market decreased 4% to $30.1 million for the six months ended June 30, 2018 from $31.2 million for the six months ended June 30, 2017. This decrease resulted from lower sales of our OraQuick® HCV product and lower domestic sales of our professional OraQuick® HIV product, partially offset by increased international sales of our OraQuick® HIV Self-Test.

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, 2018 and 2017.

	Six Months Ended June 30,		
Market	2018	2017	% Change
Domestic HIV	$ 7,293	$ 8,779	(17) %
International HIV	13,067	4,669	180
Domestic OTC HIV	2,941	3,436	(14)
Net HIV revenues	23,301	16,884	38
Domestic HCV	3,358	4,091	(18)
International HCV	2,138	9,664	(78)
Net HCV revenues	5,496	13,755	(60)
Net OraQuick® revenues	$ 28,797	$ 30,639	(6) %

Domestic OraQuick® HIV sales decreased 17% to $7.3 million for the six months ended June 30, 2018 from $8.8 million for the six months ended June 30, 2017. This decrease was primarily the result of competition from point-of-care HIV tests perceived to be more sensitive than our product, competition from fourth generation automated HIV immunoassays performed in a laboratory, and customer ordering patterns.

International sales of our OraQuick® HIV test during the first half of 2018 rose 180% to $13.1 million for the six months ended June 30, 2018 from $4.7 million for the six months ended June 30, 2017. This increase was largely due to higher sales of our OraQuick® HIV Self-Test into Africa. Funding under the charitable support agreement with the Gates Foundation began in the third quarter of 2017 and product revenues in the first half of 2018 included approximately $2.7 million of support payments under that agreement.

Sales of our OraQuick® In-Home HIV test decreased 14% to $2.9 million during the first half of 2018 from $3.4 million in the first half of 2017. Sales of this test benefitted in the first half of 2017 from higher inventory purchases by certain retail pharmacies in anticipation of additional shelf placements which began in the second quarter of 2017. Sales in the first half of 2018 are more reflective of normalized sales activity.

Domestic OraQuick® HCV sales decreased 18% to $3.4 million in the first half of 2018 from $4.1 million in the first half of 2017 primarily due to the non-renewal or delay of grant funding and a large NGO customer discontinuing its testing program. International OraQuick® HCV sales decreased 78% to $2.1 million in the first half of 2018 from $9.7 million in the first half of 2017, due to the non-renewal of a supply contract with a foreign government in support of a countrywide HCV eradication program and the loss of a multi-national humanitarian organization customer that switched to a competitive product due to pricing. These decreases were partially offset by higher sales into Asia.

Risk Assessment Market

Sales to the risk assessment market slightly decreased to $6.3 million in the first half of 2018 compared to $6.4 million in the first half of 2017.

Cryosurgical Market

Sales of our cryosurgical products decreased 17% to $5.2 million in the first half of 2018 from $6.2 million in the first half of 2017.

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, 2018 and 2017.

	Six Months Ended June 30,		
Market	2018	2017	% Change
Domestic professional	$ 1,943	$ 2,941	(34) %
International professional	413	373	11
Domestic OTC	584	632	(8)
International OTC	2,237	2,291	(2)
Net cryosurgical systems revenues	$ 5,177	$ 6,237	(17) %

Sales of our domestic Histofreezer® product to physicians' offices decreased 34% to $1.9 million from $2.9 million in the first half of 2017, primarily due to the timing of orders placed by our distributors and competitive losses from lower-priced products that have entered the market as result of the expiration of the patents associated with our cryosurgical technology.

Sales of our international OTC cryosurgical products remained relatively consistent during the first half of 2018 at $2.2 million compared to $2.3 million in the first half 2017.

Other revenues

Other revenues in the first half of 2018 increased 302% to $8.5 million from $2.1 million in the first half of 2017. The table below shows a breakdown of our other revenues (dollars in thousands) recorded during the six months ended June 30, 2018 and 2017.

	Six Months Ended June 30,		
	2018	2017	% Change
Royalty income	$ 3,694	$ -	N/A
BARDA funding	3,458	2,108	64 %
Charitable support reimbursement	1,324	-	N/A
Other revenues	$ 8,476	$ 2,108	302 %

Other revenues in the first half of 2018 included $3.7 million of royalty income earned under a litigation settlement agreement. This royalty agreement was entered into in 2017 and required royalty payments beginning in the first quarter of 2018. There were no revenues of this nature in the first half of 2017. Revenue from BARDA funding increased to $3.5 million in the first half of 2018 compared to $2.1 million in the first half of 2017 as a result of increased efforts related to our Ebola and Zika products. Other revenues in the first half of 2018 also included $1.3 million in reimbursement of certain costs under our charitable support agreement with the Gates Foundation. Reimbursement of these costs began in the third quarter of 2017 and, as such, there was no comparable revenue in the first half of 2017.

DNAG Segment

Molecular Market

	Six Months Ended June 30,		
Market	2018	2017	% Change
Commercial genomics	$ 26,519	$ 20,072	32 %
Academic genomics	5,937	5,083	17
Microbiome	3,097	1,609	92
Net molecular collection systems revenues	$ 35,553	$ 26,764	33 %

Net molecular collection systems revenues increased 33% to $35.6 million in the first half of 2018 from $26.8 million in the first half of 2017. Sales in the commercial market rose 32% in the first half of 2018 compared to the first half of 2017, largely as a result of higher customer demand, primarily from a large customer in the consumer genetics market. Sales into the academic market increased 17% in the first half of 2018 compared to the first half of 2017 largely due to increased shipments to support a study on autism coupled with customer ordering patterns and higher demand, partially offset by the loss of a large academic customer that moved to a competitive turnkey offering. Revenues in the first half of 2018 also included $3.1 million in sales of our microbiome products compared to $1.6 million in the same period of 2017, as interest in our microbiome product offerings continues to grow with both new and existing customers.

CONSOLIDATED OPERATING RESULTS

Consolidated gross profit percentage was 59% for the first half of 2018 compared to 63% for the first half of 2017. Gross profit percentage in the first six months of 2018 was negatively impacted by an increase in lower profit percentage sales, partially offset by the increase in other revenues which have a gross profit percentage of 100%.

Consolidated operating income for the first half of 2018 was $5.1 million, a $17.7 million decline from the $22.8 million of operating income reported in the first half of 2017. Operating income in the first half of 2017 included 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 addition, our results for the first half of 2018 were negatively impacted by the increase in lower profit percentage sales, the inclusion of $8.6 million of transition costs associated with executive management changes, and increased spending in research and development and sales and marketing.

OPERATING INCOME (LOSS) BY SEGMENT

OSUR Segment

OSUR's gross profit percentage was 55% in the first half of 2018 compared to 61% in the first half of 2017. OSUR's gross profit percentage in 2018 was negatively impacted by an increase in lower profit percentage revenues as a result of higher international sales, partially offset by the increase in BARDA funding and cost reimbursement from the Gates Foundation.

Research and development expenses increased 36% to $6.8 million in the first half of 2018 from $5.0 million in the first half of 2017, largely due to increased spending on our Ebola and Zika products and higher staffing costs. Sales and marketing expenses remained relatively consistent at $9.9 million in the first half of 2018 compared to $9.8 million in the first half of 2017. General and administrative expenses increased 58% to $20.6 million in the first half 2018 from $13.1 million in the first half of 2017 as a result of the inclusion of $8.6 million of transition costs associated with executive management changes.

All of the above contributed to OSUR's operating loss of $11.8 million in the first half of 2018, which included non-cash charges of $2.0 million for depreciation and amortization and $11.0 million for stock-based compensation.

DNAG Segment

DNAG's gross profit percentage was 63% in the first half of 2018 compared to 66% in the first half of 2017. This decline was attributable to an increase in lower profit percentage product sales in the first six months of 2018 compared to the same period in 2017, partially offset by the royalty income recorded in the first half of 2018. No royalty income was recorded in the first half of 2017.

Research and development expenses increased 19% to $1.6 million in the first half of 2018 from $1.3 million in the first half of 2017 due to increased staffing costs as a result of higher headcount. Sales and marketing expenses increased 10% to $5.0 million in the first half of 2018 from $4.5 million in the first half of 2017 due to higher staffing costs associated with higher head count and an increase in commission expense. General and administrative expenses decreased 19% to $1.4 million in the first half of 2018 compared to $1.8 million in the first half of 2017 primarily due to lower staffing and legal expenses.

All of the above contributed to DNAG's operating income of $16.9 million in the first half of 2018 which included non-cash charges of $1.7 million for depreciation and amortization and $245,000 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, 2018, no state income tax expense was recorded as compared to $31,000 in the six months ended June 30, 2017. Canadian income tax expense of $4.2 million and $5.4 million was recorded in the first half of 2018 and 2017, respectively. The decrease in income tax expense was largely a result of additional taxes recorded during the first half of 2017 related to the $12.5 million litigation settlement which did not re-occur in the first half of 2018, partially offset by the increase in income before taxes generated by DNAG. On December 22, 2017, the U.S. enacted the Tax Cuts and Jobs Act ("Tax Act") that instituted fundamental changes to the taxation on multinational corporations. The impact of the Tax Act on our financial results is not material given OSUR has a full valuation allowance against its total U.S. deferred tax assets and due to the net operating losses ("NOLs") and tax credits that are being generated by the U.S. entity.

Liquidity and Capital Resources

	June 30, 2018	December 31, 2017
	(In thousands)	
Cash, cash equivalents and restricted cash	$ 71,069	$ 72,869
Available for sale securities	110,097	103,718
Working capital	181,105	189,668

Our cash, cash equivalents, restricted cash and available-for-sale securities increased to $181.2 million at June 30, 2018 from $176.6 million at December 31, 2017. Our working capital decreased to $181.1 million at June 30, 2018 from $189.7 million at December 31, 2017 largely due to the increased balance of long-term investments.

During the first six months of 2018, we generated $13.9 million in cash from operating activities. Our net income of $2.0 million included non-cash charges for stock-based compensation expense of $11.3 million, depreciation and amortization expense of $3.7 million, as well as other non-cash benefits of $527,000. Additional sources of cash included a $10.2 million decrease in accounts receivable as a result of the collection of large outstanding balances, a $289,000 decrease in prepaid expenses and other assets, and a $253,000 increase in deferred revenue. Offsetting these sources of cash were a decrease in accrued expenses and other liabilities of $11.6 million largely due to the submission of tax payments to the Canadian taxing authorities and payment of our 2017 management incentive bonuses, an increase in inventory of $1.4 million required to meet expected demand, and a decrease in accounts payable of $193,000.

Net cash used in investing activities was $12.5 million for the six months ended June 30, 2018, which reflects $93.9 million used to purchase investments and $4.5 million to acquire property and equipment partially offset by $85.9 million in proceeds from the maturities and redemptions of investments.

Net cash used in financing activities was $2.0 million for the six months ended June 30, 2018, which resulted from $3.2 million used for the repurchase of common stock to satisfy withholding taxes related to the vesting of restricted shares partially offset by $1.2 million in proceeds received from the exercise of stock options.

In September 2016, we entered into a credit agreement (the "Credit Agreement") with a commercial bank, which was amended in December 2017. 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, 2018 or December 31, 2017.

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

In connection with the Credit Agreement, under certain circumstances, we must comply with a minimum fixed charge coverage ratio of 1.10 to 1.00, measured as of the last day of each fiscal month and for the twelve-fiscal month period ending on such date. As of June 30, 2018 and December 31, 2017, we were in compliance with all applicable covenants under the Credit Agreement.

Our current balances of cash and cash equivalents and available-for-sale securities and our 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. In addition, $53.2 million or 29% of our $181.2 million in cash, cash equivalents, restricted cash and available-for-sale securities belongs to our Canadian subsidiary. Repatriation of such cash into the United States exceeding certain levels could have adverse tax consequences.

Summary of Contractual Obligations

A summary of our obligations to make future payments under contracts existing at December 31, 2017 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, 2017. As of June 30, 2018, 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 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 bad debts, customer sales returns, inventories, intangible assets, income taxes, revenue recognition, performance-based compensation, contingencies and litigation. We base our judgments and estimates on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

A more detailed review of our critical accounting policies is contained in our Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC. During the first six months of 2018, 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, 2018, 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 2.8% of our total revenues for the six months ended June 30, 2018. 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 $117.9 million CDN ($89.7 million USD), which are included in the Company's consolidated balance sheet as of June 30, 2018. A 10% unfavorable change in the Canadian-to-U.S. dollar exchange rate would have decreased our comprehensive income by $9.0 million in the six months ended June 30, 2018.

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, 2018. 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, 2018 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, 2018 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 risk factors disclosed in Item 1A., entitled "Risk Factors," in our Annual Report on Form 10-K for the year ended December 31, 2017, and in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2018.

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 (1, 2)
April 1, 2018 - April 30, 2018	1,836	(3)	$ 17.77	—	11,984,720
May 1, 2018 - May 31, 2018	9,353	(3)	15.98	—	11,984,720
June 1, 2018 - June 30, 2018	1,545	(3)	17.40	—	11,984,720
	12,734			—	

(1) 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.

(2) 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.

(3) 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.

Item 3. DEFAULTS UPON SENIOR SECURITIES

None

Item 4. MINE SAFETY DISCLOSURES

Not applicable

Item 5. OTHER INFORMATION

None

Item 6. EXHIBITS

Exhibit Number	Exhibit
10.1	Description of OraSure Technologies, Inc. Compensation Policy for Non-Employee Directors, as amended as of May 8, 2018, is incorporated by reference to Item 5.02 to the Company's Current Report on Form 8-K filed May 11, 2018.*
10.2	Employment Agreement, dated as of May 4, 2018, between OraSure Technologies, Inc. and Roberto Cuca, is incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed May 4, 2018.*
31.1*	Certification of Stephen S. Tang required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.**
31.2*	Certification of Roberto Cuca required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.**
32.1*	Certification of Stephen S. Tang 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 Roberto Cuca 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 agreement

** Filed herewith

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/ Roberto Cuca

Date: August 9, 2018

Roberto Cuca
Chief Financial Officer
(Principal Financial Officer)

/s/Mark L. Kuna

Date: August 9, 2018

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

Exhibit 31.1

Certification

I, Stephen S. Tang, 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, 2018

/s/ Stephen S. Tang
Stephen S. Tang
President and Chief Executive Officer
(*Principal Executive Officer*)

Exhibit 31.2

Certification

I, Roberto Cuca, 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, 2018

/s/ Roberto Cuca
Roberto Cuca
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, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Stephen S. Tang, 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/ Stephen S. Tang

Stephen S. Tang
President and Chief Executive Officer

August 9, 2018

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, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Roberto Cuca, 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/ Roberto Cuca

Roberto Cuca
Chief Financial Officer

August 9, 2018