UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2017.

OR

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

For the transition period from _____ to _____.

Commission File Number 001-16537

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

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

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

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

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

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

Large accelerated filer	☐	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 November 3, 2017: 60,648,324 shares.

PART I. FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

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

	September 30, 2017	December 31, 2016
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 76,770	$ 107,959
Restricted cash	1,840	1,831
Short-term investments	83,372	11,160
Accounts receivable, net of allowance for doubtful accounts of $494 and $484	28,099	19,827
Inventories	16,859	11,799
Prepaid expenses	1,189	1,722
Other current assets	1,206	2,143
Total current assets	209,335	156,441
PROPERTY AND EQUIPMENT, net	21,496	20,033
INTANGIBLE ASSETS, net	8,972	10,337
GOODWILL	20,257	18,793
LONG TERM INVESTMENTS	18,290	—
OTHER ASSETS	3,909	2,331
	$ 282,259	$ 207,935
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 9,624	$ 4,633
Deferred revenue	1,186	1,388
Accrued expenses	15,813	11,314
Total current liabilities	26,623	17,335
OTHER LIABILITIES	3,928	2,304
DEFERRED INCOME TAXES	2,194	2,446
COMMITMENTS AND CONTINGENCIES (Note 7)		
STOCKHOLDERS' EQUITY		
Preferred stock, par value $.000001, 25,000 shares authorized, none issued	—	—
Common stock, par value $.000001, 120,000 shares authorized, 60,631 and 56,001 shares issued and outstanding	—	—
Additional paid-in capital	385,978	350,528
Accumulated other comprehensive loss	(9,638)	(14,220)
Accumulated deficit	(126,826)	(150,458)
Total stockholders' equity	249,514	185,850
	$ 282,259	$ 207,935

See accompanying notes to the consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
NET REVENUES:				
Product	$ 41,157	$ 25,460	$ 111,771	$ 78,286
Other	1,157	6,791	3,265	14,413
	42,314	32,251	115,036	92,699
COST OF PRODUCTS SOLD	17,670	9,576	44,605	28,626
Gross profit	24,644	22,675	70,431	64,073
OPERATING EXPENSES:				
Research and development	3,228	3,196	9,536	8,547
Sales and marketing	7,162	6,428	21,541	22,531
General and administrative	6,935	6,907	21,777	19,803
Gain on litigation settlement	—	—	(12,500)	—
	17,325	16,531	40,354	50,881
Operating income	7,319	6,144	30,077	13,192
OTHER INCOME (EXPENSE)	113	498	676	(34)
Income before income taxes	7,432	6,642	30,753	13,158
INCOME TAX EXPENSE	1,669	400	7,121	634
NET INCOME	$ 5,763	$ 6,242	$ 23,632	$ 12,524
EARNINGS PER SHARE:				
BASIC	$ 0.10	$ 0.11	$ 0.40	$ 0.23
DILUTED	$ 0.09	$ 0.11	$ 0.39	$ 0.22
SHARES USED IN COMPUTING EARNINGS PER SHARE:				
BASIC	60,090	55,653	58,511	55,549
DILUTED	62,172	56,530	60,569	56,273

See accompanying notes to the consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
NET INCOME	$ 5,763	$ 6,242	$ 23,632	$ 12,524
OTHER COMPREHENSIVE INCOME				
Currency translation adjustments	2,570	(729)	4,882	2,501
Unrealized loss on marketable securities	(245)	—	(300)	—
COMPREHENSIVE INCOME	$ 8,088	$ 5,513	$ 28,214	$ 15,025

See accompanying notes to the consolidated financial statements.

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

	Nine Months Ended September 30,	
	2017	2016
OPERATING ACTIVITIES:		
Net income	$ 23,632	$ 12,524
Adjustments to reconcile net income to net cash provided by operating activities:		
Stock-based compensation	5,213	4,438
Depreciation and amortization	4,589	4,152
Unrealized foreign currency loss	(246)	75
Deferred income taxes	(425)	(205)
Changes in assets and liabilities		
Accounts receivable	(7,706)	3,818
Inventories	(4,886)	1,236
Prepaid expenses and other assets	1,616	1,186
Accounts payable	4,593	(125)
Deferred revenue	(212)	(1,829)
Accrued expenses and other liabilities	4,193	(90)
Net cash provided by operating activities	30,361	25,180
INVESTING ACTIVITIES:		
Purchases of investments	(132,177)	(22,966)
Proceeds from maturities and redemptions of investments	42,613	22,966
Purchases of property and equipment	(3,462)	(3,512)
Net cash used in investing activities	(93,026)	(3,512)
FINANCING ACTIVITIES:		
Payments for debt issue costs	—	(367)
Proceeds from exercise of stock options	31,402	894
Repurchase of common stock	(1,234)	(3,311)
Net cash provided by (used in) financing activities	30,168	(2,784)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	1,317	558
NET (DECREASE) INCREASE IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH	(31,180)	19,442
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH, BEGINNING OF PERIOD	109,790	94,094
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH, END OF PERIOD	$ 78,610	$ 113,536
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for income taxes	$ 4,317	$ 812
Noncash investing activities (accrued property and equipment purchases)	$ 437	$ 241
Noncash unrealized losses on marketable securities	$ (300)	$ —

See accompanying notes to the consolidated financial statements.

1. The Company

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

2. Summary of Significant Accounting Policies

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

The accompanying consolidated financial statements are unaudited and, in the opinion of management, include all adjustments (consisting only of normal and recurring adjustments) necessary for a fair presentation of our financial position and results of operations for these interim periods. These financial statements should be read in conjunction with the financial statements and notes thereto included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016. Results of operations for the three and nine months ended September 30, 2017 are not necessarily indicative of the results of operations expected for the full year.

Use of Estimates. The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions about future events. These estimates and underlying assumptions affect the amounts of assets and liabilities reported, disclosures about contingent assets and liabilities, and reported amounts of revenues and expenses. Such estimates include the valuation of accounts receivable and inventories and assumptions utilized in impairment testing for intangible assets and goodwill, as well as calculations related to contingencies, accruals, and performance-based compensation expense, among others. These estimates and assumptions are based on management's best estimates and judgment. Management evaluates its estimates and assumptions on an ongoing basis, using historical experience and other factors, which management believes to be reasonable under the circumstances, including the current economic environment. 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 at September 30, 2017 and December 31, 2016:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
September 30, 2017				
Guaranteed investment certificates	$ 16,039	$ —	$ —	$ 16,039
Corporate bonds	85,923	—	(300)	85,623
Total available-for-sale securities	$101,962	$ —	$ (300)	$101,662
December 31, 2016				
Guaranteed investment certificates	$ 11,160	$ —	$ —	$ 11,160
Total available-for-sale securities	$ 11,160	$ —	$ —	$ 11,160
At September 30, 2017 maturities of our available-for-sale securities were as follows:				
Less than one year	$ 83,582	$ —	$ (210)	$ 83,372
Greater than one year	$ 18,380	$ —	$ (90)	$ 18,290

Fair Value of Financial Instruments. As of September 30, 2017 and December 31, 2016, the carrying values of cash and cash equivalents, restricted cash, accounts receivable, and accounts payable approximate their respective fair values based on their short-term nature.

Fair value measurements of all financial assets and liabilities that are being measured and reported on a fair value basis are required to be classified and disclosed in one of the following three categories:

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2: Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability; and

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

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

Included in cash and cash equivalents at September 30, 2017 and December 31, 2016, was $33,633 and $83,704 invested in government money market funds. These funds hold investments in government securities and are measured as Level 1 instruments.

We offer a nonqualified deferred compensation plan for certain eligible employees and members of our Board of Directors. The assets of the plan are held in the name of the Company at a third-party financial institution. Separate accounts are maintained for each participant to reflect the amounts deferred by the participant and all earnings and losses on those deferred amounts. The assets of the plan are held in mutual funds and Company stock. The fair value of the plan assets as of September 30, 2017 and December 31, 2016 was $3,670 and $1,980, respectively, and was calculated using the quoted market prices of the assets as of those dates. All investments in the plan are classified as trading securities and measured as Level 1 instruments. The fair value of plan assets is included in other assets with the same amount included in other liabilities in the accompanying consolidated balance sheets.

In 2017, we purchased certificates of deposit (“CDs”) from a commercial bank. The CDs bear interest at rates ranging from 0.86% to 0.94% and mature periodically through January 15, 2018. The carrying values of the CDs

approximate their fair value. These CDs serve as collateral for certain standby letters of credit and are reported as restricted cash on the accompanying consolidated balance sheets. Also see Note 7 – Commitments and Contingencies.

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

	September 30, 2017	December 31, 2016
Raw materials	$ 8,252	$ 5,399
Work in process	1,746	1,034
Finished goods	6,861	5,366
	$ 16,859	$ 11,799

Property and Equipment. Property and equipment are stated at cost. Additions or improvements are capitalized, while repairs and maintenance are charged to expense. Depreciation and amortization are provided using the straight-line method over the estimated useful lives of the related assets. Buildings are depreciated over twenty to forty years, while computer equipment, machinery and equipment, and furniture and fixtures are depreciated over two to ten years. Building improvements are amortized over their estimated useful lives. When assets are sold, retired, or discarded, the related property amounts are relieved from the accounts, and any gain or loss is recorded in the consolidated statements of income. Accumulated depreciation of property and equipment as of September 30, 2017 and December 31, 2016 was $38,689 and $36,067, respectively.

Intangible Assets. Intangible assets consist of a customer list, patents and product rights, acquired technology and tradenames. Patents and product rights consist of costs associated with the acquisition of patents, licenses, and product distribution rights. Intangible assets are amortized using the straight-line method over their estimated useful lives of seven to fifteen years. Accumulated amortization of intangible assets as of September 30, 2017 and December 31, 2016 was $18,129 and $15,197, respectively. The change in intangibles from $10,337 as of December 31, 2016 to $8,972 as of September 30, 2017 is a result of $1,984 in amortization expense and $619 in foreign currency translation gains.

Goodwill. Goodwill represents the excess of the purchase price we paid over the fair value of the net tangible and identifiable intangible assets acquired and liabilities assumed in our acquisition of DNAG in August 2011. Goodwill is not amortized but rather is tested annually for impairment or more frequently if we believe that indicators of impairment exist. Current U.S. generally accepted accounting principles permit us to make a qualitative evaluation about the likelihood of goodwill impairment. If we conclude that it is more likely than not that the carrying value of a reporting unit is greater than its fair value, then we would be required to recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value, provided the impairment charge does not exceed the total amount of goodwill allocated to the reporting unit.

We performed our last annual impairment assessment as of July 31, 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 September 30, 2017, we believe no indicators of impairment exist.

The increase in goodwill from $18,793 as of December 31, 2016 to $20,257 as of September 30, 2017 is a result of foreign currency translation.

Revenue Recognition. We recognize product revenues when there is persuasive evidence that an arrangement exists, the price is fixed or determinable, title has passed and collection is reasonably assured. Product revenues are recorded net of allowances for any discounts or rebates. Other than for sales of our OraQuick® In-Home HIV test to the retail trade, we do not grant price protection or product return rights to our customers except for warranty

returns. Historically, returns arising from warranty issues have been infrequent and immaterial. Accordingly, we expense warranty returns as incurred.

Our net revenues recorded on sales of the OraQuick® In-Home HIV test represent total gross revenues, less an allowance for expected returns, and customer allowances for cooperative advertising, discounts, rebates, and chargebacks. The allowance for expected returns is an estimate established by management, based upon currently available information, and is adjusted to reflect known changes in the factors that impact this estimate. Other customer allowances are at contractual rates and are recorded as a reduction of gross revenue when recognized in our consolidated statements of income.

We record shipping and handling charges billed to our customers as product revenue and the related expense as cost of products sold. Taxes assessed by governmental authorities, such as sales or value-added taxes, are excluded from product revenues.

In June 2014, we entered into a Master Program Services and Co-Promotion Agreement with AbbVie Bahamas Ltd., a wholly-owned subsidiary of AbbVie Inc. ("AbbVie"), to co-promote our OraQuick® HCV test in the United States. On June 30, 2016, we mutually agreed to terminate our agreement with AbbVie effective December 31, 2016. Accordingly, during the third quarter and first nine months of 2017 we did not record any revenue from this co-promotion agreement. During the third quarter and first nine months of 2016, $6,114 and $12,837, respectively, of exclusivity revenue was recognized and recorded as other revenue in our consolidated statements of income.

In June 2015, we were awarded a grant for up to $10,400 in total funding from the U.S. Department of Health and Human Services ("HHS") Office of the Assistant Secretary for Preparedness and Response's Biomedical Advanced Research and Development Authority ("BARDA") related to our OraQuick® Ebola rapid antigen test. The three-year, multi-phased grant includes an initial commitment of $1,800 and options for up to an additional $8,600 to fund certain clinical and regulatory activities. In September 2015 and July 2017, BARDA exercised an option 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 income as the activities are being performed and the related costs are incurred. During the third quarter and first nine months of 2017, $386 and $1,260, respectively, was recognized in connection with this grant. During the third quarter and first nine months of 2016, $474 and $1,373 respectively, was recognized in connection with this grant.

In August 2016, we were awarded a contract for up to $16,600 in total funding from BARDA related to our rapid Zika test. The six-year, multi-phased contract includes an initial commitment of $7,000 and options for up to an additional $9,600 to fund the evaluation of additional product enhancements, and clinical and regulatory activities. In May 2017, BARDA exercised an option to provide $2,600 in additional funding for our rapid Zika test. Funding received under this contract is recorded as other revenue in our consolidated statements of income as the activities are being performed and the related costs are incurred. During the third quarter and first nine months of 2017, $553 and $1,787, respectively, was recognized as other revenue in connection with this grant. During the third quarter and first nine months of 2016, $203 was recognized as other revenue 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 will enable us to offer our OraQuick® HIV self-test at an affordable price in 50 developing countries with funding from the Gates Foundation. The funding will consist 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 third quarter and first nine months of 2017, $458 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 income. During the third quarter and first nine months of 2017, $218 was recognized in other revenue in connection with this agreement.

Customer Sales Returns and Allowances. We do not grant return rights to our customers for any product, except for our OraQuick® In-Home HIV test. Accordingly, we have recorded an estimate of expected returns as a reduction of gross OraQuick® In-Home HIV product revenues in our consolidated statements of income. This estimate reflects our historical sales experience to retailers and consumers, as well as other retail factors, and is reviewed regularly to

ensure that it reflects potential product returns. As of September 30, 2017 and December 31, 2016, the reserve for sales returns and allowances was $186 and $217, respectively. If actual product returns differ materially from our reserve amount, or if a determination is made that this product's distribution would be discontinued in whole or in part by certain retailers, then we would need to adjust our reserve. Should the actual level of product returns vary significantly from our estimates, our operating and financial results could be materially affected.

Deferred Revenue. We record deferred revenue when funds are received prior to the recognition of the associated revenue. Deferred revenue as of September 30, 2017 and December 31, 2016 was comprised of customer prepayments of $1,186 and $1,388, respectively.

Customer and Vendor Concentrations. One of our customers accounted for 21% of our accounts receivable as of September 30, 2017. Another customer accounted for 14% and 15% of our accounts receivable as of September 30, 2017 and December 31, 2016, respectively. One of our customers accounted for approximately 25% and 19% of our net consolidated revenues for the three and nine months ended September 30, 2017, respectively. For the three and nine months ended September 30, 2016, this same customer accounted for approximately 19% and 14% of our net consolidated revenues, respectively. Another customer accounted for 11% and 10% of our net consolidated revenues for the three months and nine months ended September 30, 2017, respectively. This customer notified us in October 2017 that our supply contract for HCV rapid test will not be renewed at this time. It is unclear whether this customer will fulfill the remaining $4 million of purchase obligations under our existing contract.

We currently purchase certain products and critical components of our products from sole-supply vendors. If these vendors are unable or unwilling to supply the required components and products, we could be subject to increased costs and substantial delays in the delivery of our products to our customers. Also, our subsidiary, DNAG, uses two third-party suppliers to manufacture its products. Our inability to have a timely supply of any of these components and products could have a material adverse effect on our business, as well as our financial condition and results of operations.

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Net income	$ 5,763	$ 6,242	$23,632	$12,524
Weighted average shares of common stock outstanding:				
Basic	60,090	55,653	58,511	55,549
Dilutive effect of stock options, restricted stock, and performance units	2,082	877	2,058	724
Diluted	62,172	56,530	60,569	56,273
Earnings per share:				
Basic	$ 0.10	$ 0.11	$ 0.40	$ 0.23
Diluted	$ 0.09	$ 0.11	$ 0.39	$ 0.22

For the three-month periods ended September 30, 2017 and 2016, outstanding common stock options, unvested restricted stock, and unvested performance units representing 8 and 2,130 shares, respectively, were excluded from the computation of diluted earnings per share as their inclusion would have been anti-dilutive. For the nine months ended September 30, 2017 and 2016, outstanding common stock options, unvested restricted stock and unvested performance units representing 238 and 2,837 shares, respectively, were similarly excluded from the computation of diluted earnings per share.

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

Transaction gains and losses resulting from exchange rate changes on transactions denominated in currencies other than functional currency are included in our consolidated statements of income in the period in which the change occurs. Net foreign exchange (losses) gains resulting from foreign currency transactions that are included in other income (expense) in our consolidated statements of income were $(638) and $84 for the three months ended September 30, 2017 and 2016, respectively. Net foreign exchange losses were $(1,256) and $(564) for the nine months ended September 30, 2017 and 2016, respectively.

Accumulated Other Comprehensive Income (Loss). We classify items of other comprehensive income (loss) by their nature and disclose the accumulated balance of other comprehensive loss separately from accumulated deficit and additional paid-in capital in the stockholders' equity section of our consolidated balance sheet.

We have defined the Canadian dollar as the functional currency of our Canadian subsidiary, DNAG, and as such, the results of its operations are translated into U.S. dollars, which is the reporting currency of the Company. Accumulated other comprehensive loss at September 30, 2017 consists of $9,338 of currency translation adjustments and $300 of net unrealized losses on marketable securities.

Recent Accounting Pronouncements. In May 2014, the Financial Accounting Standards Board ("FASB") issued converged guidance on recognizing revenue in contracts with customers, ASU 2014-09, *Revenue from Contracts with Customers*. The intent of the new standard is to improve financial reporting and comparability of revenue globally. The core principle of the standard is for a company to recognize revenue in a manner that depicts the transfer of goods or services to customers in an amount that reflects the consideration which the company expects to receive in exchange for those goods or services. The standard will be effective for the first interim period within annual reporting periods beginning after December 15, 2017, at which point we plan to adopt the standard.

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

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

In July 2015, the FASB issued ASU 2015-11, *Simplifying the Measurement of Inventory*, which requires an entity that uses the first-in, first-out method for inventory measurement to report inventory cost at the lower of cost and net realizable value versus the current measurement principle of lower of cost or market. The ASU requires prospective adoption for inventory measurements for fiscal years beginning after December 15, 2016. We adopted ASU 2015-11 on January 1, 2017. The adoption of this standard did not have a material impact on our consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU 2016-02, *Leases*, which requires entities to begin recording assets and liabilities from leases on the balance sheet. The new guidance will also require significant additional disclosures about the amount, timing and uncertainty of cash flows from leases. The standard will be effective for the first

interim period within annual reporting periods beginning after December 15, 2018, using a modified retrospective approach. Early adoption is permitted. We are evaluating the effect that ASU 2016-02 may have on our consolidated financial statements and related disclosures.

In March 2016, the FASB issued authoritative guidance under ASU 2016-09, *Compensation-Stock Compensation (Topic 718) Improvements to Employee Share-Based Payment Accounting*. ASU 2016-09 provides for simplification of several aspects of the accounting for share-based payment transactions, including income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. We adopted ASU 2016-09 on January 1, 2017. Since we have a full valuation allowance against our U.S. net deferred tax assets, the adoption of this standard for recognition of the tax effect of deductions for employee share awards in excess of compensation costs ("windfall") did not have a material impact on our consolidated financial statements and related disclosures. See Note 6 – Income Taxes, for additional information. Should our full valuation allowance be reversed in future periods, the adoption of this new guidance will introduce more volatility in the calculation of our effective tax rate, depending on the Company's share price at exercise or vesting of share-based awards as compared to grant date. The other provisions of ASU 2016-09 did not have a material impact on our consolidated financial statements and related disclosures.

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

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

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 on 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 are evaluating the effect that ASU 2017-08 may have on our consolidated financial statements and related disclosures.

3. Accrued Expenses

	September 30, 2017	December 31, 2016
Payroll and related benefits	$ 8,684	$ 7,685
Income taxes payable (receivable)	3,303	(39)
Professional fees	688	982
Royalties	659	715
Other	2,479	1,971
	$ 15,813	$ 11,314

4. Credit Facility

On September 30, 2016, we entered into a credit agreement (the "Credit Agreement") with a commercial bank. The Credit Agreement provides for revolving extensions of credit in an initial aggregate amount of up to $10,000 (inclusive of a letter of credit subfacility of $2,500), with an option to request, prior to the second anniversary of the

closing date, that the lender, at its election, provide up to $5,000 of additional revolving commitments. Obligations under the Credit Agreement are secured by a first priority security interest in certain eligible accounts receivable, 65% of the equity of our subsidiary, DNAG, and certain related assets. There were no borrowings outstanding under the Credit Agreement at September 30, 2017 and December 31, 2016.

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

In connection with the Credit Agreement, under certain circumstances, we must comply with a minimum fixed charge coverage ratio of 1.10 to 1.00, measured as of the last day of each fiscal month and for the twelve-fiscal month period ending on such date. As of September 30, 2017 and December 31, 2016, we were in compliance with all applicable covenants in the Credit Agreement.

5. Stockholders' Equity

Stock-Based Awards

We grant stock-based awards under the OraSure Technologies, Inc. Stock Award Plan, as amended (the "Stock Plan"). The Stock Plan permits stock-based awards to employees, outside directors and consultants or other third-party advisors. Awards which may be granted under the Stock Plan include qualified incentive stock options, nonqualified stock options, stock appreciation rights, restricted awards, performance awards and other stock-based awards. We recognize compensation expense for stock option and restricted stock awards issued to employees and directors on a straight-line basis over the requisite service period of the award. We recognize compensation expense related to performance-based restricted stock units based on assumptions as to what percentage of each performance target will be achieved. We evaluate these target assumptions on a quarterly basis and adjust compensation expense related to these awards, as appropriate. To satisfy the exercise of options or to issue restricted stock, or redeem performance-based restricted stock units, we issue new shares rather than purchase shares on the open market.

Total compensation cost related to stock options for the three months ended September 30, 2017 and 2016 was $547 and $646, respectively. Total compensation cost related to stock options for the nine months ended September 30, 2017 and 2016 was $1,554 and $2,033, respectively. Net cash proceeds from the exercise of stock options were $31,402 and $894 for the nine months ended September 30, 2017 and 2016, respectively. As a result of the Company's net operating loss carryforward position, no actual income tax benefit was recognized in the consolidated statements of income from stock option exercises during these periods.

Compensation cost of $667 and $736 related to restricted shares was recognized during the three months ended September 30, 2017 and 2016, respectively. Compensation cost of $2,022 and $2,137 related to restricted shares was recognized during the nine months ended September 30, 2017 and 2016, respectively. In connection with the vesting of restricted shares during the nine months ended September 30, 2017 and 2016, we purchased and immediately retired 122 and 117 shares with aggregate values of $1,234 and $651, respectively, in satisfaction of minimum tax withholding obligations.

Commencing in 2016, we granted 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 will be based on a one-year earnings per share target. If the one-year target is achieved, the PSUs will then vest three years from grant date. Performance during the three-year period will be based on achievement of a three-year compound annual growth rate for consolidated product revenues. If the three-year target is achieved, the corresponding PSUs will then vest three years from grant date. PSUs are converted into shares of our common stock once vested. Upon grant of the PSUs, we recognize compensation expense related to these awards based on assumptions as to what percentage of each target will be achieved. The Company evaluates these assumptions on a quarterly basis and adjusts compensation expense related to these awards, as appropriate. Compensation cost of $368 and $114 related to PSUs

was recognized during the three months ended September 30, 2017 and 2016, respectively. Compensation cost of $1,637 and $268 related to PSUs was recognized during the nine months ended September 30, 2017 and 2016, respectively.

Stock Repurchase Program

On August 5, 2008, our Board of Directors approved a share repurchase program pursuant to which we are permitted to acquire up to $25,000 of our outstanding common shares. No shares were purchased and retired during the nine months ended September 30, 2017. During the nine months ended September 30, 2016, we purchased and retired 423 shares of common stock at an average price of $6.29 per share for a total cost of $2,660 under this share purchase agreement.

6. Income Taxes

During the three and nine months ended September 30, 2017, we recorded tax expense of $1,669 and $7,121, respectively. During the three and nine months ended September 30, 2016, we recorded tax expense of $400 and $634, respectively.

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

In 2008, we established a full valuation allowance against our U.S. deferred tax asset. Management believes the full valuation allowance is still appropriate as of both September 30, 2017 and December 31, 2016 since the facts and circumstances necessitating the allowance have not changed. As a result, no U.S. federal or state deferred income tax expense or benefit was recorded for the three and nine-month periods ended September 30, 2017 and 2016.

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

7. Commitments and Contingencies

Standby Letters of Credit

We established standby letters of credit in the aggregate amount of $1,840, naming international customers as the beneficiaries. These letters of credit were required as a performance guarantee of our obligations under our product supply contracts with those customers and are collateralized by certificates of deposit maintained at a commercial bank.

Litigation

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

8. Business Segment Information

We operate our business within two reportable segments: our “OSUR” business, which consists of the development, manufacture and sale of diagnostic products, specimen collection devices and medical devices; and our molecular collection systems or “DNAG” business, which primarily consists of the manufacture, development and sale of oral fluid collection devices that are used to collect, stabilize and store samples of genetic material for molecular testing. OSUR revenues are derived primarily from products sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations, public health organizations, distributors, government agencies, physicians’ offices, commercial and industrial entities, retail pharmacies and mass merchandisers, and to consumers over the internet. OSUR also derives other revenues, including exclusivity payments for co-promotion rights and other licensing and product development activities. DNAG revenues result primarily from products sold into the commercial market which consists of customers engaged in consumer genetics, clinical genetic testing, pharmacogenomics, personalized medicine, microbiome, animal genetic testing and research. DNAG products are also sold into the academic research market, which consists of research laboratories, universities and hospitals.

We organized our operating segments according to the nature of the products included in those segments. The accounting policies of the segments are the same as those described in the summary of significant accounting policies (see Note 2). We evaluate performance of our operating segments based on revenue and operating income. We do not allocate interest income, interest expense, other income, other expenses or income taxes to our operating segments. Reportable segments have no inter-segment revenues and inter-segment expenses have been eliminated.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Net revenues:				
OSUR	$ 23,762	$ 23,924	$ 69,720	$ 69,050
DNAG	18,552	8,327	45,316	23,649
Total	$ 42,314	$ 32,251	$ 115,036	$ 92,699
Operating income (loss):				
OSUR	$ (453)	$ 4,571	$ (235)	$ 9,098
DNAG	7,772	1,573	30,312	4,094
Total	$ 7,319	$ 6,144	$ 30,077	$ 13,192
Depreciation and amortization:				
OSUR	$ 855	$ 688	$ 2,189	$ 2,003
DNAG	843	726	2,400	2,149
Total	$ 1,698	$ 1,414	$ 4,589	$ 4,152
Capital expenditures:				
OSUR	$ 1,156	$ 283	$ 2,493	$ 1,406
DNAG	739	500	969	2,106
Total	$ 1,895	$ 783	$ 3,462	$ 3,512

	September 30, 2017	December 31, 2016
Total assets:		
OSUR	$ 192,298	$ 151,719
DNAG	89,961	56,216
Total	$ 282,259	$ 207,935

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
United States	$ 29,063	$ 26,302	$ 78,871	$ 72,493
Europe	3,204	2,171	8,765	9,006
Other regions	10,047	3,778	27,400	11,200
	$ 42,314	$ 32,251	$ 115,036	$ 92,699

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

	September 30, 2017	December 31, 2016
United States	$ 16,644	$ 15,737
Canada	4,767	4,286
Other regions	85	10
	$ 21,496	$ 20,033

Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Statements below regarding future events or performance are "forward-looking statements" within the meaning of the Federal securities laws. These may include statements about our expected revenues, earnings/loss per share, net income (loss), expenses, cash flow or other financial performance or developments, clinical trial or development activities, expected regulatory filings and approvals, planned business transactions, views of future industry, competitive or market conditions, and other factors that could affect our future operations, results of operations or financial position. These statements often include the words "believes," "expects," "anticipates," "intends," "plans," "estimates," "may," "will," "should," "could," or similar expressions. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include, but are not limited to: ability to market and sell products, whether through our internal, direct sales force or third parties; ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements; ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; ability to comply with applicable regulatory requirements; ability to effectively resolve warning letters, audit observations and other findings or comments from the U.S. Food and Drug Administration ("FDA") or other regulators; changes in relationships, including disputes or disagreements, with strategic partners or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements; ability to meet increased demand for our products; impact of increased reliance on U.S. government contracts; failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our products; impact of replacing distributors; inventory levels at distributors and other customers; ability of the Company to achieve its financial and strategic objectives and continue to increase its revenues, including the ability to expand international sales; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; impact of negative economic conditions, high unemployment levels and poor credit conditions; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products; market acceptance of oral fluid testing or other products; changes in market acceptance of products based on product performance or other factors, including changes in testing guidelines, algorithms or other recommendations by the Centers for Disease Control and Prevention ("CDC") or other agencies; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical products and components; availability of related products produced by third parties or products required for use of our products; history of losses and ability to achieve sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of the Company's stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; 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, 2016, Quarterly Reports on Form 10-Q, and other filings with the SEC. Although forward-looking statements help to provide information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. The forward-looking statements are made as of the date of this Report, and we undertake no duty to update these statements.

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

financial forecasts or projections issued by others. Thus, to the extent that reports issued by securities analysts contain any projections, forecasts or opinions, such reports are not the responsibility of OraSure.

The following discussion should be read in conjunction with our consolidated financial statements contained herein and the notes thereto, along with the Section entitled "Critical Accounting Policies and Estimates," set forth below.

Overview

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

Recent Developments

In 2016, we entered into a contract to supply a foreign government with $18 million of product, primarily to support a nationwide HCV testing and treatment program. To date, we have supplied $14.0 million of product to this customer under the contract. The contract includes a renewal option under which the government may purchase up to 100% of the original quantities of product on the same terms and conditions contained in the contract. During the past several months, we have engaged in renewal discussions with this customer, including with respect to specific quantities of product to be supplied. During these discussions, we were advised that the contract would likely be renewed at quantities substantially in excess of the original quantities under the contract. However, we were recently informed that the government has decided to move to an all laboratory testing solution and that another party had been selected to provide that solution based on cost. As a result, it is our expectation that our supply contract with this customer for rapid tests will not be renewed at this time. In light of these developments, it is unclear whether this government will fulfill the remaining purchase obligations under our existing contract.

Current Consolidated Financial Results

During the nine months ended September 30, 2017, our consolidated net revenues were $115.0 million, compared to $92.7 million for the nine months ended September 30, 2016. Net product revenues during the nine months ended September 30, 2017 increased 43% when compared to the first nine months of 2016, primarily due to higher sales of our molecular and OraQuick® HCV products and increased international sales of our OraQuick® HIV self-test. Partially offsetting these increases were lower domestic sales of our professional OraQuick® HIV product and lower domestic and OTC sales of our cryosurgical products. Other revenues for the first nine months of 2017 were $3.3 million compared to $14.4 million in the same period of 2016. Other revenues in the first nine months of 2017 largely represent revenue recognized in connection with funding received from the U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response's Biomedical Advanced Research and Development Authority ("BARDA") related to our Ebola and Zika products. Other revenues in the first nine months of 2016 included $1.6 million of BARDA funding and $12.8 million of exclusivity revenues recognized under our HCV co-promotion agreement with AbbVie, which terminated on December 31, 2016.

Our consolidated net income for the nine months ended September 30, 2017 was $23.6 million, or $0.39 per share on a fully-diluted basis, compared to consolidated net income of $12.5 million, or $0.22 per share on a fully-diluted basis for the nine months ended September 30, 2016. Results for the current nine month period include a pre-tax gain of $12.5 million associated with the settlement of our litigation against Ancestry.com DNA LLC and its contract manufacturer in the first quarter of 2017.

Cash provided by operating activities for the nine months ended September 30, 2017 was $30.4 million and included the $12.5 million litigation settlement noted above. Cash provided by operating activities during the nine months ended September 30, 2016 was $25.2 million. As of September 30, 2017, we had $180.3 million in cash (including restricted cash), cash equivalents, and available-for-sale securities, compared to $120.9 million at December 31, 2016.

Business Segments

We operate our business within two reportable segments: our "OSUR" business, which consists of the development, manufacture and sale of diagnostic products, specimen collection devices, and medical devices, and our "DNAG" or molecular collection systems business, which consists primarily of the development, manufacture and sale of oral fluid collection devices that are used to collect, stabilize, transport, and store samples of genetic material for molecular testing. OSUR revenues are derived primarily from products sold into the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations, public health organizations, distributors, government agencies, physicians' offices, commercial and industrial entities, retail pharmacies, mass merchandisers and consumers over the internet. DNAG revenues result primarily from products sold into the commercial market, which consists of customers engaged in consumer genetics, clinical genetic testing, pharmacogenomics, personalized medicine, microbiome, animal genetic testing and research, as well as products sold into the academic research market which consists of research laboratories, universities and hospitals.

Results of Operations

Three months ended September 30, 2017 compared to September 30, 2016

CONSOLIDATED NET REVENUES

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

	Three Months Ended September 30,				
	Dollars			Percentage of Total Net Revenues	
	2017	2016	% Change	2017	2016
OSUR	$22,605	$17,133	32%	53%	53%
DNAG	18,552	8,327	123	44	26
Net product revenues	41,157	25,460	62	97	79
Other	1,157	6,791	(83)	3	21
Net revenues	$42,314	$32,251	31%	100%	100%

Consolidated net product revenues increased 62% to $41.2 million in the third quarter of 2017 from $25.5 million in the comparable period of 2016. Higher sales of our molecular and OraQuick® HCV products and higher international sales of our OraQuick® HIV self-test were partially offset by lower domestic sales of our professional OraQuick® HIV product and lower domestic and OTC sales of our cryosurgical products. In the third quarter of 2017, we recognized $939,000 in other revenues in connection with funding from BARDA related to our Ebola and Zika products and $218,000 in reimbursement of certain costs under our charitable support agreement with the Bill & Melinda Gates Foundation ("Gates Foundation"). Other revenues in the third quarter of 2016 were $6.8 million and included $6.1 million in exclusivity payments received under our HCV co-promotion agreement with AbbVie and $676,000 in BARDA funding. Our co-promotion agreement with AbbVie was terminated effective as of December 31, 2016 and no further revenues were recognized under this agreement after that time.

Consolidated net revenues derived from products sold to customers outside of the United States were $13.3 million and $5.9 million, or 31% and 18% of total net revenues, in the third quarters of 2017 and 2016, respectively. Because the majority of our international sales are denominated in U.S. dollars, the impact of fluctuating foreign currency exchange rates was not material to our total consolidated net revenues.

Net Revenues by Segment

OSUR Segment

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

	Three Months Ended September 30,				
	Dollars			Percentage of Total Net Revenues	
Market	2017	2016	% Change	2017	2016
Infectious disease testing	$16,577	$10,412	59%	70%	43%
Risk assessment testing	3,149	3,481	(10)	13	15
Cryosurgical	2,879	3,240	(11)	12	14
Net product revenues	22,605	17,133	32	95	72
Other	1,157	6,791	(83)	5	28
Net revenues	$23,762	$23,924	(1)%	100%	100%

Infectious Disease Testing Market

Sales to the infectious disease testing market increased 59% to $16.6 million in the third quarter of 2017 from $10.4 million in the third quarter of 2016. This increase resulted from higher sales of our OraQuick® HCV product and higher international sales of our OraQuick® HIV self-test, partially offset by a decline in domestic sales of our professional OraQuick® HIV product.

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

Market	Three Months Ended September 30, 2017	2016	% Change
Domestic HIV	$ 3,622	$ 4,858	(25)%
International HIV	3,069	1,110	176
Domestic OTC HIV	1,515	1,311	16
Net HIV revenues	8,206	7,279	13
Domestic HCV	1,889	1,529	24
International HCV	6,154	1,293	376
Net HCV revenues	8,043	2,822	185
Net OraQuick® HIV and HCV product revenues	$ 16,249	$ 10,101	61%

Domestic OraQuick® HIV sales decreased 25% to $3.6 million for the three months ended September 30, 2017 from $4.9 million for the three months ended September 30, 2016. This reduction was primarily the result of competitive losses tied to pricing and the Centers for Disease Control and Prevention (“CDC”) testing guidelines recommending the use of competing fourth generation automated HIV immunoassays performed in a laboratory. Sales in the current quarter were also negatively impacted by customer ordering patterns, reduced government funding, and a decline in orders placed by those customers located in geographic areas severely impacted by recent weather events. We anticipate that future domestic sales of our professional HIV product will continue to be negatively affected as a result of the CDC testing guidelines, changes in government funding and continued product and price competition.

International sales of our OraQuick® HIV test during the third quarter of 2017 rose 176% to $3.1 million for the three months ended September 30, 2017 from $1.1 million for the three months ended September 30, 2016. This increase was largely due to increased sales of our OraQuick® HIV self-test into Africa. The majority of tests shipped into Africa during the current quarter were subject to support payments under our charitable support agreement with the Gates Foundation. Product revenues during the third quarter of 2017 included approximately $458,000 of support payments associated with this agreement.

Sales of our OraQuick® In-Home HIV test during the third quarter of 2017 increased 16% to $1.5 million from $1.3 million in the third quarter of 2016 largely as a result of additional shelf placement of the product in the home diagnostic section of certain retail pharmacies.

Domestic OraQuick® HCV sales increased 24% to $1.9 million in the third quarter of 2017 from $1.5 million in the third quarter of 2016 primarily due to increased HCV testing by a global nonprofit provider of infectious disease prevention, testing and healthcare services and higher sales to non-acute healthcare offices. International OraQuick® HCV sales increased 376% to $6.1 million in the third quarter of 2017 from $1.3 million in the third quarter of 2016, largely due to continued product shipments to a foreign government to support a nationwide HCV testing and treatment program, partially offset by the loss of a multi-national humanitarian organization customer who switched to a competitive product due to pricing. As discussed above, we were recently notified that our supply contract with the foreign government will not be renewed, which will negatively affect our international HCV sales in future periods.

Risk Assessment Market

Sales to the risk assessment market decreased 10% to $3.1 million in the third quarter of 2017 compared to $3.5 million in the third quarter of 2016 largely due to a change in inventory management by one of our larger customers.

Cryosurgical Market

Sales of our cryosurgical products decreased 11% to $2.9 million in the third quarter of 2017 from $3.2 million in the third quarter of 2016.

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

	Three Months Ended September 30,		
Market	2017	2016	% Change
Domestic professional	$ 1,426	$ 1,456	(2)%
International professional	179	162	10
Domestic OTC	325	339	(4)
International OTC	949	1,283	(26)
Net cryosurgical revenues	$ 2,879	$ 3,240	(11)%

Third quarter 2017 sales of our domestic and international Histofreezer® product sold to physicians' offices and our private-label wart removal product sold in the U.S. retail market remained consistent with the level of sales recorded in the third quarter of 2016.

Sales of our international OTC cryosurgical products during the third quarter of 2017 decreased 26% to $949,000 compared to $1.3 million in the third quarter of 2016 due to customer ordering patterns in Latin America and Europe.

Other revenues

Other revenues in the third quarter of 2017 decreased 83% to $1.2 million from $6.8 million in the third quarter of 2016. Other revenues in the third quarter of 2016 included $6.1 million of AbbVie exclusivity revenues. There are no similar revenues in the third quarter of 2017 due to the termination of the AbbVie co-promotion agreement on December 31, 2016. Revenue from BARDA funding increased to $939,000 in the third quarter of 2017 compared to $676,000 in the third quarter of 2016. Other revenues in the third quarter of 2017 also included $218,000 in reimbursement of certain costs under our charitable support agreement with the Gates Foundation.

DNAG Segment

Molecular Market

Net molecular revenues increased 123% to $18.6 million in the third quarter of 2017 from $8.3 million in the third quarter of 2016. Sales of our Oragene® product in the commercial market rose 157% in the third quarter of 2017 compared to the third quarter of 2016, largely as a result of higher customer demand, primarily from a large customer in the consumer genetics market. Sales of our Oragene® product in the academic market increased 46% in the third quarter of 2017 compared to the third quarter of 2016 largely due to higher customer demand and customer ordering patterns. The higher revenues in the third quarter of 2017 also included $776,000 in sales of our microbiome product compared to $362,000 in the same period of 2016. We believe interest in our microbiome product offering continues to grow with both new and existing customers.

CONSOLIDATED OPERATING RESULTS

Consolidated gross margin was 58% for the third quarter of 2017 compared to 70% for the third quarter of 2016. Gross margin in the third quarter of 2017 was negatively impacted by the absence of exclusivity revenues under our HCV co-promotion agreement with AbbVie, an increase in lower margin product sales and higher scrap and spoilage costs.

Consolidated operating income for the third quarter of 2017 was $7.3 million, a $1.2 million improvement from the $6.1 million of operating income reported in the third quarter of 2016. Operating income for the third quarter of 2017 benefited from higher product revenues as compared to the same period last year, partially offset by higher sales and marketing expense in the current period and the absence of AbbVie revenues from the prior year.

OPERATING INCOME (LOSS) BY SEGMENT

OSUR Segment

OSUR's gross margin was 55% in the third quarter of 2017 compared to 71% in the third quarter of 2016. OSUR's gross margin in the third quarter of 2017 was negatively impacted by the absence of exclusivity revenues under our AbbVie co-promotion agreement ($6.1 million was recorded in the third quarter of 2016 versus none in 2017), an increase in lower margin product revenues as a result of higher international sales, and higher scrap and spoilage costs incurred during the quarter.

Research and development expenses increased 12% to $2.5 million in the third quarter of 2017 from $2.3 million in the third quarter of 2016, largely due to increased staffing and product registration costs. Sales and marketing expenses grew 3% to $4.8 million in the third quarter of 2017 from $4.7 million in the third quarter of 2016 largely due to increased external commissions to be paid to our international distributors partially offset by lower call center costs associated with our OraQuick® In-Home HIV test. General and administrative expenses increased 14% to $6.2 million in the third quarter of 2017 from $5.5 million in the third quarter of 2016 due to higher staffing costs which includes an increase in accrued bonuses as a result of Company performance partially offset by lower consulting costs.

All of the above contributed to OSUR's third quarter 2017 operating loss of $453,000, which included non-cash charges of $855,000 for depreciation and amortization and $1.4 million for stock-based compensation.

DNAG Segment

DNAG's gross margin was 62% in the third quarter of 2017 compared to 69% in the third quarter of 2016. This decline was attributable to an increase in lower margin product sales in the third quarter of 2017 compared to the third quarter of 2016.

Research and development expenses decreased 26% to $681,000 in the third quarter of 2017 from $924,000 in the third quarter of 2016. Research and development expenses in the third quarter of 2016 included costs associated with field studies required to achieve World Health Organization ("WHO") endorsement of our OMNIgene® • Sputum product for tuberculosis. There were no similar expenses in the third quarter of 2017. Sales and marketing expenses rose 33% to $2.3 million in the third quarter of 2017 from $1.8 million in the third quarter of 2016 due to an increase in our allowance for uncollectible accounts and higher staffing costs. General and administrative expenses decreased 52% to $696,000 in the third quarter of 2017 compared to $1.4 million in the third quarter of 2016 primarily due to lower legal and staffing expenses.

All of the above contributed to DNAG's third quarter 2017 operating income of $7.8 million, which included non-cash charges of $843,000 for depreciation and amortization and $170,000 for stock-based compensation.

CONSOLIDATED INCOME TAXES

We continue to believe the full valuation allowance established in 2008 against OSUR's total U.S. deferred tax asset is appropriate as the facts and circumstances necessitating the allowance have not changed. For the three months ended September 30, 2017, no state income tax expense was recorded as compared to $200,000 in the three months ended September 30, 2016. Canadian income tax expense of $1.7 million and $200,000 was recorded in the third quarters of 2017 and 2016, respectively.

Nine months ended September 30, 2017 compared to September 30, 2016

CONSOLIDATED NET REVENUES

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

	Nine Months Ended September 30,				
	Dollars			Percentage of Total Net Revenues	
	2017	2016	% Change	2017	2016
OSUR	$ 66,455	$54,637	22%	58%	59%
DNAG	45,316	23,649	92	39	25
Net product revenues	111,771	78,286	43	97	84
Other	3,265	14,413	(77)	3	16
Net revenues	$115,036	$92,699	24%	100%	100%

Consolidated net product revenues increased 43% to $111.8 million in the first nine months of 2017 from $78.3 million in the comparable period of 2016. Higher sales of our molecular and OraQuick® HCV products and higher international sales of our OraQuick® HIV self-test were partially offset by lower domestic sales of our professional OraQuick® HIV product and lower domestic and OTC sales of our cryosurgical products. In the first nine months of 2017, we recognized $3.3 million as other revenues largely in connection with funding from BARDA related to our Ebola and Zika products. Other revenues in the first nine months of 2016 were $14.4 million and included $12.8 million in exclusivity payments received under our AbbVie co-promotion agreement and $1.6 million in BARDA funding. Our co-promotion agreement with AbbVie was terminated on December 31, 2016 and no further revenues were recognized under this agreement.

Consolidated net revenues derived from products sold to customers outside of the United States were $36.2 million and $20.2 million, or 31% and 22% of total net revenues, during the nine months ended September 30, 2017 and 2016, respectively. Because the majority of our international sales are denominated in U.S. dollars, the impact of fluctuating foreign currency exchange rates was not material to our total consolidated net revenues.

Net Revenues by Segment

OSUR Segment

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

Market	Nine Months Ended September 30, Dollars 2017	2016	% Change	Percentage of Total Net Revenues 2017	2016
Infectious disease testing	$47,822	$34,729	38%	68%	50%
Risk assessment testing	9,517	9,746	(2)	14	14
Cryosurgical systems	9,116	10,162	(10)	13	15
Net product revenues	66,455	54,637	22	95	79
Other	3,265	14,413	(77)	5	21
Net revenues	$69,720	$69,050	1%	100%	100%

Infectious Disease Testing Market

Sales to the infectious disease testing market increased 38% to $47.8 million in the first nine months of 2017 from $34.7 million in the first nine months of 2016. This increase resulted from higher sales of our OraQuick® HCV product and higher international sales of our OraQuick® HIV self-test, partially offset by a decline in domestic sales of our professional OraQuick® HIV product.

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

Market	Nine Months Ended September 30, 2017	2016	% Change
Domestic HIV	$ 12,401	$ 16,446	(25)%
International HIV	7,738	3,934	97
Domestic OTC HIV	4,951	4,574	8
Net HIV revenues	25,090	24,954	1
Domestic HCV	5,980	5,218	15
International HCV	15,817	3,722	325
Net HCV revenues	21,797	8,940	144
Net OraQuick® revenues	$ 46,887	$ 33,894	38%

Domestic OraQuick® HIV sales decreased 25% to $12.4 million for the nine months ended September 30, 2017 from $16.4 million for the nine months ended September 30, 2016. This reduction was primarily the result of competitive losses tied to pricing and the CDC's testing guidelines recommending the use of competing fourth generation automated HIV immunoassays performed in a laboratory, reduced government funding and customer ordering patterns. We anticipate that future domestic sales of our professional HIV product will continue to be negatively affected by the CDC testing guidelines, changes in government funding, and continued product and price competition.

International sales of our OraQuick® HIV products during the first nine months of 2017 rose 97% to $7.7 million from $3.9 million in the first nine months of 2016. This increase was largely due to the continued shipment of product in support of a HIV self-testing program in Africa and higher sales into the Middle East and Asia. Funding under the charitable support agreement with the Gates Foundation began in the third quarter of 2017. Sales to certain

regions in Africa during the quarter were subject to support payments under this agreement. Product revenues during the third quarter of 2017 included approximately $458,000 of such support payments.

Sales of our OraQuick® In-Home HIV test during the first nine months of 2017 of $4.9 million increased 8% compared to $4.6 million in the first nine months of 2016 largely due to expansion of public health programs that use our In-Home test and additional shelf placement of the product in the home diagnostic section of certain retail pharmacies.

Domestic OraQuick® HCV sales increased 15% to $6.0 million in the first nine months of 2017 from $5.2 million in the first nine months of 2016 primarily due to an increase in sales to our U.S. public health customers related to HCV testing program expansion and higher sales to non-acute healthcare offices, partially offset by customer ordering patterns. International OraQuick® HCV sales increased 325% to $15.8 million in the first nine months of 2017 from $3.7 million in the first nine months of 2016, largely due to continued product shipments to a foreign government to support a nationwide HCV testing and treatment program and increased sales in Asia and Africa partially offset by the loss of a multi-national humanitarian organization customer who switched to a competitive product due to pricing. As discussed above, we were recently notified that our supply contract with the foreign government will not be renewed, which will negatively affect our international HCV sales in future periods.

Risk Assessment Market

Sales to the risk assessment market decreased slightly to $9.5 million in the first nine months of 2017 compared to $9.7 million in the first nine months of 2016.

Cryosurgical Market

Sales of our cryosurgical products decreased 10% to $9.1 million in the first nine months of 2017 from $10.2 million in the first nine months of 2016.

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

	Nine Months Ended September 30,		
Market	2017	2016	% Change
Domestic professional	$4,368	$ 4,155	5%
International professional	552	607	(9)
Domestic OTC	957	1,062	(10)
International OTC	3,239	4,338	(25)
Net cryosurgical systems revenues	$9,116	$10,162	(10)%

Sales of our Histofreezer® product to physicians' offices in the United States increased 5% to $4.4 million in the first nine months of 2017 from $4.2 million in the first nine months of 2016, primarily due to the continued recovery of business previously lost to competition. International sales of our Histofreezer® product decreased to $552,000 in the first nine months of 2017 from $607,000 in the first nine months of 2016.

Sales of our private-label wart removal product in the U.S. retail market decreased to $957,000 in the first nine months of 2017 from $1.1 million in the first nine months of 2016. Sales volume in 2016 was higher as a result of initial stocking orders for a new large pharmacy customer during that period.

Sales of our international OTC cryosurgical products during the first nine months of 2017 decreased 25% to $3.2 million compared to $4.3 million in the first nine months of 2016, largely due to lower sales into Europe as a result

of customer ordering patterns and competitive pressures and lower sales in Latin America due to customer ordering patterns and the economic instability of the countries into which we sell.

Other revenues

Other revenues in the first ninth months of 2017 decreased 77% to $3.3 million from $14.4 million in the first nine months of 2016. Other revenues in 2016 included AbbVie exclusivity revenues of $12.8 million. There are no similar revenues in 2017 due to the termination of our AbbVie co-promotion agreement on December 31, 2016. Revenues related to funding from BARDA increased to $3.1 million in the first nine months of 2017 compared to $1.6 million in the first nine months of 2016. Revenues in the first nine months of 2017 also include $218,000 in reimbursement of certain costs under our charitable support agreement with the Gates Foundation.

DNAG Segment

Molecular Market

Net molecular revenues increased 92% to $45.3 million in the first nine months of 2017 from $23.6 million in the first nine months of 2016. Sales of our Oragene® product in the commercial market rose 134% in the first nine months of 2017 compared to the first nine months of 2016, largely as a result of higher customer demand primarily from a large customer in the consumer genetics market. Sales of our Oragene® product in the academic market increased 5% in the first nine months of 2017 compared to the first nine months of 2016 largely due to higher customer demand and customer ordering patterns. The higher revenues in the first nine months of 2017 also included $2.4 million in sales of our microbiome product compared to $742,000 in the same period of 2016. We believe interest in our microbiome product offering continues to grow with both new and existing customers.

CONSOLIDATED OPERATING RESULTS

Consolidated gross margin was 61% for the first nine months of 2017 compared to 69% for the first nine months of 2016. Gross margin in the first nine months of 2017 was negatively impacted by the absence of exclusivity revenues under our HCV co-promotion agreement with AbbVie, an increase in lower margin product sales, and higher scrap and spoilage costs.

Consolidated operating income for the first nine months of 2017 was $30.1 million, a $16.9 million improvement from $13.2 million of operating income reported in the first nine months of 2016. The operating income for the first nine months of 2017 benefited from the Ancestry litigation settlement gain, increased product revenues, and lower sales and marketing costs, partially offset by the loss of AbbVie exclusivity revenues recorded in the prior year and higher research and development and general and administrative expenses in the current year.

OPERATING INCOME (LOSS) BY SEGMENT

OSUR Segment

OSUR’s gross margin was 59% in the first nine months of 2017 compared to 69% in the first nine months of 2016. OSUR’s gross margin in the first nine months of 2017 was negatively impacted by the absence of exclusivity revenues under our AbbVie agreement ($12.8 million was recorded in the first nine months of 2016 versus none in 2017), an increase in lower margin product revenue as a result of higher international sales, and an increase in scrap and spoilage costs.

Research and development expenses increased 18% to $7.5 million in the first nine months of 2017 from $6.4 million in the first nine month of 2016, largely due to increased staffing expenses and higher supply costs associated with the development of our Ebola and Zika products. Sales and marketing expenses decreased 9% to $14.7 million in the first nine months of 2017 from $16.1 million in the same period of 2016. This decrease was primarily the result of the termination of our AbbVie agreement on December 31, 2016 and lower staffing costs, partially offset by higher external commissions to be paid to our international distributors. General and administrative expenses increased 20% to $19.3 million in the first nine months of 2017 from $16.0 million in the first nine months of 2016 due to higher staffing costs, which includes an increase in accrued bonuses as a result of Company performance.

All of the above contributed to OSUR's operating loss of $235,000 in the first nine months of 2017, which included non-cash charges of $2.2 million for depreciation and amortization and $4.8 million for stock-based compensation.

DNAG Segment

DNAG's gross margin was 64% in the first nine months of 2017 compared to 70% in the first nine months of 2016. This decline was attributable to an increase in lower margin sales in the first nine months of 2017 compared to the same period of 2016.

Research and development expenses decreased 8% to $2.0 million in the first nine months of 2017 from $2.2 million in the first nine months of 2016. Research and development expenses in first nine months of 2016 included costs associated with field studies required to achieve WHO endorsement of our OMNIgene® • Sputum product for tuberculosis. No similar expenses were recorded in 2017. Partially offsetting these cost savings were higher staffing costs in the first nine months of 2017. Sales and marketing expenses increased 7% to $6.9 million in the first nine months of 2017 from $6.4 million in the first nine months of 2016 due to higher staffing costs. General and administrative expenses decreased 35% to $2.5 million in the first nine months of 2017 compared to $3.8 million in the first nine months of 2016 primarily due to lower legal costs. Operating expenses in the first nine months of 2017 were offset by the $12.5 million pre-tax gain associated with the settlement of our litigation with Ancestry.com DNA, LLC and its contract manufacturer.

All of the above contributed to DNAG's operating income of $30.3 million in the first nine months of 2017, which included non-cash charges of $2.4 million for depreciation and amortization and $430,000 for stock-based compensation.

CONSOLIDATED INCOME TAXES

We continue to believe the full valuation allowance established in 2008 against OSUR's total U.S. deferred tax asset is appropriate as the facts and circumstances necessitating the allowance have not changed. For the nine months ended September 30, 2017, we recorded state income tax expense of $31,000 compared to $250,000 in the nine months ended September 30, 2016. Canadian income tax expense of $7.1 million and $384,000 was recorded in the first nine months of 2017 and 2016, respectively. Canadian taxes in the first nine months of 2017 included the additional taxes due as a result of the $12.5 million Ancestry litigation settlement gain and DNAG's increased pre-tax income.

Liquidity and Capital Resources

	September 30, 2017	December 31, 2016
	(In thousands)	
Cash, cash equivalents and restricted cash	$ 78,610	$ 109,790
Available-for-sale securities	101,662	11,160
Working capital	182,712	139,106

Our cash, cash equivalents, restricted cash and available-for-sale securities increased to $180.3 million at September 30, 2017 from $120.9 million at December 31, 2016. Our working capital increased to $182.7 million at September 30, 2017 from $139.1 million at December 31, 2016.

During the first nine months of 2017, we generated $30.4 million in cash from operating activities. Our net income of $23.6 million benefitted from non-cash stock-based compensation expense of $5.2 million and depreciation and amortization expense of $4.6 million, partially offset by a net reduction of other non-cash charges of $671,000. Additional sources of cash included an increase in accounts payable of $4.6 million largely due to inventory purchases that were invoiced at the end of the quarter, an increase in accrued expenses and other liabilities of $4.2 million largely due to an increase in our Canadian income taxes payable, and a decrease in prepaid and other assets of $1.6 million largely due to the receipt of $1.4 million as payment of a claim from one of our raw material

suppliers. This settlement was recorded as a receivable at December 31, 2016. Uses of cash in operating activities during the period include an increase in accounts receivable of $7.7 million largely resulting from the increase in orders placed near the end of the current quarter and an increase in inventory balances of $4.9 million required to meet expected demand.

Net cash used in investing activities was $93.0 million for the nine months ended September 30, 2017, which reflects $132.2 million used to purchase investments and $3.4 million to acquire property and equipment partially offset by $42.6 million in proceeds from the maturities and redemptions of investments.

Net cash provided by financing activities was $30.2 million for the nine months ended September 30, 2017, which resulted from $31.4 million in proceeds received from the exercise of stock options partially offset by $1.2 million used for the repurchase of common stock to satisfy withholding taxes related to the vesting of restricted shares.

On September 30, 2016, we entered into a credit agreement (the “Credit Agreement”) with a commercial bank. The Credit Agreement provides for revolving extensions of credit in an initial aggregate amount of up to $10.0 million (inclusive of a letter of credit subfacility of $2.5 million), with an option to request, prior to the second anniversary of the closing date, that lenders, at their election, provide up to $5.0 million of additional revolving commitments. Obligations under the Credit Agreement are secured by a first priority security interest in certain eligible accounts receivable, 65% of the equity of our subsidiary, DNAG, and certain related assets. There were no borrowings outstanding at September 30, 2017 or December 31, 2016.

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

In connection with the Credit Agreement, under certain circumstances, we must comply with a minimum fixed charge coverage ratio of 1.10 to 1.00, measured as of the last day of each fiscal month and for the twelve-fiscal month period ending on such date. As of September 30, 2017 and December 31, 2016, 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, $43.3 million or 24% of our $180.3 million in cash, cash equivalents, restricted cash and available-for-sale securities belongs to our Canadian subsidiary and any repatriation of such cash into the United States could have adverse tax consequences.

Summary of Contractual Obligations

A summary of our obligations to make future payments under contracts existing at December 31, 2016 is included in Item 7, Management’s Discussion and Analysis of Financial Condition and Results of Operations, of our Annual Report on Form 10-K for the year ended December 31, 2016. As of September 30, 2017, there were no significant changes to this information, including the absence of any off-balance sheet arrangements.

Critical Accounting Policies and Estimates

This Management’s Discussion and Analysis of Financial Condition and Results of Operations discusses our consolidated financial statements, which have been prepared in accordance with accounting principles generally

accepted in the United States of America. The preparation of these consolidated financial statements requires that we make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. On an on-going basis, we evaluate our judgments and estimates, including those related to the valuation of accounts receivable, inventories and intangible assets, as well as calculations related to contingencies accruals and the measurement of performance-based restricted stock expense. We base our judgments and estimates on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

A more detailed review of our critical accounting policies is contained in our Annual Report on Form 10-K for the year ended December 31, 2016 filed with the SEC. During the first nine months of 2017, there were no material changes in our critical accounting policies.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

As of September 30, 2017, we did not have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. Sales denominated in foreign currencies comprised 4.1% of our total revenues for the nine months ended September 30, 2017. We do have foreign currency exchange risk related to our operating subsidiary in Canada. While the majority of this subsidiary's revenues are recorded in U.S. dollars, almost all of this subsidiary's operating expenses are denominated in Canadian dollars. Fluctuations in the exchange rate between the U.S. dollar and the Canadian dollar could affect year-to-year comparability of operating results and cash flows. Our Canadian subsidiary had net assets, subject to translation, of $89.4 million CDN ($71.7 million USD), which are included in the Company's consolidated balance sheet as of September 30, 2017. A 10% unfavorable change in the Canadian-to-U.S. dollar exchange rate would have decreased our comprehensive income by $7.2 million in the nine months ended September 30, 2017.

Item 4. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures. The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) as of September 30, 2017. Based on that evaluation, the Company's management, including such officers, concluded that the Company's disclosure controls and procedures were effective as of September 30, 2017 to provide reasonable assurance that material information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act of 1934 was accumulated and communicated to the Company's management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure and was recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission.

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

PART II. OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

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

Item 1A. RISK FACTORS

There have been no material changes to the factors disclosed in Item 1A., entitled "Risk Factors," in our Annual Report on Form 10-K for the year ended December 31, 2016.

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

Period	Total number of shares purchased	Average price paid per Share	Total number of shares purchased as part of publicly announced plans or programs	Maximum number (or approximate dollar value) of shares that may yet be repurchased under the plans or programs (1, 2)
July 1, 2017 - July 31, 2017	1,440(3)	$ 17.75	N/A	11,984,720
August 1, 2017 - August 31, 2017	—	—	$ —	11,984,720
September 1, 2017 - September 30, 2017	—	—	—	11,984,720
	1,440		—	

(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
31.1*	Certification of Douglas A. Michels required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.2*	Certification of Ronald H. Spair required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
32.1*	Certification of Douglas A. Michels required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Ronald H. Spair required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

*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/ Ronald H. Spair

Date: November 9, 2017

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

/s/Mark L. Kuna

Date: November 9, 2017

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

Exhibit 31.1

Certification

I, Douglas A. Michels, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 9, 2017

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

Exhibit 31.2

Certification

I, Ronald H. Spair, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 9, 2017

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

Exhibit 32.1

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

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

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

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

/s/ Douglas A. Michels

Douglas A. Michels
President and Chief Executive Officer

November 9, 2017

Exhibit 32.2

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

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

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

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

/s/ Ronald H. Spair

Ronald H. Spair
Chief Operating Officer and
Chief Financial Officer

November 9, 2017