

ORASURE TECHNOLOGIES INC  
Form 10-Q  
May 09, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2018.

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_ .

Commission File Number 001-16537

ORASURE TECHNOLOGIES, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware 36-4370966  
(State or Other Jurisdiction of (IRS Employer Identification No.)

Incorporation or Organization)

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 May 2, 2018: 61,063,828 shares.

---

PART I. FINANCIAL INFORMATION

	Page No.
Item 1. Financial Statements (unaudited)	
<u>Consolidated Balance Sheets at March 31, 2018 and December 31, 2017</u>	3
<u>Consolidated Statements of Operations for the three months ended March 31, 2018 and 2017</u>	4
<u>Consolidated Statements of Comprehensive Income (Loss) for the three months ended March 31, 2018 and 2017</u>	5
<u>Consolidated Statements of Cash Flows for the three months ended March 31, 2018 and 2017</u>	6
<u>Notes to the Consolidated Financial Statements</u>	7
<u>Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	18
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	24
<u>Item 4. Controls and Procedures</u>	25
PART II. OTHER INFORMATION	
<u>Item 1. Legal Proceedings</u>	26
<u>Item 1A. Risk Factors</u>	26
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	26
<u>Item 3. Defaults Upon Senior Securities</u>	26
<u>Item 4. Mine Safety Disclosures</u>	26
<u>Item 5. Other Information</u>	26
<u>Item 6. Exhibits</u>	27
<u>Signatures</u>	28



## Item 1. FINANCIAL STATEMENTS

## ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

## CONSOLIDATED BALANCE SHEETS

(Unaudited)

(in thousands, except per share amounts)

	March 31, 2018	December 31, 2017
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$64,042	\$71,029
Restricted cash	23	1,840
Short-term investments	79,446	83,028
Accounts receivable, net of allowance for doubtful accounts of \$351 and \$471	28,197	42,521
Inventories	20,907	19,343
Prepaid expenses	2,213	1,658
Other current assets	1,926	2,486
Total current assets	196,754	221,905
PROPERTY AND EQUIPMENT, net	22,975	21,372
INTANGIBLE ASSETS, net	7,390	8,223
GOODWILL	19,584	20,083
LONG TERM INVESTMENTS	34,880	20,690
OTHER ASSETS	4,340	3,928
	\$285,923	\$296,201
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$9,622	\$10,228
Deferred revenue	1,799	1,314
Accrued expenses	9,765	20,695
Total current liabilities	21,186	32,237
OTHER LIABILITIES	4,258	3,932
DEFERRED INCOME TAXES	1,761	1,951
COMMITMENTS AND CONTINGENCIES (Note 8)		
<b>STOCKHOLDERS' EQUITY</b>		
Preferred stock, par value \$.000001, 25,000 shares authorized, none issued	—	—
Common stock, par value \$.000001, 120,000 shares authorized, 61,053 and 60,662 shares		
issued and outstanding	—	—
Additional paid-in capital	393,429	387,931
Accumulated other comprehensive loss	(13,006 )	(10,340 )
Accumulated deficit	(121,705)	(119,510)
Total stockholders' equity	258,718	258,081
	\$285,923	\$296,201

See accompanying notes to the consolidated financial statements.

## ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(in thousands, except per share amounts)

	Three Months Ended March 31,	
	2018	2017
<b>NET REVENUES:</b>		
Product	\$38,318	\$31,482
Other	3,669	1,064
	41,987	32,546
<b>COST OF PRODUCTS SOLD</b>	17,520	12,236
Gross profit	24,467	20,310
<b>OPERATING EXPENSES:</b>		
Research and development	4,075	2,970
Sales and marketing	7,499	6,877
General and administrative	13,391	7,092
Gain on litigation settlement	-	(12,500)
	24,965	4,439
Operating income (loss)	(498 )	15,871
<b>OTHER INCOME</b>	412	467
Income (loss) before income taxes	(86 )	16,338
<b>INCOME TAX EXPENSE</b>	2,033	3,897
<b>NET INCOME (LOSS)</b>	<b>\$(2,119 )</b>	<b>\$12,441</b>
<b>EARNINGS (LOSS) PER SHARE:</b>		
<b>BASIC</b>	<b>\$(0.03 )</b>	<b>\$0.22</b>
<b>DILUTED</b>	<b>\$(0.03 )</b>	<b>\$0.21</b>
<b>SHARES USED IN COMPUTING EARNINGS (LOSS) PER SHARE:</b>		
<b>BASIC</b>	<b>60,865</b>	<b>56,929</b>
<b>DILUTED</b>	<b>60,865</b>	<b>58,772</b>

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(Unaudited)

(in thousands)

	Three Months Ended March 31,	
	2018	2017
NET INCOME (LOSS)	\$(2,119)	\$12,441
OTHER COMPREHENSIVE INCOME (LOSS)		
Currency translation adjustments	(2,154)	450
Unrealized loss on marketable securities	(512 )	—
COMPREHENSIVE INCOME (LOSS)	\$(4,785)	\$12,891

See accompanying notes to the consolidated financial statements.

-5-

---



## ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(in thousands)

	Three Months Ended March 31,	
	2018	2017
<b>OPERATING ACTIVITIES:</b>		
Net income (loss)	\$(2,119 )	\$12,441
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Stock-based compensation	7,483	1,518
Depreciation and amortization	1,868	1,419
Unrealized foreign currency gain	(298 )	(1 )
Deferred income taxes	(141 )	(139 )
Changes in assets and liabilities		
Accounts receivable	14,206	(4,143 )
Inventories	(1,661 )	(893 )
Prepaid expenses and other assets	2	1,505
Accounts payable	(1,115 )	2,619
Deferred revenue	421	(84 )
Accrued expenses and other liabilities	(11,010)	(1,623 )
Net cash provided by operating activities	7,636	12,619
<b>INVESTING ACTIVITIES:</b>		
Purchases of investments	(57,765)	(7,514 )
Proceeds from maturities and redemptions of investments	45,893	—
Purchases of property and equipment	(1,897 )	(878 )
Net cash (used in) investing activities	(13,769)	(8,392 )
<b>FINANCING ACTIVITIES:</b>		
Proceeds from exercise of stock options	954	9,417
Repurchase of common stock	(2,959 )	(851 )
Net cash (used in) provided by financing activities	(2,005 )	8,566
<b>EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH</b>	<b>(666 )</b>	<b>99</b>
<b>NET (DECREASE) INCREASE IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH</b>	<b>(8,804 )</b>	<b>12,892</b>
<b>CASH, CASH EQUIVALENTS, AND RESTRICTED CASH, BEGINNING OF PERIOD</b>	<b>72,869</b>	<b>107,959</b>
<b>CASH, CASH EQUIVALENTS, AND RESTRICTED CASH, END OF PERIOD</b>	<b>\$64,065</b>	<b>\$120,851</b>
<b>SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:</b>		
Cash paid for income taxes	\$8,886	\$1,949
Noncash investing activities (accrued property and equipment purchases)	\$1,157	\$297
Noncash unrealized losses on marketable securities	\$(512 )	\$—

See accompanying notes to the consolidated financial statements.



## ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

### Notes to the Consolidated Financial Statements

(Unaudited)

(in thousands, except per share amounts, unless otherwise indicated)

#### 1. The Company

Our business is comprised of two segments: Our “OSUR” business consists of the development, manufacture, marketing and sale of oral fluid diagnostic products and specimen collection devices using our proprietary technologies, as well as other diagnostic products including immunoassays and other in vitro diagnostic tests that are used on other specimen types. Our molecular collections systems or “DNAG” business consists of the manufacture and sale of specimen collection kits that are used to collect, stabilize, transport and store samples of genetic material for molecular testing in the consumer genetic, clinical genetic, academic research, pharmacogenomics, personalized medicine, microbiome and animal genetics markets.

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

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

#### 2. Summary of Significant Accounting Policies

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

The accompanying consolidated financial statements are unaudited and, in the opinion of management, include all adjustments (consisting only of normal and recurring adjustments) necessary for a fair presentation of our financial position and results of operations for these interim periods. These financial statements should be read in conjunction with the financial statements and notes thereto included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017. Results of operations for the three months ended March 31, 2018 are not necessarily indicative of the results of operations expected for the full year.

Use of Estimates. The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions about future events. These estimates and underlying assumptions affect the amounts of assets and liabilities reported, disclosures about contingent assets and liabilities, and reported amounts of revenues and expenses. Such estimates include the valuation of accounts receivable and inventories and assumptions utilized in impairment testing for intangible assets and goodwill, as well as calculations related to accruals, taxes, and performance-based compensation expense, among others. These estimates and assumptions are based on management's best estimates and judgment. Management evaluates its estimates and assumptions on an ongoing basis, using historical experience and other factors, which management believes to be reasonable under the circumstances, including the current economic environment. As future events and their effects cannot be determined with precision, actual results could differ significantly from these estimates. Changes in those estimates resulting from continuing changes in the economic environment and other factors will be reflected in the financial statements in those future periods.

Investments. We consider all investments to be available-for-sale securities. These securities are comprised of guaranteed investment certificates and corporate bonds with purchased maturities greater than ninety days. Available-for-sale securities are carried at fair value, based upon quoted market prices, with unrealized gains and losses, if any, reported in stockholders' equity as a component of accumulated other comprehensive loss.

Edgar Filing: ORASURE TECHNOLOGIES INC - Form 10-Q

The following is a summary of our available-for-sale securities as of March 31, 2018 and December 31, 2017:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
<b>March 31, 2018</b>				
Guaranteed investment certificates	\$ 21,708	\$ —	\$ —	\$ 21,708
Corporate bonds	93,683	1	(1,066 )	92,618
Total available-for-sale securities	\$ 115,391	\$ 1	\$ (1,066 )	\$ 114,326
<b>December 31, 2017</b>				
Guaranteed investment certificates	\$ 22,261	\$ —	\$ —	\$ 22,261
Corporate bonds	82,010	—	(553 )	81,457
Total available-for-sale securities	\$ 104,271	\$ —	\$ (553 )	\$ 103,718
At March 31, 2018 maturities of our available-for-sale securities were as follows:				
Less than one year	\$ 80,158	\$ 1	\$ (713 )	\$ 79,446
Greater than one year	\$ 35,233	\$ —	\$ (353 )	\$ 34,880

Fair Value of Financial Instruments. As of March 31, 2018 and December 31, 2017, the carrying values of cash and cash equivalents, restricted cash, accounts receivable, and accounts payable approximate their respective fair values based on their short-term nature.

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

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

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

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

All of our available-for-sale securities are measured as Level 1 instruments as of March 31, 2018 and December 31, 2017.

Included in cash and cash equivalents at March 31, 2018 and December 31, 2017, was \$28,831 and \$40,760 invested in government money market funds and certificates of deposit. Both are measured as Level 1 instruments.

We offer a nonqualified deferred compensation plan for certain eligible employees and members of our Board of Directors. The assets of the plan are held in the name of the Company at a third-party financial institution. Separate accounts are maintained for each participant to reflect the amounts deferred by the participant and all earnings and

losses on those deferred amounts. The assets of the plan are held in mutual funds and Company stock. The fair value of the plan assets as of March 31, 2018 and December 31, 2017 was \$3,972 and \$3,514, respectively, and was calculated using the quoted market prices of the assets as of those dates. All investments in the plan are classified as trading securities and measured as Level 1 instruments. The fair value of plan assets is included in other assets with the same amount included in other liabilities in the accompanying consolidated balance sheets.

In 2018, we purchased a certificate of deposit (“CD”) from a commercial bank as collateral for a standby letter of credit. The CD bears an interest rate of 1.28% and matures on May 20, 2018. The carrying value of the CD approximates its fair value and is reported as restricted cash on the accompanying consolidated balance sheets. Also see Note 8 – Commitments and Contingencies.

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

	March 31,	December 31,
	2018	2017
Raw materials	\$ 10,990	\$ 10,299
Work in process	388	199
Finished goods	9,529	8,845
	\$ 20,907	\$ 19,343

**Property and Equipment.** Property and equipment are stated at cost. Additions or improvements are capitalized, while repairs and maintenance are charged to expense. Depreciation and amortization are provided using the straight-line method over the estimated useful lives of the related assets. Buildings are depreciated over twenty to forty years, while computer equipment, machinery and equipment, and furniture and fixtures are depreciated over two to ten years. Building improvements are amortized over their estimated useful lives. When assets are sold, retired, or discarded, the related property amounts are relieved from the accounts, and any gain or loss is recorded in the consolidated statements of operations. Accumulated depreciation of property and equipment as of March 31, 2018 and December 31, 2017 was \$40,059 and \$39,379, respectively.

**Intangible Assets.** Intangible assets consist of a customer list, patents and product rights, acquired technology and tradenames. Patents and product rights consist of costs associated with the acquisition of patents, licenses, and product distribution rights. Intangible assets are amortized using the straight-line method over their estimated useful lives of seven to fifteen years. Accumulated amortization of intangible assets as of March 31, 2018 and December 31, 2017 was \$18,990 and \$18,692, respectively. The change in intangibles from \$8,223 as of December 31, 2017 to \$7,390 as of March 31, 2018 is a result of \$664 in amortization expense and \$169 in foreign currency translation losses.

**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 March 31, 2018, we believe no indicators of impairment exist.

The decrease in goodwill from \$20,083 as of December 31, 2017 to \$19,584 as of March 31, 2018 is a result of foreign currency translation.

**Earnings (Loss) Per Share.** Basic earnings (loss) per share is computed by dividing net income or loss by the weighted-average number of shares of common stock outstanding during the period. Diluted earnings (loss) per share is computed in a manner similar to basic earnings (loss) per share except that the weighted-average number of shares outstanding is increased to include incremental shares from the assumed vesting or exercise of dilutive securities, such as common stock options, 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 (loss) per share are as follows:

	Three Months Ended March 31,	
	2018	2017
Net income (loss)	\$(2,119 )	\$12,441
Weighted-average shares of common stock outstanding:		
Basic	60,865	56,929
Dilutive effect of stock options, restricted stock, and		
performance stock units	—	1,843
Diluted	60,865	58,772
Earnings (loss) per share:		
Basic	\$(0.03 )	\$0.22
Diluted	\$(0.03 )	\$0.21

-9-



For the three-month period ended March 31, 2017, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 666 shares, respectively, were excluded from the computation of diluted earnings per share as their inclusion would have been anti-dilutive.

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

Transaction gains and losses resulting from exchange rate changes on transactions denominated in currencies other than functional currency are included in our consolidated statements of income in the period in which the change occurs. Net foreign exchange gains (losses) resulting from foreign currency transactions that are included in other income (expense) in our consolidated statements of operations were \$254 and \$(200) for the three months ended March 31, 2018 and 2017, respectively.

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

We have defined the Canadian dollar as the functional currency of our Canadian subsidiary, DNAG, and as such, the results of its operations are translated into U.S. dollars, which is the reporting currency of the Company. Accumulated other comprehensive loss at March 31, 2018 consists of \$11,941 of currency translation adjustments and \$1,065 of net unrealized losses on marketable securities, which represents the fair market value adjustment for our investment portfolio. Accumulated other comprehensive loss at December 31, 2017 consists of \$9,787 of currency translation adjustments and \$553 of net unrealized losses on marketable securities.

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

In August 2016, the FASB issued ASU 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments, which provides guidance related to cash flows presentation and is effective for annual reporting periods beginning after December 15, 2017, subject to early adoption. We adopted ASU 2016-15 on January 1, 2018 and it did not have a material impact on our consolidated financial statements.

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

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

### 3. Revenues

#### Adoption of New Revenue Recognition Standard

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

Upon adoption, we recorded a reduction of \$76 to the opening balance of accumulated deficit as of January 1, 2018. This adjustment is related to the change in revenue recognition associated with our drug testing kit sales. Sales of our drug testing kits include two performance obligations: sales of the device and laboratory services. Under this new accounting standard, we adjusted the allocation of the transaction price to the

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

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

	Balance at December 31, 2017	New Revenue Standard Adjustment	Balance at January 1, 2018
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>			
<b>CURRENT LIABILITIES:</b>			
Deferred revenue	1,314	76	1,390
<b>STOCKHOLDERS' EQUITY</b>			
Accumulated deficit	(119,510)	(76)	(119,586)

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

#### Revenue Policies

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

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

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

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

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

As part of our litigation settlement agreement with Ancestry.com DNA LLC (“Ancestry”) and its contract manufacturer, we granted Ancestry a royalty-bearing, non-exclusive, worldwide license to certain patents and patent applications related to the collection of DNA in human saliva. The license granted to Ancestry is limited to saliva DNA collection kits sold or used as part of Ancestry’s genetic testing service offerings and does not cover the sale or use of collection kits outside of Ancestry’s business. In the first quarter of 2018, we recorded \$1,602 in royalty income under this agreement.

On June 12, 2015, we were awarded a grant for up to \$10,400 in total funding from the U.S. Department of Health and Human Services (“HHS”) Office of the Assistant Secretary for Preparedness and Response’s Biomedical Advanced Research and Development Authority (“BARDA”) related to our OraQuick®Ebola rapid antigen test. The three-year, multi-phased grant included an initial commitment of \$1,800 and options for up to an additional \$8,600 to fund certain clinical and regulatory activities. In September 2015 and July 2017, BARDA exercised options to provide \$7,200 and \$1,330, respectively, in additional funding for our OraQuick® Ebola test. Amounts related to this grant are recorded as other revenue in our consolidated statements of operations as the activities are being performed and the related costs are incurred. During the first quarters of 2018 and 2017, \$836 and \$420, respectively, were recognized in connection with this grant.

In August 2016, we were awarded a contract for up to \$16,600 in total funding from BARDA related to our rapid Zika test. The six-year, multi-phased contract includes an initial commitment of \$7,000 and options for up to an additional \$9,600 to fund the evaluation of additional product enhancements, and clinical and regulatory activities. In May 2017, BARDA exercised an option to provide \$2,600 in additional funding for our rapid Zika test. Funding received under this contract is recorded as other revenue in our consolidated statements of operations as the activities are being performed and the related costs are incurred. During the first quarters of 2018 and 2017, \$702 and \$644, respectively, were 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 first quarter of 2018, \$985 of support payments were recognized in product revenue in connection with this agreement. Funding received in the form of reimbursement of certain related costs is recorded as other revenue in our consolidated statements of operations. During the first quarter of 2018, \$529 was recognized in other revenue for reimbursement of certain related costs.

**Deferred Revenue.** We record deferred revenue when funds are received prior to the recognition of the associated revenue. Deferred revenue as of March 31, 2018 and December 31, 2017 includes customer prepayments of \$1,480 and \$1,314, respectively. Deferred revenue as of March 31, 2018 also includes \$319 associated with a long-term contract that has variable pricing based on volume. The average price over the life of the contract was determined and revenue is recognized at that rate.

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

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

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

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

We do not grant return rights to our customers for any product, except for our OraQuick® In-Home HIV test. Accordingly, we have recorded an estimate of expected returns as a reduction of gross OraQuick® In-Home HIV product revenues in our consolidated statements of operations. This estimate reflects our historical sales experience to retailers and consumers, as well as other retail factors, and is reviewed regularly to ensure that it reflects potential product returns. As of March 31, 2018 and December 31, 2017, the reserve for sales returns and allowances was \$218 and \$217, respectively. If actual product returns differ materially from our reserve amount, or if a determination is made that this product's distribution would be discontinued in whole or in part by certain retailers, then we would need to adjust our reserve. Should the actual level of product returns vary significantly from our estimates, our operating and financial results could be materially affected.

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

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

-12-

---

	Three Months Ended March 31,	
	2018	2017
OraQuick®	\$13,005	\$14,109
Oragene®	17,088	9,939
Intercept®	1,915	1,927
Histofreezer®	2,354	2,680
Other products	3,956	2,827
Net product revenues	38,318	31,482
Royalty income	1,602	-
BARDA funding	1,538	1,064
Charitable support reimbursement	529	-
Other revenues	3,669	1,064
Net revenues	\$41,987	\$32,546

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

	Three Months Ended March 31,	
	2018	2017
United States	\$30,986	\$20,854
Europe	2,897	3,125
Other regions	8,104	8,567
	\$41,987	\$32,546

Customer and Vendor Concentrations. One of our customers accounted for 18% and 37% of our accounts receivable as of March 31, 2018 and December 31, 2017, respectively. The same customer accounted for approximately 23% of our net consolidated revenues for the three months ended March 31, 2018. We had no significant concentrations in net consolidated revenues for the three months ended March 31, 2017.

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

#### 4. Accrued Expenses

	March 31, 2018	December 31, 2017
Payroll and related benefits	\$5,006	\$ 9,265
Income taxes payable (receivable)	(357 )	6,469
Professional fees	1,489	1,064
Royalties	885	845
Other	2,742	3,052
	\$9,765	\$ 20,695

#### 5. Credit Facility

On September 30, 2016, we entered into a credit agreement (the “Credit Agreement”) with a commercial bank. The Credit Agreement, as amended on December 20, 2017, provides for revolving extensions of credit in an initial aggregate amount of up to \$10,000 (inclusive of a letter of credit subfacility of \$2,500), with an option to request, prior to the second anniversary of the closing date, that the lender, at its election, provide up to \$5,000 of additional revolving commitments. Obligations under the Credit Agreement are secured by a first priority security interest in certain eligible accounts receivable, 65% of the equity of our subsidiary, DNAG, and certain related assets. There were no borrowings outstanding under the facility at March 31, 2018 and December 31, 2017.

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



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

## 6. Stockholders' Equity

### Stock-Based Awards

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

Total compensation cost related to stock options for the three months ended March 31, 2018 and 2017 was \$900 and \$502, respectively. Net cash proceeds from the exercise of stock options were \$954 and \$9,417 for the three months ended March 31, 2018 and 2017, respectively. As a result of our net operating loss carryforward position, no actual income tax benefit was realized from stock option exercises during these periods.

The following table summarizes the stock option activity for the first three months ended March 31, 2018:

	Options
Outstanding on January 1, 2018	1,201
Granted	122
Exercised	(133 )
Expired	(24 )
Forfeited	(24 )
Outstanding on March 31, 2018	1,142

Compensation cost of \$3,626 and \$655 related to restricted shares was recognized during the three months ended March 31, 2018 and 2017, respectively. In connection with the vesting of restricted shares during the three months ended March 31, 2018 and 2017, we purchased and immediately retired 150 and 96 shares with aggregate values of \$2,959 and \$851, respectively, in satisfaction of minimum tax withholding obligations.

The following table summarizes restricted stock award activity for the three months ended March 31, 2018:

	Units
Issued and unvested, January 1, 2018	671
Granted	133

Vested	(407)
Forfeited	(5 )
Issued and unvested, March 31, 2018	392

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

Compensation cost of \$2,957 and \$361 related to PSUs was recognized during the three months ended March 31, 2018 and 2017, respectively.

-14-

---

	Units
Issued and unvested, January 1, 2018	852
Granted	110
Vested	-
Forfeited	-
Issued and unvested, March 31, 2018	962

### Modification of Grants

Stock compensation costs for the first quarter of 2018 include the additional expense associated with modifications of existing grants held by our retiring President and Chief Executive Officer (“CEO”) and Chief Financial Officer (“CFO”). These additional costs approximated \$5,851 during the first quarter of 2018.

### 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 three months ended March 31, 2018 and 2017.

### 7. Income Taxes

During the three months ended March 31, 2018 and 2017, we recorded tax expense of \$2,033 and \$3,897, respectively.

Tax expense reflects taxes due to Canadian taxing authorities and the tax effects of temporary differences between the basis of assets and liabilities recognized for financial reporting and tax purposes, and net operating loss and tax credit carryforwards. Tax expense in the first three months of 2017 reflects the additional Canadian taxes due as a result of the \$12,500 gain from the settlement of our patent infringement and breach of contract litigation against Ancestry.com DNA LLC and its contract manufacturer.

The significant components of our total deferred tax liability as of March 31, 2018 relate to the tax effects of the basis difference between the intangible assets acquired in the DNAG acquisition for financial reporting and tax purposes.

In 2008, we established a full valuation allowance against our U.S. deferred tax asset. Management believes the full valuation allowance is still appropriate at both March 31, 2018 and December 31, 2017 since the facts and circumstances necessitating the allowance have not changed. As a result, no U.S. federal or state deferred income tax expense or benefit was recorded for the three-month periods ended March 31, 2018 and 2017.

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

The Tax Act also imposes a U.S. tax on global intangible low taxed income (“GILTI”) that is earned by certain foreign affiliates owned by a U.S. shareholder effective in 2018. GILTI is generally intended to impose tax on the earnings of a foreign corporation that are deemed to exceed a certain threshold return relative to the underlying tangible property. We are subject to GILTI, The computation of GILTI is still subject to interpretation and additional clarifying guidance

is expected. Tax law ordering rules require that NOLs be utilized first to offset any GILTI tax liability before the use of any other tax attributes. We have sufficient NOLs to offset our projected 2018 GILTI income inclusion.

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

## 8. Commitments and Contingencies

### Standby Letters of Credit

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

-15-

---

## Litigation

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

## 9. Transition Costs

In January 2018, we announced the retirement of our President and CEO and our CFO and Chief Operating Officer. Stephen S. Tang, Ph.D., who served as Chairman of the Board of Directors (the "Board"), was appointed as the Company's new President and CEO, effective as of April 1, 2018. Dr. Tang replaced Douglas A. Michels, who retired as President and CEO, and as a member of the Board, on March 31, 2018. In addition, Ronald H. Spair, our CFO and Chief Operating Officer, will be retiring on June 8, 2018. Charges associated with these transitions approximated \$6,440 during the first quarter 2018. These charges primarily reflect non-cash charges associated with modifications to existing stock grants held by the retiring executives and expenses associated with the onboarding of the Company's new President and CEO.

## 10. Business Segment Information

Our business is comprised of two segments: Our "OSUR" business consists of the development, manufacture, marketing and sale of oral fluid diagnostic products and specimen collection devices using our proprietary technologies, as well as other diagnostic products including immunoassays and other in vitro diagnostic tests that are used on other specimen types. Our molecular collections systems or "DNAG" business consists of the manufacture and sale of specimen collection kits that are used to collect, stabilize, transport and store samples of genetic material for molecular testing in the consumer genetic, clinical genetic, academic research, pharmacogenomics, personalized medicine, microbiome and animal genetics markets.

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

The following table summarizes operating segment information for the three months ended March 31, 2018 and 2017, and asset information as of March 31, 2018 and December 31, 2017:

	Three Months Ended March 31,	
	2018	2017
Net revenues:		
OSUR	\$22,024	\$21,840
DNAG	19,963	10,706
Total	\$41,987	\$32,546
Operating income (loss):		
OSUR	\$(8,899)	\$(219)
DNAG	8,401	16,090
Total	\$(498)	\$15,871
Depreciation and amortization:		
OSUR	\$1,011	\$656

Edgar Filing: ORASURE TECHNOLOGIES INC - Form 10-Q

DNAG	857	763
Total	\$1,868	\$1,419
Capital expenditures:		
OSUR	\$1,416	\$784
DNAG	481	94
Total	\$1,897	\$878

	March 31, 2018	December 31, 2017
Total assets:		
OSUR	\$ 188,254	\$ 192,352
DNAG	97,669	103,849
Total	\$ 285,923	\$ 296,201

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

	March 31, 2018	December 31, 2017
United States	\$ 17,674	\$ 16,160
Canada	5,177	5,083
Other regions	124	129
	\$ 22,975	\$ 21,372

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

Statements below regarding future events or performance are “forward-looking statements” within the meaning of the Federal securities laws. These may include statements about our expected revenues, earnings/loss per share, net income (loss), expenses, cash flow or other financial performance or developments, clinical trial or development activities, expected regulatory filings and approvals, planned business transactions, views of future industry, competitive or market conditions, and other factors that could affect our future operations, results of operations or financial position. These statements often include the words “believes,” “expects,” “anticipates,” “intends,” “plans,” “estimates,” “may,” “will,” “should,” “could,” or similar expressions. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include, but are not limited to: ability to market and sell products, whether through our internal, direct sales force or third parties; ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements; ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; ability to comply with applicable regulatory requirements; ability to effectively resolve warning letters, audit observations and other findings or comments from the U.S. Food and Drug Administration (“FDA”) or other regulators; changes in relationships, including disputes or disagreements, with strategic partners or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements; ability to meet increased demand for our products; impact of significant customer concentration in the genomics business; impact of increased reliance on U.S. government contracts; failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our products; impact of replacing distributors; inventory levels at distributors and other customers; ability of the Company to achieve its financial and strategic objectives and continue to increase its revenues, including the ability to expand international sales; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; impact of negative economic conditions, reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products; market acceptance of oral fluid testing or other products; changes in market acceptance of products based on product performance or other factors, including changes in testing guidelines, algorithms or other recommendations by the Centers for Disease Control and Prevention (“CDC”) or other agencies; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical products and components; availability of related products produced by third parties or products required for use of our products; history of losses and ability to achieve sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of the Company’s stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; ability to successfully renew contracts or enter into new contracts with existing customers; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to meet financial covenants in credit agreements; ability to attract and retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; and general political, business and economic conditions. These and other factors are discussed more fully in our Securities and Exchange Commission (“SEC”) filings, including our registration statements, Annual Report on Form 10-K for the year ended December 31, 2017, Quarterly Reports on Form 10-Q, and other filings with the SEC. Although forward-looking statements help to provide information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. The forward-looking statements are made as of the date of this Report, and we undertake no duty to update these statements.

Investors should also be aware that while we do, from time to time, communicate with securities analysts, it is against our policy to disclose any material non-public information or other confidential commercial information. Accordingly,



stockholders should not assume that we agree with any statement or report issued by any analyst irrespective of the content of the statement or report. Furthermore, we have a policy against issuing or confirming financial forecasts or projections issued by others. Thus, to the extent that reports issued by securities analysts contain any projections, forecasts or opinions, such reports are not the responsibility of OraSure.

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

#### Overview and Business Segments

Our business is comprised of two segments: Our “OSUR” business consists of the development, manufacture, marketing and sale of oral fluid diagnostic products and specimen collection devices using our proprietary technologies, as well as other diagnostic products including immunoassays and other in vitro diagnostic tests that are used on other specimen types. Our molecular collections systems or “DNAG” business consists of the manufacture and sale of specimen collection kits that are used to collect, stabilize, transport and store samples of genetic material for molecular testing in the consumer genetic, clinical genetic, academic research, pharmacogenomics, personalized medicine, microbiome and animal genetics markets.

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

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

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

#### Recent Developments

#### Management Succession Plan

In January 2018, we announced the planned retirement of our President and Chief Executive Officer (“CEO”) and our Chief Financial Officer (“CFO”) and Chief Operating Officer. Stephen S. Tang, Ph.D., who served as Chairman of the Board of Directors (the “Board”), was appointed as the Company’s new President and CEO, effective April 1, 2018. Dr. Tang replaced Douglas A. Michels, who retired as President and CEO, and as a member of the Board, on March 31, 2018. In addition, Roberto Cuca was appointed as the Company’s new CFO, effective June 8, 2018. Mr. Cuca will be replacing Ronald H. Spair, our CFO and Chief Operating Officer, who will be retiring as CFO and Chief Operating Officer, and as a member of our Board of Directors, on the same date. Included in our first quarter 2018 financial results are \$6.4 million in transition costs associated with these changes in management. These costs largely consist of non-cash stock compensation charges.

#### Current Consolidated Financial Results

During the three months ended March 31, 2018, our consolidated net revenues were \$42.0 million, compared to \$32.5 million for the three months ended March 31, 2017. Net product revenues during the three months ended March 31, 2018 increased 22% when compared to the first three months of 2017, primarily due to higher sales of our molecular collection systems products and increased international sales of our OraQuick® HIV self-test. Partially offsetting these increases were lower sales of our OraQuick® HCV and cryosurgical systems products and lower domestic sales of our professional OraQuick® HIV product. Other revenues for the first three months of 2018 were \$3.7 million compared to \$1.1 million in the same period of 2017. Other revenues in the first three months of 2018 consisted of royalty income of \$1.6 million, funding received from the U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response’s Biomedical Advanced Research and Development Authority (“BARDA”) related to our Ebola and Zika products of \$1.5 million and reimbursement of certain costs under our charitable support agreement with the Bill & Melinda Gates Foundation (“Gates Foundation”) of \$529,000. Other revenues in the first three months of 2017 consisted of \$1.1 million of BARDA funding.

Our consolidated net loss for the three months ended March 31, 2018 was \$2.1 million, or \$0.03 per share, compared to consolidated net income of \$12.4 million, or \$0.21 per share on a fully-diluted basis for the three months ended March 31, 2017. Results in the first quarter of 2018 included \$6.4 million of management transition costs as noted above, which approximate \$0.10 per share. Results for the first quarter of 2017 included a gain of \$12.5 million associated with the settlement of our litigation against Ancestry.com DNA LLC and its contract manufacturer in that period, which approximates \$0.16 per share on an after-tax and fully-diluted basis.

Cash provided by operating activities for the three months ended March 31, 2018 was \$7.6 million. Cash provided by operating activities during the three months ended March 31, 2017 was \$12.6 million and included the \$12.5 million litigation settlement noted above. As of March 31, 2018, we had \$178.4 million in cash (including restricted cash), cash equivalents, and available-for-sale securities, compared to \$176.6 million at December 31, 2017.

-19-

---

## Results of Operations

Three months ended March 31, 2018 compared to March 31, 2017

## CONSOLIDATED NET REVENUES

The table below shows a breakdown of total consolidated net revenues (dollars in thousands) generated by each of our business segments for the three months ended March 31, 2018 and 2017.

	Three Months Ended March 31,			Percentage of	
	Dollars		%	Total Net	
	2018	2017		Change	2018
OSUR	\$19,957	\$20,776	(4)%	47%	64%
DNAG	18,361	10,706	72	44	33
Net product revenues	38,318	31,482	22	91	97
Other	3,669	1,064	245	9	3
Net revenues	\$41,987	\$32,546	29%	100%	100%

Consolidated net product revenues increased 22% to \$38.3 million in the first quarter of 2018 from \$31.5 million in the comparable period of 2017. Higher sales of our molecular collection systems products and higher international sales of our OraQuick® HIV self-test were partially offset by lower sales of our OraQuick® HCV and cryosurgical systems products and lower domestic sales of our professional OraQuick® HIV test. Other revenues for the first quarter of 2018 were \$3.7 million compared to \$1.1 million in the same period of 2017. Other revenues in the first quarter of 2018 included \$1.6 million in royalty income earned under a litigation settlement agreement, \$1.5 million in funding from BARDA related to our Ebola and Zika products and \$529,000 in reimbursement of certain costs under our charitable support agreement with the Gates Foundation. Other revenues in the first quarter of 2017 consisted entirely of BARDA funding.

Consolidated net revenues derived from products sold to customers outside of the United States were \$11.0 million and \$11.7 million, or 26% and 36% of total net revenues, in the first quarters of 2018 and 2017, respectively. Because the majority of our international sales are denominated in U.S. dollars, the impact of fluctuating foreign currency exchange rates was not material to our total consolidated net revenues.

## Net Revenues by Segment

## OSUR Segment

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

Market	Three Months Ended March 31,			Percentage of	
	Dollars		%	Total Net	
	2018	2017		Change	2018

Edgar Filing: ORASURE TECHNOLOGIES INC - Form 10-Q

Infectious disease testing	\$14,170	\$14,583	(3 )%	64 %	67 %
Risk assessment testing	3,002	3,130	(4 )	14	14
Cryosurgical systems	2,785	3,063	(9 )	13	14
Net product revenues	19,957	20,776	(4 )	91	95
Other	2,067	1,064	94	9	5
Net revenues	\$22,024	\$21,840	1 %	100 %	100 %

Infectious Disease Testing Market

Sales to the infectious disease testing market decreased 3% to \$14.2 million in the first quarter of 2018 from \$14.6 million in the first quarter of 2017. This decrease resulted from lower sales of our OraQuick® HCV product and lower domestic sales of our professional OraQuick® HIV product, partially offset by higher international sales of our OraQuick® HIV self-test.

-20-

---

Edgar Filing: ORASURE TECHNOLOGIES INC - Form 10-Q

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

Market	Three Months Ended March 31,		
	2018	2017	% Change
Domestic HIV	\$3,344	\$3,812	(12 )%
International HIV	5,737	2,644	117
Domestic OTC HIV	1,632	1,542	6
Net HIV revenues	10,713	7,998	34
Domestic HCV	1,627	1,709	(5 )
International HCV	665	4,402	(85 )
Net HCV revenues	2,292	6,111	(62 )
Net OraQuick® revenues	\$13,005	\$14,109	(8 )%

Domestic OraQuick® HIV sales decreased 12% to \$3.3 million for the three months ended March 31, 2018 from \$3.8 million for the three months ended March 31, 2017. This decrease was primarily the result of competition from point-of-care HIV tests perceived to be more sensitive than our product, competition from fourth generation automated HIV immunoassays performed in a laboratory, and customer ordering patterns.

International sales of our OraQuick® HIV test during the first quarter of 2018 rose 117% to \$5.7 million for the three months ended March 31, 2018 from \$2.6 million for the three months ended March 31, 2017. This increase was largely due to higher sales of our OraQuick® HIV self-test into Africa and higher sales of our professional product in parts of Asia and Europe, partially offset by a decline in sales in the Middle East. Funding under the charitable support agreement with the Gates Foundation began in the third quarter of 2017 and product revenues in the first quarter of 2018 included approximately \$985,000 of support payments under that agreement.

Sales of our OraQuick® In-Home HIV test increased to \$1.6 million in the first quarter of 2018 from \$1.5 million in the first quarter of 2017.

Domestic OraQuick® HCV sales decreased 5% to \$1.6 million in the first quarter of 2018 from \$1.7 million in the first quarter of 2017 primarily due to the non-renewal or delay of grant funding for certain hospital customers and due to a large NGO customer discontinuing its testing program. International OraQuick® HCV sales decreased 85% to \$665,000 in the first quarter of 2018 from \$4.4 million in the first quarter of 2017, due to the non-renewal of a supply contract with a foreign government in support of a countrywide HCV eradication program, the loss of a multi-national humanitarian organization customer who switched to a competitive product due to pricing, and a one-time order that was shipped in the first quarter of 2017 that did not recur in the first quarter of 2018.

#### Risk Assessment Market

Sales to the risk assessment market slightly decreased to \$3.0 million in the first quarter of 2018 compared to \$3.1 million in the first quarter of 2017.

#### Cryosurgical Market

Sales of our cryosurgical products decreased 9% to \$2.8 million in the first quarter of 2018 from \$3.1 million in the first quarter of 2017.

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

Market	Three Months Ended March 31,		
	2018	2017	% Change
Domestic professional	\$875	\$1,496	(42)%
International professional	150	130	15
Domestic OTC	289	285	1
International OTC	1,471	1,152	28
Net cryosurgical systems revenues	\$2,785	\$3,063	(9)%

First quarter 2018 sales of our domestic Histofreezer® product sold to physicians' offices decreased 42% to \$875,000 from \$1.5 million in the first quarter of 2017, primarily due to the timing of orders placed by our distributors and competitive losses from lower-priced product that has entered the market as result of the expiration of the patents associated with our cryosurgical technology.

Sales of our international OTC cryosurgical products during the first quarter of 2018 increased 28% to \$1.5 million compared to \$1.2 million in the first quarter of 2017 due to increased sales in Latin America resulting from the economic recovery of certain countries in that region.

## Other revenues

Other revenues in the first quarter of 2018 increased 245% to \$3.7 million from \$1.1 million in the first quarter of 2017. The table below shows a breakdown of our other revenues (dollars in thousands) recorded during the first quarters of 2018 and 2017.

	Three Months Ended March 31,			% Change
	2018	2017		
Royalty income	\$1,602	\$-	100	%
BARDA funding	1,538	1,064	45	
Charitable support reimbursement	529	-	100	
Other revenues	\$3,669	\$1,064	245	%

Other revenues in the first quarter of 2018 included \$1.6 million of royalty income earned under a litigation settlement agreement. This royalty agreement was entered into in 2017 and required royalty payments beginning in the first quarter of 2018. There were no revenues of this nature in the first quarter of 2017. Revenue from BARDA funding increased to \$1.5 million in the first quarter of 2018 compared to \$1.1 million in the first quarter of 2017 as a result of increased efforts related to our Ebola and Zika products. Other revenues in the first quarter of 2018 also included \$529,000 in reimbursement of certain costs under our charitable support agreement with the Gates Foundation. Reimbursement of these costs began in the third quarter of 2017 and as such there was no comparable revenue in the first quarter of 2017.

## DNAG Segment

## Molecular Market

Market	Three Months Ended March 31,			% Change
	2018	2017		
Commercial genomics	\$14,256	\$7,254	97	%
Academic genomics	2,832	2,685	5	
Microbiome	1,273	767	66	
Net molecular collection systems revenues	\$18,361	\$10,706	72	%

Net molecular collection systems revenues increased 72% to \$18.4 million in the first quarter of 2018 from \$10.7 million in the first quarter of 2017. Sales in the commercial market rose 97% in the first quarter of 2018 compared to the first quarter of 2017, largely as a result of higher customer demand, primarily from a large customer in the consumer genetics market. Sales into the academic market increased 5% in the first quarter of 2018 compared to the first quarter of 2017 largely due to higher customer demand, partially offset by the loss of a large academic customer to a competing product. Revenues in the first quarter of 2018 also included \$1.3 million in sales of our microbiome products compared to \$767,000 in the same period of 2017, as interest in our microbiome product offerings continues to grow with both new and existing customers.

## CONSOLIDATED OPERATING RESULTS

Consolidated gross margin was 58% for the first quarter of 2018 compared to 62% for the first quarter of 2017. Gross margin in the first quarter of 2018 was negatively impacted by an increase in lower margin product sales and a



decrease in the absorption of fixed costs as a result of lower production levels in the first quarter of 2018. These negative impacts were partially offset by an increase in other revenues and a decrease in scrap and spoilage costs as compared to the first quarter of 2017.

Consolidated operating loss for the first quarter of 2018 was \$498,000, a \$16.4 million decline from the \$15.9 million of operating income reported in the first quarter of 2017. Operating income for the first quarter of 2017 included a pre-tax gain of \$12.5 million associated with the settlement of our litigation against Ancestry.com DNA LLC and its contract manufacturer in that period. In addition, our results for the first quarter of 2018 were negatively impacted by the increase in lower margin sales, the inclusion of \$6.4 million transition costs associated with executive management changes, and increased spending in research and development and sales and marketing.

#### OPERATING INCOME (LOSS) BY SEGMENT

##### OSUR Segment

OSUR's gross margin was 54% in the first quarter of 2018 compared to 60% in the first quarter of 2017. OSUR's gross margin in the first quarter of 2018 was negatively impacted by an increase in lower margin product revenues as a result of higher international sales and a decrease in the absorption of fixed costs as a result of lower production levels in the first quarter of 2018 compared to the first quarter of 2017. These negative impacts were partially offset by the increase in BARDA funding and cost reimbursement from the Gates Foundation and by lower scrap and spoilage costs incurred during the quarter.

Research and development expenses increased 40% to \$3.3 million in the first quarter of 2018 from \$2.4 million in the first quarter of 2017, largely due to increased spending on our Ebola and Zika products and higher staffing costs. Sales and marketing expenses grew 5% to \$4.9 million in the first quarter of 2018 from \$4.7 million in the first quarter of 2017 largely due to increased staffing costs. General and administrative

expenses increased 103% to \$12.7 million in the first quarter of 2018 from \$6.3 million in the first quarter of 2017 as a result of the inclusion of \$6.4 million of transition costs associated with the retirement of our CEO and CFO and the additional costs incurred associated with the hiring of their successors.

All of the above contributed to OSUR's first quarter 2018 operating loss of \$8.9 million, which included non-cash charges of \$1.0 million for depreciation and amortization and \$7.4 million for stock-based compensation.

#### DNAG Segment

DNAG's gross margin was 62% in the first quarter of 2018 compared to 67% in the first quarter of 2017. This decline was attributable to an increase in lower margin product sales in the first quarter of 2018 compared to the first quarter of 2017 partially offset by the royalty income recorded in the first quarter of 2018. No royalty income was recorded in the first quarter of 2017.

Research and development expenses increased 27% to \$769,000 in the first quarter of 2018 from \$603,000 in the first quarter of 2017 due to increased staffing costs. Sales and marketing expenses rose 18% to \$2.6 million in the first quarter of 2018 from \$2.2 million in the first quarter of 2017 due higher consulting and staffing costs, partially offset by a decrease in the allowance for uncollectible accounts. General and administrative expenses decreased 15% to \$709,000 in the first quarter of 2018 compared to \$831,000 in the first quarter of 2017 primarily due to lower legal expenses. Total operating expenses in the first quarter of 2017 were reduced by the \$12.5 million gain associated with the settlement of our Ancestry litigation. There was no similar gain recorded during the first quarter of 2018.

All of the above contributed to DNAG's first quarter 2018 operating income of \$8.4 million, which included non-cash charges of \$857,000 for depreciation and amortization and \$107,000 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 March 31, 2018, no state income tax expense was recorded as compared to \$31,000 in the three months ended March 31, 2017. Canadian income tax expense of \$2.0 million and \$3.9 million was recorded in the first quarters of 2018 and 2017, respectively. The decrease in income tax expense was largely a result of additional taxes recorded during the first quarter of 2017 related to the \$12.5 million litigation settlement which did not occur in the first quarter of 2018. On December 22, 2017, the U.S. enacted the Tax Cuts and Jobs Act ("Tax Act") that instituted fundamental changes to the taxation on multinational corporations. The impact of the Tax Act on our financial results is not material given OSUR has a full valuation allowance against its total U.S. deferred tax assets and due to the net operating losses ("NOLs") and tax credits that are being generated by the U.S. entity.

#### Liquidity and Capital Resources

	March 31, 2018	December 31, 2017
	(In thousands)	
Cash, cash equivalents and restricted cash	\$64,065	\$72,869
Available for sale securities	114,326	103,718
Working capital	175,568	189,668

Our cash, cash equivalents, restricted cash and available-for-sale securities increased to \$178.4 million at March 31, 2018 from \$176.6 million at December 31, 2017. Our working capital decreased to \$175.6 million at March 31, 2018

from \$189.7 million at December 31, 2017 largely due to the increased balance of long-term investments.

During the first three months of 2018, we generated \$7.6 million in cash from operating activities. Our net loss of \$2.1 million included non-cash charges for stock-based compensation expense of \$7.5 million and depreciation and amortization expense of \$1.9 million, as well as non-cash benefits of \$439,000. Additional uses of cash included a decrease in accrued expenses and other liabilities of \$11.0 million largely due to the submission of tax payments to the Canadian taxing authorities and payment of our 2017 management incentive bonuses, an increase in inventory balances of \$1.7 million required to meet expected demand, and a decrease in accounts payable of \$1.1 million due to the payment of year end invoices. Offsetting these uses of cash was a \$14.2 million decrease in accounts receivable as a result of the collection of large outstanding balances and a \$421,000 increase in deferred revenue.

Net cash used in investing activities was \$13.8 million for the three months ended March 31, 2018, which reflects \$57.8 million used to purchase investments and \$1.9 million to acquire property and equipment partially offset by \$45.9 million in proceeds from the maturities and redemptions of investments.

Net cash used in financing activities was \$2.0 million for the three months ended March 31, 2018, which resulted from \$2.9 million used for the repurchase of common stock to satisfy withholding taxes related to the vesting of restricted shares partially offset by \$954,000 in proceeds received from the exercise of stock options.

In September 2016, we entered into a credit agreement (the “Credit Agreement”) with a commercial bank, which was amended in December 2017. The Credit Agreement provides for revolving extensions of credit in an initial aggregate amount of up to \$10.0 million (inclusive of a letter of credit subfacility of \$2.5 million), with an option to request, prior to the second anniversary of the closing date, that lenders, at their election, provide up to \$5.0 million of additional revolving commitments. Obligations under the Credit Agreement are secured by a first priority security interest in certain eligible accounts receivable, 65% of the equity of our subsidiary, DNAG, and certain related assets. There were no borrowings outstanding at March 31, 2018 or December 31, 2017.

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

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

Our current balances of cash and cash equivalents and available-for-sale securities and our available borrowing capacity are expected to be sufficient to fund our current operating and capital needs for the foreseeable future. Our cash requirements, however, may vary materially from those now planned due to many factors, including, but not limited to, the scope and timing of future strategic acquisitions, the progress of our research and development programs, the scope and results of clinical testing, the cost of any future litigation, the magnitude of capital expenditures, changes in existing and potential relationships with business partners, the timing and cost of obtaining regulatory approvals, the timing and cost of future stock purchases, the costs involved in obtaining and enforcing patents, proprietary rights and any necessary licenses, the cost and timing of expansion of sales and marketing activities, market acceptance of new products, competing technological and market developments, the impact of the current economic environment and other factors. In addition, \$48.4 million or 27% of our \$178.4 million in cash, cash equivalents, restricted cash and available-for-sale securities belongs to our Canadian subsidiary. Repatriation of such cash into the United States exceeding certain levels could have adverse tax consequences.

#### Summary of Contractual Obligations

A summary of our obligations to make future payments under contracts existing at December 31, 2017 is included in Item 7, Management’s Discussion and Analysis of Financial Condition and Results of Operations, of our Annual Report on Form 10-K for the year ended December 31, 2017. As of March 31, 2018, there were no significant changes to this information, including the absence of any off-balance sheet arrangements.

#### Critical Accounting Policies and Estimates

This Management’s Discussion and Analysis of Financial Condition and Results of Operations discusses our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires that we make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. On an on-going basis, we evaluate our judgments and estimates, including those related to the bad debts, customer sales returns, inventories, intangible assets, income taxes, revenue recognition, performance-based compensation, contingencies and litigation. We base our judgments and estimates on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources.

Actual results may differ from these estimates under different assumptions or conditions.

A more detailed review of our critical accounting policies is contained in our Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC. During the first three months of 2018, there were no material changes in our critical accounting policies.

**Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

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

As of March 31, 2018, we did not have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. Sales denominated in foreign currencies comprised 3.0% of our total revenues for the three months ended March 31, 2018. We do have foreign currency exchange risk related to our operating subsidiary in Canada. While the majority of this subsidiary's revenues are recorded in U.S. dollars, almost all of this subsidiary's operating expenses are denominated in Canadian dollars. Fluctuations in the exchange rate between the U.S. dollar and the Canadian dollar could affect year-to-year comparability of operating results and cash flows. Our Canadian subsidiary had net assets, subject to translation, of \$110.2 million CDN (\$85.5 million USD), which are included in the Company's consolidated balance sheet as of March 31, 2018. A 10% unfavorable change in the Canadian-to-U.S. dollar exchange rate would have decreased our comprehensive income by \$8.5 million in the three months ended March 31, 2018.

Item 4. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures. The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) as of March 31, 2018. Based on that evaluation, the Company's management, including such officers, concluded that the Company's disclosure controls and procedures were effective as of March 31, 2018 to provide reasonable assurance that material information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act of 1934 was accumulated and communicated to the Company's management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure and was recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission.

(b) Changes in Internal Control Over Financial Reporting. There was no change in the Company's internal control over financial reporting that occurred during the three months ended March 31, 2018 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

-25-

---

## 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

Other than the risk factor discussed below, 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, 2017.

## Failure to Comply With New European Data Protection Requirements Could Increase Our Costs

The European Union ("EU") has adopted a comprehensive overhaul of its data protection regime from the current national legislative approach to a single European Economic Area Privacy Regulation called the General Data Protection Regulation ("GDPR"), which comes into effect on May 25, 2018. The new EU data protection regime extends the scope of the EU data protection law to all foreign companies processing data of EU residents. It provides for a harmonization of the data protection regulations throughout the EU, thereby making it easier for non-European companies to comply with these regulations. It imposes a strict data protection compliance regime with severe penalties of up to the greater of 4% of worldwide turnover and €20 million and includes new rights such as the "portability" of personal data. Although the GDPR will apply across the EU without a need for local implementing legislation, as had been the case under the current data protection regime, local data protection authorities will still have the ability to interpret the GDPR, which has the potential to create inconsistencies on a country-by-country basis. We are evaluating these new requirements and implementing a plan to ensure compliance. Complying with the enhanced obligations imposed by the GDPR may result in significant costs to our business and require us to amend certain of our business practices. Further, we have no assurances that violations will not occur, particularly given the complexity of the GDPR, as well as the uncertainties that accompany new, comprehensive legislation.

## 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 <sup>(1, 2)</sup>
January 1, 2018 - March 31, 2018	—	\$ 0.00	—	11,984,720
February 1, 2018 - February 28, 2018	93,770	<sup>(3)</sup> 21.51	—	11,984,720
March 1, 2018 - March 31, 2018	56,078	<sup>(3)</sup> 16.79	—	11,984,720
	149,848		—	

- (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

-26-

---



Item 6. EXHIBITS

Exhibit

Number	Exhibit
3.2	<u>Bylaws of OraSure Technologies, Inc., as amended and restated as of February 19, 2018, is incorporated by reference to the Exhibit 3.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2017.</u>
10.1	<u>Employment Agreement, dated as of January 3, 2018, between OraSure Technologies, Inc. and Stephen S. Tang, Ph.D., is incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed January 4, 2018.</u>
10.2	<u>Retirement Agreement, dated as of January 3, 2018, between OraSure Technologies, Inc. and Douglas A. Michels, is incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed January 4, 2018.**</u>
10.3	<u>Retirement Agreement, dated as of January 31, 2018, between OraSure Technologies, Inc. and Ronald H. Spair, is incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed February 2, 2018.**</u>
10.4	<u>Description of 2018 Long-Term Incentive Policy Equity Awards to Executives is incorporated by reference to Item 5.02 to the Company's Current Report on Form 8-K filed February 2, 2018.**</u>
10.5	<u>Description of OraSure Technologies, Inc. 2018 Incentive Plan is incorporated by reference to Item 5.02 to the Company's Current Report on Form 8-K filed February 22, 2018.**</u>
31.1*	<u>Certification of Stephen S. Tang required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.</u>
31.2*	<u>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.</u>
32.1*	<u>Certification of Stephen S. Tang required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
32.2*	<u>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.</u>
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

\*\* Management contract or compensatory plan or agreement

-27-

---

SIGNATURES

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

ORASURE TECHNOLOGIES, INC.

Date: May 9, 2018	/s/ Ronald H. Spair Ronald H. Spair Chief Operating Officer and Chief Financial Officer (Principal Financial Officer)
Date: May 9, 2018	/s/Mark L. Kuna Mark L. Kuna Senior Vice President, Finance and Controller (Principal Accounting Officer)