

ORASURE TECHNOLOGIES INC
Form 10-Q
November 08, 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 September 30, 2018.

OR

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

For the transition period from _____ to _____ .

Commission File Number 001-16537

ORASURE TECHNOLOGIES, INC.

(Exact Name of Registrant as Specified in Its Charter)

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

Incorporation or Organization)

220 East First Street, Bethlehem, Pennsylvania 18015

Edgar Filing: ORASURE TECHNOLOGIES INC - Form 10-Q

(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 every Interactive Data File required to be submitted 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 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 Smaller reporting company

Emerging growth company

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

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

Number of shares of Common Stock, par value \$.000001 per share, outstanding as of November 2, 2018: 61,249,469 shares.

PART I. FINANCIAL INFORMATION

| | Page No. |
|--|-------------|
| Item 1. Financial Statements (unaudited) | |
| <u>Consolidated Balance Sheets at September 30, 2018 and December 31, 2017</u> | 3 |
| <u>Consolidated Statements of Income for the three and nine months ended September 30, 2018 and 2017</u> | 4 |
| <u>Consolidated Statements of Comprehensive Income for the three and nine months ended September 30, 2018 and 2017</u> | 5 |
| <u>Consolidated Statements of Cash Flows for the nine months ended September 30, 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> | 17 |
| <u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u> | 26 |
| <u>Item 4. Controls and Procedures</u> | 27 |
| PART II. OTHER INFORMATION | |
| <u>Item 1. Legal Proceedings</u> | 28 |
| <u>Item 1A. Risk Factors</u> | 28 |
| <u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u> | 28 |
| <u>Item 3. Defaults Upon Senior Securities</u> | 28 |
| <u>Item 4. Mine Safety Disclosures</u> | 28 |
| <u>Item 5. Other Information</u> | 28 |
| <u>Item 6. Exhibits</u> | 29 |
| <u>Signatures</u> | 30 |

Item 1. FINANCIAL STATEMENTS

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(Unaudited)

(in thousands, except per share amounts)

| | September 30, 2018 | December 31, 2017 |
|--|--------------------|-------------------|
| ASSETS | | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | \$ 78,146 | \$71,029 |
| Restricted cash | — | 1,840 |
| Short-term investments | 72,192 | 83,028 |
| Accounts receivable, net of allowance for doubtful accounts of \$292 and \$471 | 33,284 | 42,521 |
| Inventories | 19,899 | 19,343 |
| Prepaid expenses | 1,356 | 1,658 |
| Other current assets | 3,020 | 2,486 |
| Total current assets | 207,897 | 221,905 |
| PROPERTY AND EQUIPMENT, net | 24,395 | 21,372 |
| INTANGIBLE ASSETS, net | 6,053 | 8,223 |
| GOODWILL | 19,568 | 20,083 |
| LONG TERM INVESTMENTS | 41,788 | 20,690 |
| OTHER ASSETS | 4,606 | 3,928 |
| | \$ 304,307 | \$296,201 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| CURRENT LIABILITIES: | | |
| Accounts payable | \$ 8,064 | \$10,228 |
| Deferred revenue | 3,106 | 1,314 |
| Accrued expenses | 10,250 | 20,695 |
| Total current liabilities | 21,420 | 32,237 |
| OTHER LIABILITIES | 4,649 | 3,932 |
| DEFERRED INCOME TAXES | 1,484 | 1,951 |
| COMMITMENTS AND CONTINGENCIES (Note 8) | | |
| STOCKHOLDERS' EQUITY | | |
| Preferred stock, par value \$.000001, 25,000 shares authorized, none issued | — | — |
| Common stock, par value \$.000001, 120,000 shares authorized, 61,237 and 60,662 shares | | |
| issued and outstanding | — | — |
| Additional paid-in capital | 398,956 | 387,931 |
| Accumulated other comprehensive loss | (12,715) | (10,340) |
| Accumulated deficit | (109,487) | (119,510) |
| Total stockholders' equity | 276,754 | 258,081 |
| | \$ 304,307 | \$296,201 |

See accompanying notes to the consolidated financial statements.

-3-

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF INCOME

(Unaudited)

(in thousands, except per share amounts)

| | Three Months Ended | | Nine Months Ended | |
|---|-----------------------|----------|-----------------------|-----------|
| | September 30, 2018 | 2017 | September 30, 2018 | 2017 |
| NET REVENUES: | | | | |
| Product | \$43,450 | \$41,157 | \$120,586 | \$111,771 |
| Other | 2,435 | 1,157 | 10,911 | 3,265 |
| | 45,885 | 42,314 | 131,497 | 115,036 |
| COST OF PRODUCTS SOLD | | | | |
| Gross profit | 28,545 | 24,644 | 78,907 | 70,431 |
| OPERATING EXPENSES: | | | | |
| Research and development | 3,855 | 3,228 | 12,191 | 9,536 |
| Sales and marketing | 7,304 | 7,162 | 22,232 | 21,541 |
| General and administrative | 6,529 | 6,935 | 28,567 | 21,777 |
| Gain on litigation settlement | - | - | — | (12,500) |
| | 17,688 | 17,325 | 62,990 | 40,354 |
| Operating income | 10,857 | 7,319 | 15,917 | 30,077 |
| OTHER INCOME | | | | |
| Income before income taxes | 11,367 | 7,432 | 17,575 | 30,753 |
| INCOME TAX EXPENSE | | | | |
| NET INCOME | \$8,096 | \$5,763 | \$10,098 | \$23,632 |
| EARNINGS PER SHARE: | | | | |
| BASIC | \$0.13 | \$0.10 | \$0.17 | \$0.40 |
| DILUTED | \$0.13 | \$0.09 | \$0.16 | \$0.39 |
| SHARES USED IN COMPUTING EARNINGS PER SHARE: | | | | |
| BASIC | 61,208 | 60,090 | 61,059 | 58,511 |
| DILUTED | 62,606 | 62,172 | 62,539 | 60,569 |

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(Unaudited)

(in thousands)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|--|---------|---------------------------------------|----------|
| | 2018 | 2017 | 2018 | 2017 |
| NET INCOME | \$8,096 | \$5,763 | \$10,098 | \$23,632 |
| OTHER COMPREHENSIVE INCOME | | | | |
| Currency translation adjustments | 1,783 | 2,570 | (2,023) | 4,882 |
| Unrealized loss on marketable securities | (34) | (245) | (352) | (300) |
| COMPREHENSIVE INCOME | \$9,845 | \$8,088 | \$7,723 | \$28,214 |

See accompanying notes to the consolidated financial statements.

-5-

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(in thousands)

| | Nine Months Ended September 30, | |
|---|------------------------------------|------------------|
| | 2018 | 2017 |
| OPERATING ACTIVITIES: | | |
| Net income | \$ 10,098 | \$ 23,632 |
| Adjustments to reconcile net income to net cash provided by operating activities: | | |
| Stock-based compensation | 12,526 | 5,213 |
| Depreciation and amortization | 5,588 | 4,589 |
| Unrealized foreign currency gain | (48) | (246) |
| Deferred income taxes | (415) | (425) |
| Changes in assets and liabilities | | |
| Accounts receivable | 8,832 | (7,706) |
| Inventories | (649) | (4,886) |
| Prepaid expenses and other assets | 615 | 1,616 |
| Accounts payable | (2,179) | 4,593 |
| Deferred revenue | 1,741 | (212) |
| Accrued expenses and other liabilities | (11,302) | 4,193 |
| Net cash provided by operating activities | 24,807 | 30,361 |
| INVESTING ACTIVITIES: | | |
| Purchases of investments | (135,625) | (132,177) |
| Proceeds from maturities and redemptions of investments | 124,071 | 42,613 |
| Purchases of property and equipment | (5,938) | (3,462) |
| Net cash used in investing activities | (17,492) | (93,026) |
| FINANCING ACTIVITIES: | | |
| Proceeds from exercise of stock options | 1,684 | 31,402 |
| Repurchase of common stock | (3,181) | (1,234) |
| Net cash (used in) provided by financing activities | (1,497) | 30,168 |
| EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH | (541) | 1,317 |
| NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH | 5,277 | (31,180) |
| CASH, CASH EQUIVALENTS, AND RESTRICTED CASH, BEGINNING OF PERIOD | 72,869 | 109,790 |
| CASH AND CASH EQUIVALENTS, END OF PERIOD | \$ 78,146 | \$ 78,610 |
| SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION: | | |
| Cash paid for income taxes | \$ 14,482 | \$ 4,317 |
| Noncash investing activities (accrued property and equipment purchases) | \$ 592 | \$ 437 |
| Noncash unrealized losses on marketable securities | \$(352) | \$(300) |

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, other diagnostic products including immunoassays and other in vitro diagnostic tests that are used on other specimen types, and other medical devices. 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 market and we offer our customers a suite of genomics and microbiome services called “GenoFINDM”, which range from package customization and study design optimization to extraction, analysis and reporting services. We serve customers worldwide, including many leading research universities and hospitals.

2. Summary of Significant Accounting Policies

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

The accompanying consolidated financial statements are unaudited and, in the opinion of management, include all adjustments (consisting only of normal and recurring adjustments) necessary for a fair presentation of our financial position and results of operations for these interim periods. These financial statements should be read in conjunction with the financial statements and notes thereto included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017. Results of operations for the three and nine months ended September 30, 2018 are not necessarily indicative of the results of operations expected for the full year.

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

Investments. We consider all investments in debt securities 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 September 30, 2018 and December 31, 2017:

| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|---|-------------------|------------------------------|-------------------------------|---------------|
| September 30, 2018 | | | | |
| Guaranteed investment certificates | \$ 24,401 | \$ — | \$ — | \$ 24,401 |
| Corporate bonds | 90,484 | — | (905) | 89,579 |
| Total available-for-sale securities | \$ 114,885 | \$ — | \$ (905) | \$ 113,980 |
| December 31, 2017 | | | | |
| Guaranteed investment certificates | \$ 22,261 | \$ — | \$ — | \$ 22,261 |
| Corporate bonds | 82,010 | — | (553) | 81,457 |
| Total available-for-sale securities | \$ 104,271 | \$ — | \$ (553) | \$ 103,718 |
| At September 30, 2018, maturities of our available-for-sale securities were as follows: | | | | |
| Less than one year | \$ 72,758 | \$ — | \$ (566) | \$ 72,192 |
| Greater than one year | \$ 42,127 | \$ — | \$ (339) | \$ 41,788 |

Fair Value of Financial Instruments. As of September 30, 2018 and December 31, 2017, the carrying values of cash and cash equivalents, restricted cash, accounts receivable, and accounts payable approximate their respective fair values based on their short-term nature.

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

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

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

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

All of our available-for-sale debt securities are measured as Level 1 instruments as of September 30, 2018 and December 31, 2017.

Included in cash and cash equivalents at September 30, 2018 and December 31, 2017, was \$30,199 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 September 30, 2018 and December 31, 2017 was \$5,180 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.

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:

| | September 30, December 31, | |
|-----------------|----------------------------|-----------|
| | 2018 | 2017 |
| Raw materials | \$ 11,648 | \$ 10,299 |
| Work in process | 429 | 199 |
| Finished goods | 7,822 | 8,845 |
| | \$ 19,899 | \$ 19,343 |

-8-

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 September 30, 2018 and December 31, 2017 was \$42,109 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 September 30, 2018 and December 31, 2017 was \$20,309 and \$18,692, respectively. The change in intangibles from \$8,223 as of December 31, 2017 to \$6,053 as of September 30, 2018 is a result of \$2,009 in amortization expense and \$161 in foreign currency translation.

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

We performed our last annual impairment assessment as of July 31, 2018 utilizing a qualitative evaluation and concluded that it was more likely than not that the fair value of our DNAG reporting unit is greater than its carrying value. We believe we have made reasonable estimates and assumptions to calculate the fair value of our reporting unit. If actual future results are not consistent with management's estimates and assumptions, we may have to take an impairment charge in the future related to our goodwill. Future impairment tests will continue to be performed annually in the fiscal third quarter, or sooner if a triggering event occurs. As of September 30, 2018, we believe no indicators of impairment exist.

The decrease in goodwill from \$20,083 as of December 31, 2017 to \$19,568 as of September 30, 2018 is a result of foreign currency translation.

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

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

Edgar Filing: ORASURE TECHNOLOGIES INC - Form 10-Q

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|--|---------|---------------------------------------|----------|
| | 2018 | 2017 | 2018 | 2017 |
| Net income | \$8,096 | \$5,763 | \$10,098 | \$23,632 |
| Weighted-average shares of common stock outstanding: | | | | |
| Basic | 61,208 | 60,090 | 61,059 | 58,511 |
| Dilutive effect of stock options, restricted stock, and performance stock units | 1,398 | 2,082 | 1,480 | 2,058 |
| Diluted | 62,606 | 62,172 | 62,539 | 60,569 |
| Earnings per share: | | | | |
| Basic | \$0.13 | \$0.10 | \$0.17 | \$0.40 |
| Diluted | \$0.13 | \$0.09 | \$0.16 | \$0.39 |

-9-

For the three months ended September 30, 2018 and 2017, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 304 and 8 shares, respectively, were excluded from the computation of diluted earnings per share as their inclusion would have been anti-dilutive. For the nine months ended September 30, 2018 and 2017, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 256 and 238 shares, respectively, were similarly excluded from the computation of diluted earnings per share.

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

Transaction gains and losses resulting from exchange rate changes on transactions denominated in currencies other than functional currency are included in our consolidated statements of income in the period in which the change occurs. Net foreign exchange gains (losses) resulting from foreign currency transactions that are included in other income (expense) in our consolidated statements of operations were (\$375) and (\$638) for the three months ended September 30, 2018 and 2017, respectively. Net foreign exchange gains (losses) were (\$30) and (\$1,256) for the nine months ended September 30, 2018 and 2017, respectively.

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

We have defined the Canadian dollar as the functional currency of our Canadian subsidiary, DNAG, and as such, the results of its operations are translated into U.S. dollars, which is the reporting currency of the Company. Accumulated other comprehensive loss at September 30, 2018 consists of \$11,810 of currency translation adjustments and \$905 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 by recognizing a cumulative effect adjustment to the opening balance of retained earnings. Early adoption is permitted. In July 2018, companies were provided with an option to apply the modified retrospective approach as of either the date of adoption or as of the earliest date presented. We expect to adopt this guidance effective January 1, 2019 by applying the modified retrospective approach as of the date of adoption with the available practical expedients. We are currently evaluating the effect that ASU 2016-02 may have on our consolidated financial statements and related disclosures and have identified two large facility leases and several smaller equipment leases which would fall under the new accounting guidance.

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

In March 2017, the FASB issued ASU 2017-08, Receivables-Nonrefundable Fees and Other Costs (Subtopic 310-20): Premium Amortization on Purchased Callable Debt Securities, which shortens the premium amortization period for

purchased non-contingently callable debt securities. Shortening the amortization period is generally expected to more closely align the interest income recognition with the expectations incorporated in the market pricing of the underlying securities. This ASU is effective for annual and interim periods in fiscal years beginning after December 15, 2018. Early adoption is permitted. We adopted ASU 2017-08 on January 1, 2018 and this standard did not have a material impact on our consolidated financial statements.

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

3. Revenues

Adoption of New Revenue Recognition Standard

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

Upon adoption, we recorded a reduction of \$75 to the opening balance of accumulated deficit as of January 1, 2018. This adjustment is related to the change in revenue recognition associated with our drug testing kit sales. Sales of our drug testing kits include two performance obligations: sales of the device and laboratory services. Under this new accounting standard, we adjusted the allocation of the transaction price to the performance obligations and the estimate of unexercised rights (“breakage”) associated with the contracts. Prior to the adoption of the new guidance, we used the residual value method to allocate the transaction prices. With the adoption of ASU 2014-09, we allocated transition prices based upon the stand-alone selling price, or fair value method. This change in methodology also impacted our estimated breakage amount.

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

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

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

Revenue Policies

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

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

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

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

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

As part of our litigation settlement agreement with Ancestry.com DNA LLC (“Ancestry”) and its contract manufacturer, we granted Ancestry a royalty-bearing, non-exclusive, worldwide license to certain patents and patent applications related to the collection of DNA in human saliva. The license granted to Ancestry is limited to saliva DNA collection kits sold or used as part of Ancestry’s genetic testing service offerings and does not cover the sale or use of collection kits outside of Ancestry’s business. During the three and nine months ended September 30, 2018, we recorded \$1,132 and \$4,827, respectively, in royalty income under this agreement.

On June 12, 2015, we were awarded a grant for up to \$10,400 in total funding from the U.S. Department of Health and Human Services (“HHS”) Office of the Assistant Secretary for Preparedness and Response’s Biomedical Advanced Research and Development Authority (“BARDA”) related to our OraQuick® Ebola rapid antigen test. The three-year, multi-phased grant, with an original expiration date of October 2018, was recently amended and extended through December 31, 2019, included an initial commitment of \$1,800 and options for up to an additional \$8,600 to fund certain clinical and regulatory activities. In September 2015 and July 2017, BARDA exercised options to provide \$7,200 and \$1,330, respectively, in additional funding for our OraQuick® Ebola test. Amounts related to this grant are recorded as other revenue in our consolidated statements of operations as the activities are being performed and the related costs are incurred. During the three and nine

months ended September 30, 2018, \$782 and \$2,581, respectively, were recognized in connection with this grant. During the three and nine months ended September 30, 2017, \$386 and \$1,260, respectively, were recognized in connection with this grant.

In August 2016, we were awarded a contract for up to \$16,600 in total funding from BARDA related to our rapid Zika test. The six-year, multi-phased contract includes an initial commitment of \$7,000 and options for up to an additional \$9,600 to fund the evaluation of additional product enhancements, and clinical and regulatory activities. In May 2017, BARDA exercised an option to provide \$2,600 in additional funding for our rapid Zika test. Funding received under this contract is recorded as other revenue in our consolidated statements of operations as the activities are being performed and the related costs are incurred. During the three and nine months ended September 30, 2018, \$301 and \$1,959, respectively, were recognized as other revenue in connection with this grant. During the three and nine months ended September 30, 2017, \$553 and \$1,787, respectively, were recognized in connection with this grant.

In June 2017, we entered into a four-year Charitable Support Agreement with the Bill & Melinda Gates Foundation (“Gates Foundation”) that allows us to offer our OraQui®HIV self-test at an affordable price in 50 developing countries with funding from the Gates Foundation. The funding consists of support payments tied to volume of product sold by us and reimbursement of certain related costs. The funding from the Gates Foundation will be in an aggregate amount not to exceed \$20,000 over the four-year term or \$6,000 each year of the agreement. Funding received under this agreement in the form of support payments for product purchases is recorded as a component of product revenue. During the three and nine months ended September 30, 2018, \$840 and \$3,571, respectively, of support payments were recognized in product revenue in connection with this agreement. During the three and nine months ended September 30, 2017, \$458 related to support payments was recognized in product revenue. Funding received in the form of reimbursement of certain related costs is recorded as other revenue in our consolidated statements of operations. During the three and nine months ended September 30, 2018, \$220 and \$1,544, respectively, were recognized in other revenue for reimbursement of certain related costs. During the three and nine months ended September 30, 2017 \$218 was recognized in other revenue in connection with this agreement.

Deferred Revenue. We record deferred revenue when funds are received prior to the recognition of the associated revenue. Deferred revenue as of September 30, 2018 and December 31, 2017 includes customer prepayments of \$1,882 and \$1,045, respectively. Deferred revenue as of September 30, 2018 and December 31, 2017 also includes \$1,224 and \$269, respectively, associated with a long-term contract that has variable pricing based on volume. The average price over the life of the contract was determined and revenue is recognized at that rate.

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

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

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

Other than for sales of our OraQuick® In-Home HIV test to the retail trade, we generally 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.

As a result of the return rights granted to our customers for our OraQuick® In-Home HIV test, 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 September 30, 2018 and December 31, 2017, the reserve for sales returns and allowances was \$181 and \$217, respectively. If actual product returns differ materially from our reserve amount, or if a determination is made that this product's distribution would be discontinued in whole or in part by certain retailers, then we would need to adjust our reserve. Should the actual level of product returns vary significantly from our estimates, our operating and financial results could be materially affected.

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

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

| | Three Months | | Nine Months Ended | |
|----------------------------------|---------------|---------------|-------------------|---------------|
| | Ended | | September 30, | |
| | September 30, | September 30, | September 30, | September 30, |
| | 2018 | 2017 | 2018 | 2017 |
| OraQuick® | \$12,016 | \$16,248 | \$40,813 | \$46,887 |
| Oragene® | 23,803 | 17,777 | 56,259 | 42,931 |
| Intercept® | 1,743 | 1,860 | 5,811 | 6,026 |
| Histofreezer® | 2,199 | 2,426 | 6,526 | 7,676 |
| Other products | 3,689 | 2,846 | 11,177 | 8,251 |
| Net product revenues | 43,450 | 41,157 | 120,586 | 111,771 |
| Royalty income | 1,132 | - | 4,827 | - |
| BARDA funding | 1,083 | 939 | 4,540 | 3,047 |
| Charitable support reimbursement | 220 | 218 | 1,544 | 218 |
| Other revenues | 2,435 | 1,157 | 10,911 | 3,265 |
| Net revenues | \$45,885 | \$42,314 | \$131,497 | \$115,036 |

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

| | Three Months | | Nine Months Ended | |
|---------------|---------------|---------------|-------------------|---------------|
| | Ended | | September 30, | |
| | September 30, | September 30, | September 30, | September 30, |
| | 2018 | 2017 | 2018 | 2017 |
| United States | \$36,883 | \$29,063 | \$99,860 | \$78,871 |
| Europe | 1,982 | 3,204 | 7,187 | 8,765 |
| Other regions | 7,020 | 10,047 | 24,450 | 27,400 |
| | \$45,885 | \$42,314 | \$131,497 | \$115,036 |

Customer and Vendor Concentrations. One of our customers accounted for 18% and 37% of our accounts receivable as of September 30, 2018 and December 31, 2017, respectively. The same customer accounted for approximately 39% and 27% of our net consolidated revenues for the three and nine months ended September 30, 2018 and 25% and 19% of our net consolidated revenues for the three and nine months ended September 30, 2017, respectively. Another customer accounted for 11% and 10% of our net consolidated revenues for the three and nine months ended September 30, 2017, respectively.

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

products could have a material adverse effect on our business, as well as our financial condition and results of operations.

4. Accrued Expenses

| | September 30, 2018 | December 31, 2017 |
|------------------------------|--------------------|-------------------|
| Payroll and related benefits | \$ 6,629 | \$ 9,265 |
| Professional fees | 1,171 | 1,064 |
| Royalties | 107 | 845 |
| Income taxes payable | — | 6,469 |
| Other | 2,343 | 3,052 |
| | \$ 10,250 | \$ 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). 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 September 30, 2018 and December 31, 2017.

Borrowings under the Credit Agreement are subject to compliance with borrowing base limitations tied to eligibility of accounts receivable. Interest under the Credit Agreement is payable at the London Interbank Offered Rate for one, two, three or six-month loans, as selected by the

Company, plus 2.50% per year. The Credit Agreement is subject to an unused line fee of 0.375% per year on the unused portion of the commitment under the Credit Agreement during the revolving period. The maturity date of the Credit Agreement is September 30, 2019.

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

6. Stockholders' Equity

Stock-Based Awards

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

Total compensation cost related to stock options for the nine months ended September 30, 2018 and 2017 was \$1,734 and \$1,554, respectively. Net cash proceeds from the exercise of stock options were \$1,684 and \$31,402 for the nine months ended September 30, 2018 and 2017, respectively. As a result of our net operating loss carryforward position, no actual income tax benefit was realized from stock option exercises during these periods.

Compensation cost of \$5,634 and \$2,022 related to restricted shares was recognized during the nine months ended September 30, 2018 and 2017, respectively. In connection with the vesting of restricted shares during the nine months ended September 30, 2018 and 2017, we purchased and immediately retired 164 and 122 shares with aggregate values of \$3,181 and \$1,234, respectively, in satisfaction of minimum tax withholding obligations.

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

Compensation cost of \$5,158 and \$1,637 related to PSUs was recognized during the nine months ended September 30, 2018 and 2017, respectively.

Modification of Grants

Stock compensation costs for the three and nine months ended September 30, 2018 include the additional expense associated with modifications of existing grants held by our retiring President and Chief Executive Officer (“CEO”) and Chief Financial Officer (“CFO”). These additional costs were \$8,039 during the nine months ended September 30, 2018 and is included in general and administrative expenses in the accompanying consolidated statement of income.

Stock Repurchase Program

On August 5, 2008, our Board of Directors approved a share repurchase program pursuant to which we are permitted to acquire up to \$25,000 of our outstanding common shares. No shares were purchased and retired during the nine months ended September 30, 2018 and 2017.

7. Income Taxes

During the three and nine months ended September 30, 2018, we recorded tax expense of \$3,271 and \$7,477, respectively. During the three and nine months ended September 30, 2017, we recorded tax expense of \$1,669 and \$7,121, 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 nine months of 2017 also includes the additional Canadian taxes due as a result of the \$12,500 gain from the settlement of our patent infringement and breach of contract litigation against Ancestry.com DNA LLC and its contract manufacturer.

The significant components of our total deferred tax liability as of September 30, 2018 and December 31, 2017 relate to the tax effects of the basis difference between the intangible assets acquired in the DNAG acquisition for financial reporting and tax purposes.

In 2008, we established a full valuation allowance against our U.S. deferred tax asset. Management believes the full valuation allowance is still appropriate at both September 30, 2018 and December 31, 2017 since the facts and circumstances necessitating the allowance have not changed. As a result, no U.S. federal or state deferred income tax expense or benefit was recorded for the three and nine-month periods ended September 30, 2018 and 2017.

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

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

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

8. Commitments and Contingencies

Litigation

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

9. Transition Costs

In January 2018, we announced the retirement of our President and CEO and our CFO and Chief Operating Officer. Stephen S. Tang, Ph.D., who served as Chairman of the Board of Directors (the “Board”), was appointed as the Company’s new President and CEO, effective as of April 1, 2018. Dr. Tang replaced Douglas A. Michels, who retired as President and CEO, and as a member of the Board, on March 31, 2018. In addition, Roberto Cuca was appointed as the Company’s new CFO, effective June 8, 2018. Mr. Cuca replaced Ronald H. Spair, our former CFO and Chief

Operating Officer, who retired on that same date. Charges associated with these transitions were \$8,628 during the nine months ended September 30, 2018 and are included in general and administrative expenses in the accompanying consolidated statement of income. 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. No transition costs were recorded during the three months ended September 30, 2018.

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, other diagnostic products including immunoassays and other in vitro diagnostic tests that are used on other specimen types, and medical devices used to remove benign skin lesions by cryotherapy or "freezing." 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.

-15-

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

The following table summarizes operating segment information for the three and nine months ended September 30, 2018 and 2017, and asset information as of September 30, 2018 and December 31, 2017:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---------------------------------------|--|----------|------------------------------------|-----------|
| | 2018 | 2017 | 2018 | 2017 |
| Net revenues: | | | | |
| OSUR | \$19,258 | \$23,762 | \$65,623 | \$69,720 |
| DNAG | 26,627 | 18,552 | 65,874 | 45,316 |
| Total | \$45,885 | \$42,314 | \$131,497 | \$115,036 |
| Operating income (loss): | | | | |
| OSUR | \$(2,599) | \$(453) | \$(14,420) | \$(235) |
| DNAG | 13,456 | 7,772 | 30,337 | 30,312 |
| Total | \$10,857 | \$7,319 | \$15,917 | \$30,077 |
| Depreciation and amortization: | | | | |
| OSUR | \$879 | \$855 | \$2,883 | \$2,189 |
| DNAG | 963 | 843 | 2,705 | 2,400 |
| Total | \$1,842 | \$1,698 | \$5,588 | \$4,589 |
| Capital expenditures: | | | | |
| OSUR | \$908 | \$1,156 | \$3,682 | \$2,493 |
| DNAG | 546 | 739 | 2,256 | 969 |
| Total | \$1,454 | \$1,895 | \$5,938 | \$3,462 |

| | September 30, 2018 | December 31, 2017 |
|----------------------|--------------------|-------------------|
| Total assets: | | |
| OSUR | \$ 189,132 | \$ 192,352 |
| DNAG | 115,175 | 103,849 |
| Total | \$ 304,307 | \$ 296,201 |

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

| | September 30, 2018 | December 31, 2017 |
|---------------|--------------------|-------------------|
| United States | \$ 17,493 | \$ 16,160 |
| Canada | 6,183 | 5,083 |
| Other regions | 719 | 129 |
| | \$ 24,395 | \$ 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 or other 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, collection 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; ability to maintain sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of the Company's stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to meet financial covenants in credit agreements; ability to attract and retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; and general political, business and economic conditions. These and other factors that could affect our results 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, other diagnostic products including immunoassays and other in vitro diagnostic tests that are used on other specimen types, and other medical devices. 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 market and we offer our customers a suite of genomics and microbiome services called “GenoFIND™”, which range from package customization and study design optimization to extraction, analysis and reporting services. We serve customers worldwide, including many leading research universities and hospitals.

Current Consolidated Financial Results

During the nine months ended September 30, 2018, our consolidated net revenues increased 14% to \$131.5 million, compared to \$115.0 million for the nine months ended September 30, 2017. Net product revenues during the nine months ended September 30, 2018 increased 8% when compared to the first nine 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 nine months of 2018 were \$10.9 million compared to \$3.3 million in the same period of 2017. Other revenues in the first nine months of 2018 consisted of royalty income of \$4.8 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 \$4.5 million and reimbursement of certain costs under our charitable support agreement with the Bill & Melinda Gates Foundation (“Gates Foundation”) of \$1.5 million. Other revenues in the first nine months of 2017 consisted of \$3.1 million of BARDA funding and \$218,000 of reimbursement of costs from the Gates Foundation.

Our consolidated net income for the nine months ended September 30, 2018 was \$10.1 million, or \$0.16 per share on a fully-diluted basis, compared to consolidated net income of \$23.6 million, or \$0.39 per share on a fully-diluted basis for the nine months ended September 30, 2017. Results in the first nine months of 2018 included \$8.6 million of management transition costs associated with the retirement of the Company’s Chief Executive Officer (“CEO”) and Chief Financial Officer (“CFO”) and Chief Operating Officer and the appointment of their successors, which approximates \$0.14 per share. Results for the first nine months 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 \$0.15 per share on a fully-diluted after-tax basis.

Cash provided by operating activities for the nine months ended September 30, 2018 was \$24.8 million. Cash provided by operating activities during the nine months ended September 30, 2017 was \$30.4 million and included the \$12.5 million litigation settlement noted above. As of September 30, 2018, we had \$192.1 million in cash, cash equivalents, and available-for-sale securities, compared to \$176.6 million at December 31, 2017.

Results of Operations

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

CONSOLIDATED NET REVENUES

The table below shows a breakdown of total consolidated net revenues (dollars in thousands) generated by each of our business segments for the three months ended September 30, 2018 and 2017.

| | Three Months Ended September 30, | | | Percentage of | |
|----------------------|----------------------------------|----------|--------|--------------------|-------|
| | Dollars | | % | Total Net Revenues | |
| | 2018 | 2017 | Change | 2018 | 2017 |
| OSUR | \$17,955 | \$22,605 | (21)% | 39 % | 53 % |
| DNAG | 25,495 | 18,552 | 37 | 56 | 44 |
| Net product revenues | 43,450 | 41,157 | 6 | 95 | 97 |
| Other | 2,435 | 1,157 | 110 | 5 | 3 |
| Net revenues | \$45,885 | \$42,314 | 8 | % 100 % | 100 % |

Consolidated net product revenues increased 6% to \$43.5 million in the third quarter of 2018 from \$41.2 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 international sales of our OraQuick® HCV test and lower domestic sales of our professional OraQuick® HIV test. Other revenues for the third quarter of 2018 were \$2.4 million compared to \$1.2 million in the same period of 2017. Other revenues in the third quarter of 2018 included \$1.1 million in royalty income earned under a litigation settlement agreement, \$1.1 million in funding from BARDA related to our Ebola and Zika products and \$220,000 in reimbursement of certain costs under our charitable support agreement with the Gates Foundation.

Edgar Filing: ORASURE TECHNOLOGIES INC - Form 10-Q

Other revenues in the third quarter of 2017 consisted of \$939,000 in BARDA funding and \$218,000 in cost reimbursement from the Gates Foundation.

Consolidated net revenues derived from products sold to customers outside of the United States were \$9.0 million and \$13.3 million, or 20% and 31% of total net revenues, in the third quarters of 2018 and 2017, respectively. Because the majority of our international sales are denominated in U.S. dollars, the impact of fluctuating foreign currency exchange rates was not material to our total consolidated net revenues.

Net Revenues by Segment

OSUR Segment

The table below shows a breakdown of total net revenues (dollars in thousands) generated by our OSUR segment during the third quarters of 2018 and 2017.

| Market | Three Months Ended September 30, | | | Percentage of Total Net Revenues | |
|----------------------------|----------------------------------|----------|--------|----------------------------------|-------|
| | Dollars | | % | 2018 | 2017 |
| | 2018 | 2017 | Change | | |
| Infectious disease testing | \$12,417 | \$16,577 | (25)% | 64 % | 70 % |
| Risk assessment testing | 2,842 | 3,149 | (10) | 15 | 13 |
| Cryosurgical systems | 2,696 | 2,879 | (6) | 14 | 12 |
| Net product revenues | 17,955 | 22,605 | (21) | 93 | 95 |
| Other | 1,303 | 1,157 | 13 | 7 | 5 |
| Net revenues | \$19,258 | \$23,762 | (19)% | 100 % | 100 % |

Infectious Disease Testing Market

Sales to the infectious disease testing market decreased 25% to \$12.4 million in the third quarter of 2018 from \$16.6 million in the third quarter of 2017. This decrease resulted from lower international sales of our OraQuick® HCV product and lower domestic sales of our professional OraQuick® HIV product, partially offset by higher international sales of our OraQuick® HIV Self-Test.

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

| Market | Three Months Ended September 30, | | |
|------------------------|----------------------------------|----------|----------|
| | 2018 | 2017 | % Change |
| Domestic HIV | \$2,749 | \$3,622 | (24)% |
| International HIV | 4,328 | 3,069 | 41 |
| Domestic OTC HIV | 1,706 | 1,515 | 13 |
| Net HIV revenues | 8,783 | 8,206 | 7 |
| Domestic HCV | 2,066 | 1,889 | 9 |
| International HCV | 1,168 | 6,154 | (81) |
| Net HCV revenues | 3,234 | 8,043 | (60) |
| Net OraQuick® revenues | \$12,017 | \$16,249 | (26)% |

Domestic OraQuick® HIV sales decreased 24% to \$2.7 million for the three months ended September 30, 2018 from \$3.6 million for the three months ended September 30, 2017. This decrease was primarily the result of competition from point-of-care HIV tests perceived to be more sensitive than our product, competition from fourth generation automated HIV immunoassays performed in a laboratory, reduced government funding of HIV programs, and customer ordering patterns.

International sales of our OraQuick® HIV test during the third quarter of 2018 rose 41% to \$4.3 million for the three months ended September 30, 2018 from \$3.1 million for the three months ended September 30, 2017. This increase was largely due to higher sales of our OraQuick® HIV Self-Test into Africa. Funding under the charitable support agreement with the Gates Foundation began in the third quarter of 2017 and product revenues in the third quarter of 2018 and 2017 included approximately \$840,000 and \$458,000, respectively, of support payments under that agreement.

Sales of our OraQuick® In-Home HIV test increased 13% to \$1.7 million in the third quarter of 2018 from \$1.5 million in the third quarter of 2017 largely due to customer ordering patterns.

Domestic OraQuick® HCV sales increased 9% to \$2.1 million in the third quarter of 2018 from \$1.9 million in the third quarter of 2017 primarily due to customer ordering patterns.

International OraQuick® HCV sales decreased 81% to \$1.2 million in the third quarter of 2018 from \$6.2 million in the third quarter of 2017, due to the non-renewal of a supply contract with a foreign government in support of a countrywide HCV eradication program.

Risk Assessment Market

Sales to the risk assessment market decreased 10% to \$2.8 million in the third quarter of 2018 compared to \$3.1 million in the third quarter of 2017 due to a reduction in pre-employment drug screening as employers move to more questionnaire-based evaluations for new employees.

Cryosurgical Market

Sales of our cryosurgical products decreased 6% to \$2.7 million in the third quarter of 2018 from \$2.9 million in the third quarter of 2017.

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

| Market | Three Months Ended September 30, | | |
|-----------------------------------|-------------------------------------|---------|-------------|
| | 2018 | 2017 | % Change |
| Domestic professional | \$1,349 | \$1,426 | (5)% |
| International professional | 220 | 179 | 23 |
| Domestic OTC | 333 | 325 | 2 |
| International OTC | 794 | 949 | (16) |
| Net cryosurgical systems revenues | \$2,696 | \$2,879 | (6)% |

Third quarter 2018 sales of our domestic Histofreezer® product sold to physicians' offices decreased 5% to \$1.3 million from \$1.4 million in the third quarter of 2017, primarily due to competitive losses from lower-priced products that have entered the market as result of the expiration of the patents associated with our cryosurgical technology.

Sales of our international OTC cryosurgical products during the third quarter of 2018 decreased 16% to \$794,000 compared to \$949,000 in the third quarter of 2017 primarily due to lower sales in Europe partially offset by higher sales in Latin America.

Other revenues

Other revenues in the third quarter of 2018 increased 110% to \$2.4 million from \$1.2 million in the third quarter of 2017. The table below shows a breakdown of our other revenues (dollars in thousands) recorded during the third quarters of 2018 and 2017.

| | Three Months Ended September 30, | | |
|--|-------------------------------------|------|-------------|
| | 2018 | 2017 | % Change |

Edgar Filing: ORASURE TECHNOLOGIES INC - Form 10-Q

| | | | | |
|----------------------------------|---------|---------|-----|---|
| Royalty income | \$1,132 | \$- | N/A | |
| BARDA funding | 1,083 | 939 | 15 | % |
| Charitable support reimbursement | 220 | 218 | 1 | |
| Other revenues | \$2,435 | \$1,157 | 110 | % |

Other revenues in the third quarter of 2018 included \$1.1 million of royalty income earned under a litigation settlement agreement. The settlement agreement was entered into in 2017 and required royalty payments beginning in the first quarter of 2018. There were no revenues of this nature in the third quarter of 2017. Revenue from BARDA funding increased to \$1.1 million in the third quarter of 2018 compared to \$939,000 in the third quarter of 2017 as a result of increased efforts related to our Ebola product partially offset by lower funding related to our Zika product. Other revenues in the third quarter of 2018 and 2017 also included \$220,000 and \$218,000, respectively, in reimbursement of certain costs under our charitable support agreement with the Gates Foundation, which are separate from the above-referenced support payments received under this agreement.

DNAG Segment

Molecular Market

| Market | Three Months Ended September 30, | | |
|---|-------------------------------------|----------|-------------|
| | 2018 | 2017 | % Change |
| Commercial genomics | \$21,505 | \$14,544 | 48 % |
| Academic genomics | 2,299 | 3,232 | (29) |
| Microbiome | 1,691 | 776 | 118 |
| Net molecular collection systems revenues | \$25,495 | \$18,552 | 37 % |

Net molecular collection systems revenues increased 37% to \$25.5 million in the third quarter of 2018 from \$18.6 million in the third quarter of 2017. Sales in the commercial market increased 48% in the third quarter of 2018 compared to the third quarter of 2017, largely due to higher customer demand, primarily from a large consumer genetics customer. Sales into the academic market decreased 29% in the third quarter of 2018 compared to the third quarter of 2017 largely due to the loss of a large academic customer to a competing product coupled with the completion of certain research programs that did not repeat in the third quarter of 2018. Revenues in the third quarter of 2018 also included \$1.7 million in sales of our microbiome products which represents a 118% increase over the \$776,000 in microbiome revenues generated in the same period of 2017, as interest in our microbiome product offerings continues to grow with both new and existing customers.

CONSOLIDATED OPERATING RESULTS

Consolidated gross profit percentage (gross margin) was 62% for the third quarter of 2018 compared to 58% for the third quarter of 2017. Gross profit percentage in the third quarter of 2018 benefited from decreased manufacturing costs associated with our Oragene[®] product, lower royalty expense, and from the increase in other revenues which have a gross profit percentage of 100%.

Consolidated operating income for the third quarter of 2018 was \$10.9 million, a \$3.5 million increase from the \$7.3 million of operating income reported in the third quarter of 2017. Our results for the third quarter of 2018 benefited from the higher revenues and improved gross profit percentage and lower general and administrative costs, partially offset by higher spending on research and development and sales and marketing.

OPERATING INCOME (LOSS) BY SEGMENT

OSUR Segment

OSUR's gross profit percentage was 56% in the third quarter of 2018 compared to 55% in the third quarter of 2017 and was positively impacted by a reduction in royalty expense in the quarter as a result of the expiration of the associated royalty agreement partially offset by an increase in lower profit percentage revenues as a result of the higher international sales.

Research and development expenses increased 18% to \$3.0 million in the third quarter of 2018 from \$2.5 million in the third quarter of 2017, largely due to increased spending on our Ebola products, higher staffing costs, and increased product registration costs. Sales and marketing expenses decreased 4% to \$4.6 million in the third quarter of 2018 from \$4.8 million in the third quarter of 2017 largely due to lower third-party commission expense and advertising fees. General and administrative expenses decreased 7% to \$5.8 million in the third quarter of 2018 from \$6.2 million in the third quarter of 2017 as a result of lower staffing costs partially offset by higher consulting fees.

All of the above contributed to OSUR's third quarter 2018 operating loss of \$2.6 million, which included non-cash charges of \$879,000 for depreciation and amortization and \$1.1 million for stock-based compensation.

DNAG Segment

DNAG's gross profit percentage was 67% in the third quarter of 2018 compared to 62% in the third quarter of 2017. This increase was attributable to Oragene[®] manufacturing costs savings that resulted from sales volume increases. The gross profit percentage also benefitted from the royalty income recorded in the third quarter of 2018. No royalty income was recorded in the third quarter of 2017.

Research and development expenses increased 23% to \$839,000 in the third quarter of 2018 from \$681,000 in the third quarter of 2017 due to increased staffing costs as a result of higher headcount and increased travel expenses. Sales and marketing expenses rose 15% to \$2.7 million in the third quarter of 2018 from \$2.3 million in the third

quarter of 2017 due to higher staffing costs associated with increased headcount and an increase in commission expense. General and administrative expenses remained relatively flat at \$754,000 in the third quarter of 2018 compared to \$696,000 in the third quarter of 2017.

All of the above contributed to DNAG's third quarter 2018 operating income of \$13.5 million, which included non-cash charges of \$963,000 for depreciation and amortization and \$132,000 for stock-based compensation.

CONSOLIDATED INCOME TAXES

We continue to believe the full valuation allowance established in 2008 against OSUR's total U.S. deferred tax asset is appropriate as the facts and circumstances necessitating the allowance have not changed. For the three months ended September 30, 2018 and 2017, no state income tax expense was recorded. Canadian income tax expense of \$3.3 million and \$1.7 million was recorded in the third quarters of 2018 and 2017, respectively. The increase in income tax expense is directly related to the increase in income before taxes generated by DNAG. On December 22, 2017, the United States enacted the Tax Cuts and Jobs Act ("Tax Act") that instituted fundamental changes to the taxation on multinational corporations. The impact of the Tax Act on our financial results is not material given that OSUR has a full valuation allowance against its total U.S. deferred tax assets and due to the net operating losses ("NOLs") and tax credits that are being generated by the U.S. entity.

Results of Operations

Nine months ended September 30, 2018 compared to September 30, 2017

CONSOLIDATED NET REVENUES

The table below shows a breakdown of total consolidated net revenues (dollars in thousands) generated by each of our business segments for the nine months ended September 30, 2018 and 2017.

| | Nine Months Ended September 30, | | | Percentage of | |
|----------------------|---------------------------------|-----------|-------------|---------------|-------|
| | Dollars | | | Total Net | |
| | 2018 | 2017 | % Change | 2018 | 2017 |
| OSUR | \$59,539 | \$66,455 | (10)% | 46 % | 58 % |
| DNAG | 61,047 | 45,316 | 35 | 46 | 39 |
| Net product revenues | 120,586 | 111,771 | 8 | 92 | 97 |
| Other | 10,911 | 3,265 | 234 | 8 | 3 |
| Net revenues | \$131,497 | \$115,036 | 14 % | 100 % | 100 % |

Consolidated net product revenues increased 8% to \$120.6 million in the first nine months of 2018 from \$111.8 million in the same period of 2017. Higher sales of our molecular collection systems products and higher international sales of our OraQuick® HIV Self-Test were partially offset by lower sales of our OraQuick® HCV product, lower domestic sales of our professional OraQuick® HIV test and lower sales of our cryosurgical systems products. Other revenues in the first nine months of 2018 were \$10.9 million compared to \$3.3 million in the same period of 2017. Other revenues in the first nine months of 2018 included \$4.8 million in royalty income earned under a litigation settlement agreement, \$4.5 million in funding from BARDA related to our Ebola and Zika products and \$1.5 million in reimbursement of certain costs under our charitable support agreement with the Gates Foundation. Other revenues in the first nine months of 2017 consisted of \$3.1 million in BARDA funding and \$218,000 in cost reimbursement from the Gates Foundation.

Consolidated net revenues derived from products sold to customers outside of the United States were \$31.6 million and \$36.2 million, or 24% and 31% of total net revenues, during the nine months ended September 30, 2018 and 2017, respectively. Because the majority of our international sales are denominated in U.S. dollars, the impact of fluctuating foreign currency exchange rates was not material to our total consolidated net revenues.

Net Revenues by Segment

OSUR Segment

The table below shows a breakdown of total net revenues (dollars in thousands) generated by our OSUR segment for the nine months ended September 30, 2018 and 2017.

Infectious Disease Testing Market

Nine Months Ended September 30,
Dollars

| Market | 2018 | 2017 | % Change | Percentage of Total Net Revenues | |
|----------------------------|----------|----------|-------------|--|-------|
| | | | | 2018 | 2017 |
| Infectious disease testing | \$42,506 | \$47,822 | (11)% | 65 % | 68 % |
| Risk assessment testing | 9,159 | 9,517 | (4) | 14 | 14 |
| Cryosurgical systems | 7,874 | 9,116 | (14) | 12 | 13 |
| Net product revenues | 59,539 | 66,455 | (10) | 91 | 95 |
| Other | 6,084 | 3,265 | 86 | 9 | 5 |
| Net revenues | \$65,623 | \$69,720 | (6)% | 100 % | 100 % |

Sales to the infectious disease testing market decreased 11% to \$42.5 million for the nine months ended September 30, 2018 from \$47.8 million for the nine months ended September 30, 2017. This decrease resulted from lower sales of our OraQuick® HCV product and lower domestic sales of our professional OraQuick® HIV product, partially offset by increased international sales of our OraQuick® HIV Self-Test.

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 nine months ended September 30, 2018 and 2017.

| Market | Nine Months Ended | | % Change |
|------------------------|-------------------|-----------|----------|
| | 2018 | 2017 | |
| Domestic HIV | \$ 10,043 | \$ 12,401 | (19)% |
| International HIV | 17,395 | 7,738 | 125 |
| Domestic OTC HIV | 4,646 | 4,951 | (6) |
| Net HIV revenues | 32,084 | 25,090 | 28 |
| Domestic HCV | 5,424 | 5,980 | (9) |
| International HCV | 3,306 | 15,817 | (79) |
| Net HCV revenues | 8,730 | 21,797 | (60) |
| Net OraQuick® revenues | \$ 40,814 | \$ 46,887 | (13)% |

Domestic OraQuick® HIV sales decreased 19% to \$10.0 million for the nine months ended September 30, 2018 from \$12.4 million for the nine months ended September 30, 2017. This decrease was primarily the result of competition from point-of-care HIV tests perceived to be more sensitive than our product, competition from fourth generation automated HIV immunoassays performed in a laboratory, and customer ordering patterns.

International sales of our OraQuick® HIV test during the first nine of 2018 rose 125% to \$17.4 million for the nine months ended September 30, 2018 from \$7.7 million for the nine months ended September 30, 2017. This increase was largely due to higher sales of our OraQuick® HIV Self-Test into Africa. Funding under the charitable support agreement with the Gates Foundation began in the third quarter of 2017 and product revenues in the first nine months of 2018 and 2017 included approximately \$3.6 million and \$458,000 of support payments under that agreement, respectively.

Sales of our OraQuick® In-Home HIV test decreased 6% to \$4.6 million during the first nine months of 2018 from \$5.0 million in the first nine months of 2017 as a result of the timing of testing programs managed by certain of our public health customers.

Domestic OraQuick® HCV sales decreased 9% to \$5.4 million in the first nine months of 2018 from \$6.0 million in the first nine months of 2017 primarily due to the non-renewal of, or reductions in, grant funding of HCV testing programs. International OraQuick® HCV sales decreased 79% to \$3.3 million in the first nine months of 2018 from \$15.8 million in the first nine months of 2017, due to the non-renewal of a supply contract with a foreign government in support of a countrywide HCV eradication program and the loss of a multi-national humanitarian organization customer that switched to a competitive product due to pricing.

Risk Assessment Market

Sales to the risk assessment market slightly decreased to \$9.2 million in the first nine months of 2018 compared to \$9.5 million in the first nine months of 2017.

Cryosurgical Market

Sales of our cryosurgical products decreased 14% to \$7.9 million in the first nine months of 2018 from \$9.1 million in the first nine months of 2017.

Edgar Filing: ORASURE TECHNOLOGIES INC - Form 10-Q

The table below shows a breakdown of our total net cryosurgical revenues (dollars in thousands) generated in each market during the nine months ended September 30, 2018 and 2017.

| Market | Nine Months Ended September 30, | | |
|-----------------------------------|------------------------------------|---------|-------------|
| | 2018 | 2017 | % Change |
| Domestic professional | \$3,292 | \$4,368 | (25)% |
| International professional | 633 | 552 | 15 |
| Domestic OTC | 917 | 957 | (4) |
| International OTC | 3,032 | 3,239 | (6) |
| Net cryosurgical systems revenues | \$7,874 | \$9,116 | (14)% |

Sales of our domestic Histofreezer® product to physicians' offices decreased 25% to \$3.3 million from \$4.4 million in the first nine months of 2017, primarily due to competitive losses from lower-priced products that have entered the market as result of the expiration of the patents associated with our cryosurgical technology.

Sales of our international OTC cryosurgical products decreased 6% to \$3.0 million during the first nine months of 2018 from \$3.2 million the first nine months 2017 primarily due to lower sales in Europe partially offset by higher sales in Latin America.

Other revenues

Other revenues in the first nine months of 2018 increased 234% to \$10.9 million from \$3.3 million in the first nine months of 2017. The table below shows a breakdown of our other revenues (dollars in thousands) recorded during the nine months ended September 30, 2018 and 2017.

| | Nine Months Ended September 30, | | | % Change |
|----------------------------------|------------------------------------|---------|-----|-------------|
| | 2018 | 2017 | | |
| Royalty income | \$4,827 | \$- | | N/A |
| BARDA funding | 4,540 | 3,047 | 49 | % |
| Charitable support reimbursement | 1,544 | 218 | 608 | |
| Other revenues | \$10,911 | \$3,265 | 234 | % |

Other revenues in the first nine months of 2018 included \$4.8 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 nine months of 2017. Revenue from BARDA funding increased to \$4.5 million in the first nine months of 2018 compared to \$3.0 million in the first nine months of 2017 as a result of increased efforts related to our Ebola and Zika products. Other revenues in the first nine months of 2018 also included \$1.5 million in reimbursement of certain costs under our charitable support agreement with the Gates Foundation. Reimbursement of these costs began in the third quarter of 2017 and other revenue in the first nine months of 2017 included \$218,000 of such reimbursement.

DNAG Segment

Molecular Market

| Market | Nine Months Ended September 30, | | | % Change |
|---|------------------------------------|----------|-----|-------------|
| | 2018 | 2017 | | |
| Commercial genomics | \$48,024 | \$34,615 | 39 | % |
| Academic genomics | 8,236 | 8,316 | (1) |) |
| Microbiome | 4,787 | 2,385 | 101 | |
| Net molecular collection systems revenues | \$61,047 | \$45,316 | 35 | % |

Net molecular collection systems revenues increased 35% to \$61.0 million in the first nine months of 2018 from \$45.3 million in the first nine months of 2017. Sales in the commercial market rose 39% in the first nine months of 2018 compared to the first nine months of 2017, largely as a result of higher customer demand, primarily from a large consumer genetics customer. Sales into the academic market remained relatively flat at \$8.2 million the first nine months of 2018 compared to \$8.3 million in the first nine months of 2017. Revenues in the first nine months of 2018 also included \$4.8 million in sales of our microbiome products compared to \$2.4 million in the same period of 2017, as interest in our microbiome product offerings continues to grow with both new and existing customers.

CONSOLIDATED OPERATING RESULTS

Consolidated gross profit percentage was 60% for the first nine months of 2018 compared to 61% for the first nine months of 2017. Gross profit percentage in the first nine months of 2018 was negatively impacted by an increase in lower profit percentage sales, partially offset by the increase in other revenues which have a gross profit percentage of 100%.

Consolidated operating income for the first nine months of 2018 was \$15.9 million, a \$14.2 million decline from the \$30.1 million of operating income reported in the first nine months of 2017. Operating income in the first nine months of 2017 included a pre-tax gain of \$12.5 million associated with the settlement of our litigation against Ancestry.com DNA LLC and its contract manufacturer. In addition, our results for the first nine months of 2018 were negatively impacted by the increase in lower profit percentage sales, the inclusion of \$8.6 million of transition costs associated with executive management changes, and increased spending on research and development and sales and marketing.

OPERATING INCOME (LOSS) BY SEGMENT

OSUR Segment

OSUR's gross profit percentage was 55% in the first nine months of 2018 compared to 59% in the first nine months of 2017. OSUR's gross profit percentage in 2018 was negatively impacted by an increase in lower profit percentage revenues as a result of higher international sales, partially offset by the increase in BARDA funding and cost reimbursement from the Gates Foundation.

Research and development expenses increased 30% to \$9.8 million in the first nine months of 2018 from \$7.5 million in the first nine months of 2017, largely due to increased spending on our Ebola and Zika products and higher staffing costs. Sales and marketing expenses remained relatively consistent at \$14.5 million in the first nine months of 2018 compared to \$14.7 million in the first nine months of 2017. General and administrative expenses increased 37% to \$26.4 million in the first nine months 2018 from \$19.3 million in the first nine months of 2017 as a

result of the inclusion of \$8.6 million of transition costs associated with executive management changes and higher consulting costs partially offset by a decrease in other staffing related costs.

All of the above contributed to OSUR's operating loss of \$14.4 million in the first nine months of 2018, which included non-cash charges of \$2.9 million for depreciation and amortization and \$12.1 million for stock-based compensation.

DNAG Segment

DNAG's gross profit percentage was 65% in the first nine months of 2018 compared to 64% in the first nine months of 2017. This increase was attributable to the royalty income recorded in the first nine months of 2018 partially offset by an increase in lower profit percentage product sales in the first nine months of 2018 compared to the same period in 2017. No royalty income was recorded in the first nine months of 2017.

Research and development expenses increased 20% to \$2.4 million in the first nine months of 2018 from \$2.0 million in the first nine months of 2017 due to increased staffing costs as a result of higher headcount. Sales and marketing expenses increased 12% to \$7.7 million in the first nine months of 2018 from \$6.9 million in the first nine months of 2017 due to higher staffing costs associated with higher head count and an increase in commission expense. General and administrative expenses decreased 12% to \$2.2 million in the first nine months of 2018 compared to \$2.5 million in the first nine months of 2017 primarily due to lower legal and staffing expenses.

All of the above contributed to DNAG's operating income of \$30.3 million in the first nine months of 2018 which included non-cash charges of \$2.7 million for depreciation and amortization and \$377,000 for stock-based compensation.

CONSOLIDATED INCOME TAXES

We continue to believe the full valuation allowance established in 2008 against OSUR's total U.S. deferred tax asset is appropriate as the facts and circumstances necessitating the allowance have not changed. For the nine months ended September 30, 2018, no state income tax expense was recorded as compared to \$31,000 in the nine months ended September 30, 2017. Canadian income tax expense of \$7.5 million and \$7.1 million was recorded in the first nine months of 2018 and 2017, respectively. The increase in income tax expense was largely a result of the increase in income before taxes generated by DNAG partially offset by the additional taxes recorded during the first nine months of 2017 related to the \$12.5 million litigation settlement which did not re-occur in 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

| | September 30, | December 31, |
|--|----------------|--------------|
| | 2018 | 2017 |
| | (In thousands) | |
| Cash, cash equivalents and restricted cash | \$78,146 | \$ 72,869 |
| Available for sale securities | 113,980 | 103,718 |
| Working capital | 186,477 | 189,668 |

Our cash, cash equivalents, restricted cash and available-for-sale securities increased to \$192.1 million at September 30, 2018 from \$176.6 million at December 31, 2017. Our working capital decreased to \$186.5 million at September 30, 2018 from \$189.7 million at December 31, 2017 largely due to the increased balance of long-term investments.

During the first nine months of 2018, we generated \$24.8 million in cash from operating activities. Our net income of \$10.1 million included non-cash charges for stock-based compensation expense of \$12.5 million, depreciation and amortization expense of \$5.6 million, as well as other non-cash benefits of \$463,000. Additional sources of cash included an \$8.8 million decrease in accounts receivable as a result of the collection of large outstanding balances, a \$1.7 million increase in deferred revenue due to the revenue recognition associated with a multi-year contract with variable pricing, and a \$615,000 decrease in prepaid expenses and other assets. Offsetting these sources of cash were a decrease in accrued expenses and other liabilities of \$11.3 million largely due to the submission of tax payments to the Canadian taxing authorities and payment of our 2017 management incentive bonuses, a decrease in accounts payable of \$2.2 million associated with a reduction in inventory purchases as compared to the fourth quarter of 2017, and an increase in inventory of \$649,000.

Net cash used in investing activities was \$17.5 million for the nine months ended September 30, 2018, which reflects \$135.6 million used to purchase investments and \$5.9 million to acquire property and equipment partially offset by \$124.1 million in proceeds from the maturities and redemptions of investments.

Net cash used in financing activities was \$1.5 million for the nine months ended September 30, 2018, which resulted from \$3.2 million used for the repurchase of common stock to satisfy withholding taxes related to the vesting of restricted shares partially offset by \$1.7 million in proceeds received from the exercise of stock options.

In September 2016, we entered into a credit agreement (the "Credit Agreement") with a commercial bank, which was amended in December 2017. The Credit Agreement provides for revolving extensions of credit in an initial aggregate amount of up to \$10.0 million (inclusive of a letter of credit subfacility of \$2.5 million). Obligations under the Credit Agreement are secured by a first priority security interest in certain eligible accounts receivable, 65% of the equity of our subsidiary, DNAG, and certain related assets. There were no borrowings outstanding at September 30, 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 September 30, 2018 and December 31, 2017, we were in compliance with all applicable covenants under the Credit Agreement.

Our current balances of cash and cash equivalents and available-for-sale securities and our available borrowing capacity are expected to be sufficient to fund our current operating and capital needs for the foreseeable future. Our cash requirements, however, may vary materially from those now planned due to many factors, including, but not limited to, the scope and timing of future strategic acquisitions, the progress of our research and development programs, the scope and results of clinical testing, the cost of any future litigation, the magnitude of capital expenditures, changes in existing and potential relationships with business partners, the timing and cost of obtaining regulatory approvals, the timing and cost of future stock purchases, the costs involved in obtaining and enforcing patents, proprietary rights and any necessary licenses, the cost and timing of expansion of sales and marketing activities, market acceptance of new products, competing technological and market developments, the impact of the current economic environment and other factors. In addition, \$58.5 million or 30% of our \$192.1 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 September 30, 2018, there were no significant changes to this information, including the absence of any off-balance sheet arrangements.

Critical Accounting Policies and Estimates

This Management's Discussion and Analysis of Financial Condition and Results of Operations discusses our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires that we make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. On an on-going basis, we evaluate our judgments and estimates, including those related to the bad debts, customer sales returns, inventories, intangible assets, income taxes, revenue recognition, performance-based

compensation, contingencies and litigation. We base our judgments and estimates on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

A more detailed review of our critical accounting policies is contained in our Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC. During the first nine 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 September 30, 2018, we did not have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. Sales denominated in foreign currencies comprised 2.6% of our total revenues for the nine months ended September 30, 2018. We do have foreign currency exchange risk related to our operating subsidiary in Canada. While the majority of this subsidiary's revenues are recorded in U.S. dollars, almost all of this subsidiary's operating expenses are denominated in Canadian dollars. Fluctuations in the exchange rate between the U.S. dollar and the Canadian dollar could affect year-to-year comparability of operating results and cash flows. Our Canadian subsidiary had net assets, subject to translation, of \$130.0 million CAD (\$100.7 million USD), which are included in the Company's consolidated balance sheet

as of September 30, 2018. A 10% unfavorable change in the Canadian-to-U.S. dollar exchange rate would have decreased our comprehensive income by \$10.1 million in the nine months ended September 30, 2018.

Item 4. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures. The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) as of September 30, 2018. Based on that evaluation, the Company's management, including such officers, concluded that the Company's disclosure controls and procedures were effective as of September 30, 2018 to provide reasonable assurance that material information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act of 1934 was accumulated and communicated to the Company's management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure and was recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission.

(b) Changes in Internal Control Over Financial Reporting. There was no change in the Company's internal control over financial reporting that occurred during the three months ended September 30, 2018 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

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

Item 1A. RISK FACTORS

There have been no material changes to the risk factors disclosed in Item 1A., entitled "Risk Factors," in our Annual Report on Form 10-K for the year ended December 31, 2017, and in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2018.

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

| Period | Total number of shares purchased | Average price paid per Share | Total number of shares purchased as part of publicly announced plans or programs | Maximum number (or approximate dollar value) of shares that may yet be repurchased under the plans or programs (1, 2) |
|--|----------------------------------|------------------------------|--|---|
| July 1, 2018 - July 31, 2018 | — | (3) \$ — | — | 11,984,720 |
| August 1, 2018 - August 31, 2018 | 600 | (3) 16.44 | — | 11,984,720 |
| September 1, 2018 - September 30, 2018 | — | (3) — | — | 11,984,720 |
| | 600 | | — | |

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

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

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

Item 3. DEFAULTS UPON SENIOR SECURITIES

None

Item 4. MINE SAFETY DISCLOSURES

Not applicable

Item 5. OTHER INFORMATION

None

Item 6. EXHIBITS

Exhibit

| Number | Exhibit |
|---------|---|
| 10.1 | <u>Description of amendment to OraSure Technologies, Inc. Long-Term Incentive Policy and compensation change for a Named Executive Officer, is incorporated by reference to Item 5.02 to the Company's Current Report on Form 8-K filed August 17, 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 Roberto Cuca 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 Roberto Cuca required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**</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 |

* Management contract or compensatory plan or agreement

** Filed herewith

SIGNATURES

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

ORASURE TECHNOLOGIES, INC.

Date: November 8, 2018 /s/ Roberto Cuca
Roberto Cuca
Chief Financial Officer
(Principal Financial Officer)

Date: November 8, 2018 /s/Michele M. Miller
Michele M. Miller
Vice President, Finance and Controller
(Principal Accounting Officer)