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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2019.

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

Registrant's telephone number, including area code: (610) 882-1820

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.000001 par value per share	OSUR	The NASDAQ Stock Market LLC

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 ☒

As of August 2, 2019, the registrant had 61,724,870 shares of common stock, $.000001 par value per share, outstanding.

PART I. FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

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

	June 30, 2019	December 31, 2018
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 72,567	$ 88,438
Short-term investments	74,446	68,134
Accounts receivable, net of allowance for doubtful accounts of $571 and $418	29,390	34,842
Inventories	25,670	22,888
Prepaid expenses	2,128	1,925
Other current assets	5,057	3,085
Total current assets	209,258	219,312
Noncurrent Assets:		
Property, plant and equipment, net	27,793	24,299
Operating right-of-use assets, net	3,685	—
Finance right-of-use assets, net	1,462	—
Intangible assets, net	12,472	5,137
Goodwill	29,280	18,521
Long-term investments	39,555	44,752
Other noncurrent assets	3,960	3,550
Total noncurrent assets	118,207	96,259
TOTAL ASSETS	**$ 327,465**	**$ 315,571**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 10,956	$ 10,598
Deferred revenue	3,914	3,521
Accrued expenses	8,638	13,861
Finance lease liability	448	—
Operating lease liability	746	—
Acquisition-related contingent consideration obligation	5,249	—
Total current liabilities	29,951	27,980
Noncurrent Liabilities:		
Finance lease liability	930	—
Operating lease liability	3,266	—
Acquisition-related contingent consideration obligation	649	—
Other noncurrent liabilities	3,538	3,312
Deferred income taxes	910	901
Total noncurrent liabilities	9,293	4,213
TOTAL LIABILITIES	39,244	32,193
Commitments and contingencies (Note 10)		
STOCKHOLDERS' EQUITY		
Preferred stock, par value $.000001, 25,000 shares authorized, none issued	—	—
Common stock, par value $.000001, 120,000 shares authorized, 61,725 and 61,276 shares issued and outstanding	—	—
Additional paid-in capital	399,585	401,273
Accumulated other comprehensive loss	(13,315)	(18,706)
Accumulated deficit	(98,049)	(99,189)
Total stockholders' equity	288,221	283,378
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 327,465**	**$ 315,571**

See accompanying notes to the consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
NET REVENUES:				
Products and services	$ 37,267	$ 38,818	$ 65,599	$ 77,136
Other	1,559	4,807	3,349	8,476
	38,826	43,625	68,948	85,612
COST OF PRODUCTS SOLD	13,808	17,730	25,850	35,250
Gross profit	25,018	25,895	43,098	50,362
OPERATING EXPENSES:				
Research and development	4,535	4,261	8,906	8,336
Sales and marketing	7,687	7,429	14,982	14,928
General and administrative	7,262	8,647	16,192	22,038
Change in the estimated fair value of acquisition-related contingent consideration	249	—	1,544	-
	19,733	20,337	41,624	45,302
Operating income	5,285	5,558	1,474	5,060
OTHER INCOME	524	736	1,048	1,148
Income before income taxes	5,809	6,294	2,522	6,208
INCOME TAX EXPENSE	1,411	2,173	1,382	4,206
NET INCOME	$ 4,398	$ 4,121	$ 1,140	$ 2,002
EARNINGS PER SHARE:				
BASIC	$ 0.07	$ 0.07	$ 0.02	$ 0.03
DILUTED	$ 0.07	$ 0.07	$ 0.02	$ 0.03
SHARES USED IN COMPUTING EARNINGS PER SHARE:				
BASIC	61,709	61,100	61,621	60,983
DILUTED	62,128	62,244	62,191	62,379

See accompanying notes to the consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
NET INCOME	$ 4,398	$ 4,121	$ 1,140	$ 2,002
OTHER COMPREHENSIVE INCOME (LOSS)				
Currency translation adjustments	2,476	(1,652)	4,708	(3,806)
Unrealized gain (loss) on marketable securities	186	194	683	(318)
COMPREHENSIVE INCOME (LOSS)	$ 7,060	$ 2,663	$ 6,531	$ (2,122)

See accompanying notes to the consolidated financial statements.

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

	Six Months Ended June 30, 2019	Six Months Ended June 30, 2018
OPERATING ACTIVITIES:		
Net income	$ 1,140	$ 2,002
Adjustments to reconcile net income to net cash provided by operating activities:		
Stock-based compensation	1,848	11,262
Depreciation and amortization	3,610	3,746
Unrealized foreign currency (gain)/loss	365	(255)
Interest expense on finance leases	13	-
Deferred income taxes	(467)	(272)
Change in the estimated fair value of acquisition-related contingent consideration	1,544	-
Changes in assets and liabilities		
Accounts receivable	6,175	10,166
Inventories	(2,298)	(1,429)
Prepaid expenses and other assets	632	289
Accounts payable	81	(193)
Deferred revenue	301	253
Accrued expenses and other liabilities	(8,283)	(11,641)
Net cash provided by operating activities	4,661	13,928
INVESTING ACTIVITIES:		
Purchases of investments	(55,317)	(93,917)
Proceeds from maturities and redemptions of investments	55,624	85,926
Purchases of property and equipment	(5,513)	(4,484)
Acquisition of businesses, net of cash acquired	(13,217)	-
Net cash used in investing activities	(18,423)	(12,475)
FINANCING ACTIVITIES:		
Repayments of loans	(724)	-
Cash payments for lease liability	(124)	-
Proceeds from exercise of stock options	169	1,201
Repurchase of common stock	(3,704)	(3,171)
Net cash used in financing activities	(4,383)	(1,970)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	2,274	(1,283)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(15,871)	(1,800)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	88,438	72,869
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 72,567	$ 71,069
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for income taxes	$ 6,097	$ 11,159
Non-cash investing and financing activities		
Accrued property and equipment purchases	$ 490	$ 665
Unrealized gain (loss) on marketable securities	$ 683	$ (318)

See accompanying notes to the consolidated financial statements.

1. The Company

Our business is composed 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. Our molecular collections systems or "DNAG" business consists of the development, manufacture, marketing 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 collection kits are also used for the collection of first-void urine for liquid biopsy in the prostate and bladder cancer markets, and in the sexually transmitted infection screening market. In addition, our DNAG business provides microbiome laboratory services that accelerate research and discovery for customers in the pharmaceutical, agricultural, and academic research 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, 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 subsidiaries, DNA Genotek Inc. ("DNAG"), CoreBiome Inc. ("CoreBiome"), and Novosanis NV ("Novosanis"). DNAG's specimen collection devices provide all-in-one systems for the collection, stabilization, transportation and storage of nucleic acids from human saliva and other sample types for genetic and microbiome applications. Novosanis' Colli-Pee collection device is designed for the volumetric collection of first-void urine for use in research, screening and diagnostics for the liquid biopsy and sexually transmitted disease markets. We also sell research use only sample collection products into the microbiome and tuberculosis markets and we offer our customers a suite of genomics and microbiome services, which range from package customization and study design optimization to extraction, analysis and reporting services. We serve customers worldwide in the research, healthcare, pharmaceutical and agricultural communities.

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 subsidiaries, DNAG, CoreBiome, and Novosanis. All intercompany transactions and balances have been eliminated. References herein to "we," "us," "our," or the "Company" mean OraSure and its consolidated subsidiaries, 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, 2018. Results of operations for the three and six months ended June 30, 2019 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, contingent consideration, 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 consist of guaranteed investment certificates and corporate bonds with purchased maturities greater than ninety days. Available-for-sale debt securities are carried at fair value, based upon quoted market prices, with unrealized gains and losses, if any, reported in stockholders' equity as a component of accumulated other comprehensive loss.

The following is a summary of our available-for-sale securities as of June 30, 2019 and December 31, 2018:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
June 30, 2019				
Guaranteed investment certificates	$ 24,193	$ —	$ —	$ 24,193
Corporate bonds	90,042	230	(464)	89,808
Total available-for-sale securities	$ 114,235	$ 230	$ (464)	$ 114,001
December 31, 2018				
Guaranteed investment certificates	$ 23,096	$ —	$ —	$ 23,096
Corporate bonds	90,707	—	(917)	89,790
Total available-for-sale securities	$ 113,803	$ —	$ (917)	$ 112,886
At June 30, 2019, maturities of our available-for-sale securities were as follows:				
Less than one year	$ 74,710	$ 141	$ (405)	$ 74,446
Greater than one year	$ 39,525	$ 89	$ (59)	$ 39,555

Fair Value of Financial Instruments. As of June 30, 2019 and December 31, 2018, the carrying values of cash and cash equivalents, 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 June 30, 2019 and December 31, 2018.

Included in cash and cash equivalents at June 30, 2019 and December 31, 2018, was $7,399 and $21,631 invested in government money market funds and certificates of deposit. Both are measured as Level 1 instruments.

We offer a nonqualified deferred compensation plan for certain eligible employees and members of our Board of Directors. The assets of the plan are held in the name of the Company at a third-party financial institution. Separate accounts are maintained for each participant to reflect the amounts deferred by the participant and all earnings and losses on those deferred amounts. The assets of the plan are held in mutual funds and Company stock. The fair value of the plan assets as of June 30, 2019 and December 31, 2018 was $4,227 and $3,884, 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.

See Note 3 for discussion of the contingent consideration liabilities.

Accounts Receivable. Accounts receivable have been reduced by an estimated allowance for amounts that may become uncollectible in the future. This estimated allowance is based primarily on management's evaluation of specific balances as they become past due, the financial condition of our customers and our historical experience related to write-offs.

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

	June 30, 2019	December 31, 2018
Raw materials	$ 15,551	$ 14,092
Work in process	650	544
Finished goods	9,469	8,252
	$ 25,670	$ 22,888

Property, Plant and Equipment. Property, plant 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, plant and equipment as of June 30, 2019 and December 31, 2018 was $45,040 and $42,797, respectively.

Intangible Assets. Intangible assets consist of customer lists, 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 five to fifteen years. Accumulated amortization of intangible assets as of June 30, 2019 and December 31, 2018 was $21,984 and $20,105, respectively. The change in intangibles from $5,137 as of December 31, 2018 to $12,472 as of June 30, 2019 is a result of intangibles acquired in our acquisitions of CoreBiome and Novosanis of $8,400 and $163 in foreign currency translation gains, partially offset by $1,228 in amortization expense.

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 acquisitions of DNAG, CoreBiome, and Novosanis. 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.

The increase in goodwill from $18,521 as of December 31, 2018 to $29,280 as of June 30, 2019 is a result of the additional goodwill associated with our acquisitions of CoreBiome and Novosanis of $9,994 and an increase of $765 associated with foreign currency translation. All acquired goodwill has been allocated to our DNAG segment.

Leases. In February 2016, the FASB issued ASU No. 2016-02, Leases. The standard requires lessees to recognize lease assets and lease liabilities on the balance sheet and requires expanded disclosures about leasing arrangements. We adopted this standard on January 1, 2019 on a modified retrospective basis and will not restate comparative amounts. Also, we elected the practical expedients permitted under the transition guidance, which allows us to carryforward our historical lease classification, our assessment on whether a contract is or contains a lease, and our initial direct costs for any leases that exist prior to adoption of the new standard. Leases with an initial term of 12 months or less are not recognized on the balance sheet and the associated lease payments are included in the consolidated statements of operations on a straight-line basis over the lease term. As a result, on January 1, 2019, we recorded right-of-use assets of $4,027 and lease liabilities of $4,263 on our consolidated balance sheet.

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
Net income	$ 4,398	$ 4,121	$ 1,140	$ 2,002
Weighted-average shares of common stock outstanding:				
Basic	61,709	61,100	61,621	60,983
Dilutive effect of stock options, restricted stock, and performance stock units	419	1,144	570	1,396
Diluted	62,128	62,244	62,191	62,379
Earnings per share:				
Basic	$ 0.07	$ 0.07	$ 0.02	$ 0.03
Diluted	$ 0.07	$ 0.07	$ 0.02	$ 0.03

For the three months ended June 30, 2019 and 2018, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 698 and 210 shares, respectively, were excluded from the computation of diluted earnings per share as their inclusion would have been anti-dilutive. For the six months ended June 30, 2019 and 2018, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 222 and 205 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 operations in the period in which the change occurs. Net foreign exchange gains (losses) resulting from foreign currency transactions that are included in other income in our consolidated statements of operations were $(317) and $91 for the three months ended June 30, 2019 and 2018, respectively. Net foreign exchange gains (losses) were $(926) and $345 for the six months ended June 30, 2019 and 2018, 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 we have defined the Euro as the functional currency of our Belgian subsidiary, Novosanis. The results of operations for those subsidiaries are translated into U.S. dollars, which is the reporting currency of the Company. Accumulated other comprehensive loss at June 30, 2019 consists of $13,081 of currency translation adjustments and $234 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, 2018 consists of $17,789 of currency translation adjustments and $917 of net unrealized losses on marketable securities.

Recent Accounting Pronouncements

In June 2016, the FASB issued guidance on the measurement of credit losses, which requires measurement and recognition of expected credit losses for financial assets, including trade receivables and capital lease receivables, held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. The method to determine a loss is different from the existing guidance, which requires a credit loss to be recognized when it is probable. The guidance is effective beginning in fiscal year 2020, with early adoption permitted beginning in fiscal year 2020. We are evaluating the impact this guidance will have on our consolidated financial statements.

In February 2018, the FASB issued guidance allowing a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the U.S. Tax Cuts and Jobs Act. The guidance is effective in fiscal year 2020, with early adoption permitted, including adoption in an interim period. If elected, the reclassification can be applied in either the period of adoption or retrospectively to the period of the enactment of the U.S. Tax Cuts and Jobs Act (i.e., our first quarter of fiscal year 2018). We are evaluating the impact of this guidance and expect no impact to our consolidated financial statements.

3. Business Combinations

On January 4, 2019, the Company acquired all of the outstanding stock of CoreBiome, pursuant to the terms of a merger agreement, dated January 3, 2019. Also on January 4, 2019, the Company, through a wholly-owned subsidiary, acquired all of the outstanding stock of Novosanis, pursuant to a share purchase agreement, dated January 3, 2019. We began operating these entities as of the January 4, 2019 closing date. The aggregate purchase price for both of these transactions was $13,320 adjusted for certain transaction costs, indebtedness, and holdback amounts, and was funded with cash on hand. A portion of the purchase price was deposited into escrow accounts for a limited period after closing, in order to secure the potential payment of certain indemnification obligations of the selling stockholders under each agreement noted above.

During the six months ended June 30, 2019, we incurred a total of $597 of acquisition-related costs, including success-based investment banking fees and accounting, legal and other professional fees, related to both acquisitions, all of which were expensed and reported as a component of general and administrative expenses in the consolidated statement of income.

Pursuant to our acquisition agreements, we may pay up to an additional $32,400 of contingent consideration over the next three years based on the achievement of certain performance criteria as defined under the agreements, including generating certain revenue dollars, the achievement of a large customer contract, and the development of certain new technology. The Company, with the assistance of an independent valuation specialist, utilized a Monte Carlo simulation to determine the estimated acquisition-date fair value of the acquisition-related contingent consideration of $4,350. The simulation calculates the probability-weighted payments based on our assessment of the likelihood that the benchmarks will be achieved. The probability-weighted payments were then discounted using a discount rate based on an internal rate of return analysis using the probability-weighted cash flows. The fair value measurement was based on significant inputs, including revenue forecasts, not observable in the market and thus represents a Level 3 measurement within the fair value hierarchy. The fair value of the contingent consideration is reviewed quarterly over the earn-out period to compare actual results with the estimates used in our forecasts. The change in the fair value of the contingent consideration obligation from $4,350 as of the acquisition date to $5,898 as of June 30, 2019 is a result of changes in our estimated revenue forecasts and the probability of achieving certain technical milestones.

The following table summarizes the preliminary estimated fair values of the assets acquired and liabilities assumed as of the acquisition date:

Assets Acquired		
Accounts receivable	$	791
Inventories		310
Other current assets		82
Property, plant, and equipment, net		414
Other assets		5
Acquired intangible assets		8,400
Goodwill		9,994
Total assets acquired		19,996
Liabilities Assumed		
Current liabilities		1,180
Notes payable, short-term		730
Deferred tax liability		445
Other long-term liabilities		74
Total liabilities assumed		2,429
Net Assets Acquired		17,567
Estimated fair value of contingent consideration		(4,350)
Net Cash Paid (net of cash acquired of $103)	$	13,217

The purchase price was allocated to the tangible assets and identifiable intangible assets acquired and liabilities assumed based on their acquisition-date estimate fair values. The identifiable intangible assets principally included developed technology, customer relationships, and tradenames, all of which are subject to amortization on a straight-line basis and are being amortized over estimated useful lives as summarized below:

Description	Estimated Useful Life (in yrs)		Amount
Developed Technology	10	$	5,000
Customer relationships	10		2,200
Tradenames	8.34		1,200
Total acquired intangibles		$	8,400

The Company, with the assistance of an independent valuation specialist, assessed the fair value of the assets of CoreBiome and Novosanis. The income approach was used to value the acquired intangibles and the fair value measurements were primarily based on significant inputs that are not observable in the market and are considered Level 3 fair value measurements. The income approach estimates fair value for an asset based on the present value of cash flows projected to be generated by the asset. Projected cash flows are discounted at a required rate of return that reflects the relative risk of achieving the cash flows and the time value of money.

The useful lives of the intangible assets were estimated based on the expected future economic benefit of the assets and are being amortized over the estimated useful life in proportion to the economic benefits consumed using the straight-line method.

The amortization of intangible assets is not deductible for income tax purposes.

Goodwill is calculated as the difference between the acquisition date fair value of the consideration transferred and the fair value of the net assets acquired, and represents the future economic benefits that we expect to achieve as a result of the acquisition. We believe the goodwill related to the acquisitions was a result of providing us a complementary service and product offering that will enable us to leverage those services and products with existing and new customers. The goodwill is not deductible for income tax purposes. All of the goodwill identified above has been allocated to our DNAG segment.

We continue to evaluate the fair value of certain assets acquired and liabilities assumed, including the fair valuation of deferred tax assets acquired, related to the acquisition. Additional information, which existed as of the acquisition date, but was at that time unknown to us, may become known during the remainder of the measurement period. Changes to amounts recorded as a result of the final determination may result in a corresponding adjustment to these assets and liabilities, including goodwill. The determination of the estimated fair values of all assets acquired is expected to be completed within one year from the date of acquisition.

Revenues from CoreBiome primarily consist of microbiome laboratory services that utilize optimal analytical algorithms to deliver speed and scalability in the lab with precise analytics. Revenues from Novosanis primarily consist of the sale of its Colli-Pee collection device which was designed for the standard collection of first-void urine used in the liquid biopsy and sexually transmitted infection screening market. For the three and six months ended June 30, 2019, combined revenues of $907 and $2,046 and net losses of $1,112 and $2,613 associated with the operations of CoreBiome and Novosanis, were included in our consolidated statement of operations since the acquisition date. Effective as of January 4, 2019, the financial results of CoreBiome and Novosanis are included in our DNAG segment.

Unaudited Pro Forma Financial Information

The unaudited pro forma results presented below include the results of the CoreBiome and Novosanis acquisitions as if they had been consummated as of January 1, 2018. The unaudited pro forma results include the amortization associated with acquired intangible assets and the estimated tax effect of adjustments to income before income taxes but do not include changes in the fair value of our contingent consideration obligations. Material nonrecurring charges, directly attributable to the transactions, including direct acquisition costs, are also excluded. In addition, the unaudited pro forma results do not include any expected benefits of the acquisitions. Accordingly, the unaudited pro forma results are not necessarily indicative of either future results of operations or results that might have been achieved had the acquisitions been consummated as of January 1, 2018.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenue	$ 38,826	$ 44,129	$ 68,948	$ 86,522
Net income (loss)	4,398	3,179	1,737	(314)
Net income (loss) per share, basic and diluted	0.07	0.05	0.03	(0.01)

4. Revenues

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
OraQuick®	$ 12,967	$ 15,791	$ 24,557	$ 28,796
Oragene®	10,904	14,421	15,726	30,349
ORAcollect®	3,318	947	6,543	2,107
Intercept®	2,070	2,154	3,914	4,069
Histofreezer®	2,935	1,973	5,149	4,327
Other products	5,073	3,532	9,710	7,488
Net product revenues	37,267	38,818	65,599	77,136
Royalty income	1,114	2,092	2,198	3,694
Research and development funding	441	1,920	862	3,458
Charitable support reimbursement	-	795	118	1,324
Grant funding	4	-	171	
Other revenues	1,559	4,807	3,349	8,476
Net revenues	$ 38,826	$ 43,625	$ 68,948	$ 85,612

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
United States	$ 27,902	$ 31,991	$ 48,467	$ 62,977
Europe	2,990	2,308	5,421	5,205
Other regions	7,934	9,326	15,060	17,430
	$ 38,826	$ 43,625	$ 68,948	$ 85,612

Customer and Vendor Concentrations. We had no significant customer concentrations (greater than 10%) in accounts receivable as of June 30, 2019 or December 31, 2018, respectively. One of our customers accounted for approximately 13% of our net consolidated revenues for the three months ended June 30, 2019. We had no customer concentrations in our net consolidated revenues for the six months ended June 30, 2019. One of our customers accounted for approximately 18% and 21% of our net consolidated revenues for the three and six months ended June 30, 2018.

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.

Deferred Revenue. We record deferred revenue when funds are received prior to the recognition of the associated revenue. Deferred revenue as of June 30, 2019 and December 31, 2018 includes customer prepayments of $2,291 and $2,057, respectively. Deferred revenue as of June 30, 2019 and December 31, 2018 also includes $ 1,623 *and $1,464, 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.*

5. Accrued Expenses

	June 30, 2019	December 31, 2018
Payroll and related benefits	$ 5,413	$ 8,926
Professional fees	1,160	1,541
Income taxes payable	—	1,447
Other	2,065	1,947
	$ 8,638	$ 13,861

6. Credit Facility

On March 29, 2019, we terminated our credit agreement with a commercial bank which was entered into on September 30, 2016 and had a maturity date of September 30, 2019.

7. Leases

In February 2016, the FASB issued ASU No. 2016-02, Leases. The standard requires lessees to recognize lease assets and lease liabilities on the balance sheet and requires expanded disclosures about leasing arrangements. We adopted this standard on January 1, 2019 on a modified retrospective basis and will not restate comparative amounts.

We determine whether an arrangement is a lease at inception. We have operating and finance leases for corporate offices, warehouse space and equipment (including vehicles). As of June 30, 2019, we are the lessee in all agreements. Our leases have remaining lease terms of 1 to 8 years, some of which include options to extend the leases based on agreed upon terms, and some of which include options to terminate the leases within 1 year.

As most of our leases do not provide an implicit rate, we use our incremental borrowing rate based on the information available at the lease commencement date in determining the present value of lease payments.

We have lease agreements that contain both lease and non-lease components (e.g., common-area maintenance). For these agreements, we account for lease components separate from non-lease components.

The components of lease expense are as follows:

	Three months ended June 30, 2019	Six months ended June 30, 2019
Operating Lease Cost	$ 232	$ 463
Finance Lease Cost		
Amortization of right-of use assets	113	152
Interest on lease liabilities	9	13
Total Finance Lease Cost	$ 122	$ 165

Lease cost for the three and six months ended June 30, 2018 was $388 and $730.

Supplemental cash flow information related to leases is as follows:

	Three months ended June 30, 2019	Six months ended June 30, 2019
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 230	$ 458
Operating cash flows from financing leases	10	13
Financing cash flows from financing leases	89	124
Non-cash activity		
Right-of-use assets obtained in exchange for operating lease obligations	-	240
Right-of-use assets obtained in exchange for finance lease obligations	82	1,249

Supplemental balance sheet information related to leases is as follows:

	June 30, 2019
Operating Leases	
Right-of-use assets	$ 3,685
Current lease liabilities	746
Non-current lease liabilities	3,266
Total operating lease liabilities	$ 4,012
Finance Leases	
Right-of-use assets	$ 1,462
Current lease liabilities	448
Non-current lease liabilities	930
Total finance lease liabilities	$ 1,378
Weighted Average Remaining Lease Term	
Weighted-average remaining lease term—operating leases	5.11
Weighted-average remaining lease term—finance leases	3.46
Weighted Average Discount Rate	
Weighted-average discount rate—operating leases	4.24%
Weighted-average discount rate—finance leases	2.86%

As of June 30, 2019, minimum lease payments by period are expected to be as follows:

	Finance	Operating
2019 (excluding the six months ended June 30, 2019)	$ 240	$ 465
2020	454	957
2021	325	928
2022	324	903
2023	94	543
Thereafter	4	815
Total Minimum Lease Payments	1,441	4,611
Less: imputed interest	(63)	(599)
Present Value of Lease Liabilities	$ 1,378	$ 4,012

As of December 31, 2018, minimum lease payments under non-cancelable operating leases by period were expected to be as follows:

2019	$ 903
2020	902
2021	877
2022	850
2023	506
Thereafter	737
	$ 4,775

8. Stockholders' Equity

Reconciliation of the changes in stockholders' equity for the three and six months ended June 30, 2019 and 2018

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balance at December 31, 2018	61,276	$ —	$ 401,273	$ (18,706)	$ (99,189)	$ 283,378
Common stock issued upon exercise of options	4	—	22	—	—	22
Vesting of restricted stock and performance stock units	664	—	—	—	—	—
Purchase and retirement of common shares	(277)	—	(3,595)	—	—	(3,595)
Compensation cost for restricted stock	—	—	653	—	—	653
Compensation cost for stock option grants	—	—	324	—	—	324
Compensation cost for performance stock units	—	—	254	—	—	254
Net loss	—	—	—	—	(3,258)	(3,258)
Currency translation adjustments				2,232		2,232
Unrealized gain on marketable securities	—	—	—	497	—	497
Balance at March 31, 2019	61,667	$ —	$ 398,931	$ (15,977)	$ (102,447)	$ 280,507
Common stock issued upon exercise of options	18	—	147	—	—	147
Vesting of restricted stock and performance stock units	51	—	—	—	—	—
Purchase and retirement of common shares	(11)	—	(109)	—	—	(109)
Compensation cost for restricted stock	—	—	874	—	—	874
Compensation cost for stock option grants	—	—	311	—	—	311
Compensation cost for performance stock units	—	—	(569)	—	—	(569)
Net income	—	—	—	—	4,398	4,398
Currency translation adjustments				2,476		2,476
Unrealized gain on marketable securities	—	—	—	186	—	186
Balance at June 30, 2019	61,725	$ —	$ 399,585	$ (13,315)	$ (98,049)	$ 288,221

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
Balance at December 31, 2017	60,662	$ —	$ 387,931	$ (10,340)	$ (119,510)	$ 258,081
Adoption of ASU 2014-9					(75)	(75)
Common stock issued upon exercise of options	133	—	974	—	—	974
Vesting of restricted stock and performance stock units	407	—	—	—	—	—
Purchase and retirement of common shares	(149)	—	(2,959)	—	—	(2,959)
Compensation cost for restricted stock	—	—	3,626	—	—	3,626
Compensation cost for stock option grants	—	—	900	—	—	900
Compensation cost for performance stock units	—	—	2,957	—	—	2,957
Net loss	—	—	—	—	(2,119)	(2,119)
Currency translation adjustments				(2,154)		(2,154)
Unrealized loss on marketable securities	—	—	—	(512)	—	(512)
Balance at March 31, 2018	61,053	$ —	$ 393,429	$ (13,006)	$ (121,704)	$ 258,719
Adoption of ASU 2014-9						—
Common stock issued upon exercise of options	29	—	222	—	—	222
Vesting of restricted stock and performance stock units	106	—	—	—	—	—
Purchase and retirement of common shares	(14)	—	(212)	—	—	(212)
Compensation cost for restricted stock	—	—	1,419	—	—	1,419
Compensation cost for stock option grants	—	—	475	—	—	475
Compensation cost for performance stock units	—	—	1,885	—	—	1,885
Net income	—	—	—	—	4,121	4,121
Currency translation adjustments				(1,652)		(1,652)
Unrealized gain on marketable securities	—	—	—	194	—	194
Balance at June 30, 2018	61,174	$ —	$ 397,218	$ (14,464)	$ (117,583)	$ 265,171

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 account for stock-based compensation to employees and directors using the fair value method. 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, issuance of restricted stock, or redemption of performance-based restricted stock units, we issue new shares rather than shares purchased on the open market.

Total compensation cost related to stock options for the six months ended June 30, 2019 and 2018 was $635 and $1,375 respectively.

Compensation cost of $1,527 and $5,045 related to restricted shares was recognized during the six months ended June 30, 2019 and 2018, respectively. In connection with the vesting of restricted shares during the six months ended June 30, 2019 and 2018, we purchased and immediately retired 288 and 163 shares with aggregate values of $3,704 and $3,171, 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 generally 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.

Compensation cost of $(315) and $4,842 related to PSUs was recognized during the six months ended June 30, 2019 and 2018, respectively.

Modification of Grants

Stock compensation costs for the three and six months ended June 30, 2018 include the additional expense associated with modifications of existing grants held by our retired President and Chief Executive Officer (“CEO”) and our Chief Financial Officer (“CFO”). These additional costs were $2,188 and $8,039 during the three and six months ended June 30, 2018, respectively, and are 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 six months ended June 30, 2019 and 2018.

9. Income Taxes

During the three and six months ended June 30, 2019, we recorded income tax expense of $1,411 and $1,382, respectively. During the three and six months ended June 30, 2018, we recorded tax expense of $2,173 and $4,206, respectively.

Tax expense reflects taxes due to the taxing authorities and the tax effects of temporary differences between the basis of assets and liabilities recognized for financial reporting and tax purposes, and net operating loss and tax credit carryforwards. The significant components of our total deferred tax liability as of June 30, 2019 and December 31, 2018 relate to the tax effects of the basis difference between the intangible assets acquired in our acquisitions for financial reporting and for tax purposes.

In 2008, we established a full valuation allowance against our U.S. deferred tax asset. Management believes the full valuation allowance is still appropriate at both June 30, 2019 and December 31, 2018 since the facts and circumstances necessitating the allowance have not changed. As a result, no U.S. federal or state deferred income tax expense or benefit was recorded for the three and six month period ended June 30, 2019.

10. 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.

11. Transition Costs

In January 2018, we announced the retirement of Douglas A. Michels, our then President and CEO, and Ronald H. Spair, our then 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 Mr. 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 Mr. Spair, who retired as CFO and Chief Operating Officer, and as a member of our Board of Directors, on that same date. Charges associated with these transitions were $2,188 and $8,628 during the three and six months ended June 30, 2018 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 related transition costs were recorded during the three and six months ended June 30, 2019.

12. Business Segment Information

Our business consists 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. Our molecular collections systems or “DNAG” business consists of the development, manufacture, marketing 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 collection kits are also used for the collection of first-void urine for liquid biopsy in the prostate and bladder cancer markets; and in the sexually transmitted infection screening market. In addition, our DNAG business provides microbiome laboratory services that accelerate research and discovery for customers in the pharmaceutical, agricultural, and academic research markets. Effective as of January 4, 2019, the financial results of CoreBiome and Novosanis are included in our DNAG segment.

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.

Operating income (loss) for the three and six months ended June 30, 2018 has been modified to conform to the classification of the intercompany service fee presentation for 2019. Beginning with the first quarter of 2019, we have included the fees for intercompany services in our segment operating income (loss) in order to more accurately reflect the results of each segment.

The following table summarizes operating segment information for the three and six months ended June 30, 2019 and 2018, and asset information as of June 30, 2019 and December 31, 2018:

	Three Months Ended June 30, 2019	Three Months Ended June 30, 2018	Six Months Ended June 30, 2019	Six Months Ended June 30, 2018
Net revenues:				
OSUR	$ 20,372	$ 24,341	$ 38,605	$ 46,365
DNAG	18,454	19,284	30,343	39,247
Total	$ 38,826	$ 43,625	$ 68,948	$ 85,612
Operating income (loss):				
OSUR	$ 14	$ (2,666)	$ (3,485)	$ (11,310)
DNAG	5,271	8,224	4,959	16,370
Total	$ 5,285	$ 5,558	$ 1,474	$ 5,060
Depreciation and amortization:				
OSUR	$ 844	$ 993	$ 1,666	$ 2,004
DNAG	1,040	885	1,944	1,742
Total	$ 1,884	$ 1,878	$ 3,610	$ 3,746
Capital expenditures:				
OSUR	$ 1,616	$ 1,358	$ 3,545	$ 2,774
DNAG	1,269	1,229	1,968	1,710
Total	$ 2,885	$ 2,587	$ 5,513	$ 4,484

	June 30, 2019	December 31, 2018
Total assets:		
OSUR	$ 173,390	$ 190,178
DNAG	154,075	125,393
Total	$ 327,465	$ 315,571

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, losses, expenses, or other financial performance, future product performance or development, expected regulatory filings and approvals, planned business transactions, expected manufacturing performance, 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 words such as "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 successfully manage and integrate acquisitions of other companies in a manner that complements or leverages our existing business, or otherwise expands or enhances our portfolio of products and our end-to-end service offerings, and the diversion of management's attention from our ongoing business and regular business responsibilities to effect such integration; the expected economic benefits of acquisitions (and increased returns for our stockholders), including that the anticipated synergies, revenue enhancement strategies and other benefits from the acquisitions may not be fully realized or may take longer to realize than expected and our actual integration costs may exceed our estimates; ability to market and sell products, whether through our internal, direct sales force or third parties; impact of significant customer concentration in the genomics business; failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our products; 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 the Company's 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; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products; market acceptance of oral fluid or urine testing, collection or other products; market acceptance and uptake of microbiome informatics, microbial genetics technology and related analytics services; 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; impact of increased reliance on U.S. government contracts; impact of negative economic conditions; 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 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, 2018, 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 consists 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. Our molecular collections systems or "DNAG" business consists of the development, manufacture, marketing 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 collection kits are also used for the collection of first-void urine for liquid biopsy in the prostate and bladder cancer markets and in the sexually transmitted infection screening market. In addition, our DNAG business provides microbiome laboratory services that accelerate research and discovery for customers in the pharmaceutical, agricultural, and research 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, 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 subsidiaries, DNA Genotek Inc. ("DNAG"), CoreBiome Inc. ("CoreBiome"), and Novosanis NV ("Novosanis"). DNAG's specimen collection devices provide all-in-one systems for the collection, stabilization, transportation and storage of nucleic acids from human saliva and other sample types for genetic and microbiome applications. Novosanis' Colli-Pee collection device is designed for the volumetric collection of first-void urine for use in research, screening and diagnostics for the liquid biopsy and sexually transmitted disease markets. We also sell research use only sample collection products into the microbiome and tuberculosis markets and we offer our customers a suite of genomics and microbiome services, which range from package customization and study design optimization to extraction, analysis and reporting services. We serve customers worldwide in the research, healthcare, pharmaceutical and agricultural communities.

Current Consolidated Financial Results

During the six months ended June 30, 2019, our consolidated net revenues decreased 19% to $68.9 million, compared to $85.6 million for the six months ended June 30, 2018. Net product revenues during the six months ended June 30, 2019 decreased 15% when compared to the first half of 2018, primarily due to lower sales of our genomics and OraQuick® HIV products. Partially offsetting these decreases were higher sales of our microbiome and OraQuick® HCV products and higher cryosurgical systems sales. Other revenues for the first half of 2019 were $3.3 million compared to $8.5 million in the same period of 2018. Other revenues in the first half of 2019 consisted of royalty income of $2.2 million and other revenues of $1.1 million associated with funded research and development, reimbursement of certain costs under our charitable support agreement with the Bill & Melinda Gates Foundation ("Gates Foundation"), and grant revenue. Other revenues in the first half of 2018 consisted of royalty income of $3.7 million and $4.8 million of other revenue associated with funded research and development and cost reimbursement from the Gates Foundation.

Our consolidated net income for the six months ended June 30, 2019 was $1.1 million, or $0.02 per share on a fully diluted basis, compared to consolidated net income of $2.0 million, or $0.03 per share on a fully diluted basis, for the six months ended June 30, 2018. Results in the first half of 2019 included $1.5 million of a non-cash pre-tax charge associated with the change in the fair value of our acquisition-related contingent consideration and $597,000 of acquisition-related transaction costs. The combined impact of these charges reduced earnings per share by approximately $0.03. Results for the first half of 2018 included $8.6 million of management transition costs associated with the 2018 retirement of Douglas A. Michels, our then President and Chief Executive Officer ("CEO"), and Ronald H. Spair, our then Chief Financial Officer ("CFO") and Chief Operating Officer, and the appointment of their successors, which approximated $0.14 per share.

Cash provided by operating activities for the six months ended June 30, 2019 was $4.7 million. Cash provided by operating activities during the six months ended June 30, 2018 was $13.9 million. As of June 30, 2019, we had $186.6 million in cash, cash equivalents, and available-for-sale securities, compared to $201.3 million at December 31, 2018.

Results of Operations

Three months ended June 30, 2019 compared to June 30, 2018

CONSOLIDATED NET REVENUES

The table below shows a breakdown of total consolidated net revenues (dollars in thousands) generated by each of our business segments for the three months ended June 30, 2019 and 2018.

	Three Months Ended June 30,				
	Dollars			Percentage of Total Net Revenues	
	2019	2018	% Change	2019	2018
OSUR	$ 19,963	$ 21,626	(8) %	51 %	50 %
DNAG	17,304	17,192	1	45	39
Net product revenues	37,267	38,818	(4)	96	89
Other	1,559	4,807	(68)	4	11
Net revenues	$ 38,826	$ 43,625	(11) %	100 %	100 %

Consolidated net product revenues decreased 4% to $37.3 million in the second quarter of 2019 from $38.8 million in the comparable period of 2018. Lower sales of our OraQuick® HIV and genomics products and lower international sales of our OraQuick® HCV test were partially offset by higher sales of cryosurgical system products, higher microbiome sales and higher domestic sales of our OraQuick® HCV test. Other revenues for the second quarter of 2019 were $1.6 million compared to $4.8 million in the same period of 2018. Other revenues in the second quarter of 2019 included $1.1 million in royalty income earned under a litigation settlement agreement and $445,000 in research and development funding and grant revenue. Other revenues in the second quarter of 2018 consisted of $2.1 million in royalty income and $2.7 million in research and development funding and cost reimbursement from the Gates Foundation.

Consolidated net revenues derived from products sold to customers outside of the United States were $10.9 million and $11.6 million, or 28% and 27% of total net revenues, in the second quarters of 2019 and 2018, respectively. Because the majority of our international sales are denominated in U.S. dollars, the impact of fluctuating foreign currency exchange rates was not material to our total consolidated net revenues.

Net Revenues by Segment

OSUR Segment

The table below shows a breakdown of total net revenues (dollars in thousands) generated by our OSUR segment during the second quarters of 2019 and 2018.

	Three Months Ended June 30,				
	Dollars			Percentage of Total Net Revenues	
Market	2019	2018	% Change	2019	2018
Infectious disease testing	$ 13,348	$ 15,919	(16) %	66 %	65 %
Risk assessment testing	3,097	3,315	(7)	15	14
Cryosurgical systems	3,518	2,392	47	17	10
Net product revenues	19,963	21,626	(8)	98	89
Other	409	2,715	(85)	2	11
Net revenues	$ 20,372	$ 24,341	(16) %	100 %	100 %

Infectious Disease Testing Market

Sales to the infectious disease testing market decreased 16% to $13.3 million in the second quarter of 2019 from $15.9 million in the second quarter of 2018. This decrease resulted from lower domestic and international sales of our OraQuick® HIV products and lower international sales of our professional OraQuick® HCV products, partially offset by higher domestic sales of our professional OraQuick® HCV products.

The table below shows a breakdown of our total net OraQuick® HIV and HCV product revenues (dollars in thousands) during the second quarters of 2019 and 2018.

	Three Months Ended June 30,		
Market	2019	2018	% Change
Domestic HIV	$ 4,460	$ 5,189	(14) %
International HIV	5,422	7,397	(27)
Net HIV revenues	9,882	12,586	(21)
Domestic HCV	2,102	1,730	22
International HCV	983	1,473	(33)
Net HCV revenues	3,085	3,203	(4)
Net OraQuick® revenues	$ 12,967	$ 15,789	(18) %

Domestic OraQuick® HIV sales decreased 14% to $4.5 million for the three months ended June 30, 2019 from $5.2 million for the three months ended June 30, 2018. This decrease was primarily the result of reduced sales of our professional product due to price competition and competition from fourth generation automated HIV immunoassays performed in a laboratory and customer ordering patterns.

International sales of our OraQuick® HIV test during the second quarter of 2019 decreased 27% to $5.4 million for the three months ended June 30, 2019 from $7.4 million for the three months ended June 30, 2018. This decrease was largely due to the timing of orders of our OraQuick® HIV Self-Test placed by our customers in Africa, partially offset by higher sales of this product into Asia and certain parts of Europe. Product revenues in the second quarter of 2019 and 2018 included approximately $1.1 million and $1.7 million, respectively, of support payments under the charitable support agreement with the Gates Foundation.

Domestic OraQuick® HCV sales increased 22% to $2.1 million in the second quarter of 2019 from $1.7 million in the second quarter of 2018 primarily due to increased government funding that allowed for the expansion of existing HCV programs and the addition of new programs as well as customer ordering patterns.

International OraQuick® HCV sales decreased 33% to $983,000 in the second quarter of 2019 from $1.5 million in the second quarter of 2018 due to the timing of customer orders.

Risk Assessment Market

Sales to the risk assessment market decreased 7% to $3.1 million in the second quarter of 2019 compared to $3.3 million in the second quarter of 2018 due to the continued reduction in pre-employment drug screening as employers move to more questionnaire-based evaluations for new employees.

Cryosurgical Market

Sales of our cryosurgical products increased 47% to $3.5 million in the second quarter of 2019 from $2.4 million in the second quarter of 2018 due to higher sales in the international over-the-counter markets and the domestic professional market.

Other revenues

Other revenues in the second quarter of 2019 decreased 85% to $409,000 from $2.7 million in the second quarter of 2018. Revenue associated with funding of our research and development efforts decreased to $409,000 in the second quarter of 2019 compared to $1.9 million in the second quarter of 2018 as a result of the completion of our contract with the Biomedical Advanced Research Development Authority (“BARDA”) associated with the development of our Zika product and due to lower spend on the development of our Ebola product as the project reaches completion. During 2018, because of difficulties in completing development and optimizing our Zika test and because of significant uncertainty regarding the commercial demand for this product, the scope of the work covered by this contract was reduced and substantially completed in the first quarter of 2019. Other revenues in the second quarter of 2018 also included $795,000 in reimbursement of certain costs under our charitable support agreement with the Gates Foundation, which are separate from the above-referenced support payments received under the agreement included in product revenues. There were no similar revenues in the second quarter of 2019.

DNAG Segment

Molecular Collection Systems

Sales of our molecular collection systems products decreased 4% to $18.5 million in the second quarter of 2019 from $19.3 million in the second quarter of 2018.

The table below shows a breakdown of our total net molecular collection systems revenues (dollars in thousands) during the second quarters of 2019 and 2018.

	Three Months Ended June 30,		
Market	2019	2018	% Change
Genomics	$ 14,221	$ 15,368	(7) %
Microbiome	2,975	1,824	63
Other product revenues	108	—	100
Net molecular collection systems product and service revenues	$ 17,304	$ 17,192	1
Other	1,150	2,092	(45)
Net molecular collection systems revenues	$ 18,454	$ 19,284	(4) %

Sales of our genomics products decreased 7% to $14.2 million in the second quarter of 2019 compared to $15.4 million in the second quarter of 2018, largely due to lower customer demand, primarily from a large consumer genomics customer that changed its promotional tactics resulting in a change in purchasing patterns.

Microbiome sales increased 63% to $3.0 million in the second quarter of 2019 compared to $1.8 million in the second quarter of 2018 largely due to the inclusion of laboratory service revenues generated by our newly acquired subsidiary, CoreBiome, and increased product sales.

Other product revenues represent sales of our Colli-Pee product sold by our newly acquired subsidiary, Novosanis.

Other revenues in the second quarter of 2019 decreased 45% to $1.2 million from $2.1 million in the second quarter of 2018 largely as a result of lower royalty income partially offset by funded research and development and grant revenues recognized by Novosanis and CoreBiome. Royalty income decreased to $1.1 million in the second quarter of 2019 compared to $2.1 million in the second quarter of 2018.

CONSOLIDATED OPERATING RESULTS

Consolidated gross profit percentage was 64% for the second quarter of 2019 compared to 59% for the second quarter of 2018. Gross profit percentage in the second quarter of 2019 benefited from improved product mix associated with an increase in higher gross profit percentage product sales and lower royalty expense, partially offset by the decrease in other revenues and lower margins generated by CoreBiome and Novosanis.

Consolidated operating income for the second quarter of 2019 was $5.3 million, a $273,000 decrease from the $5.6 million of operating income reported in the second quarter of 2018. Our results for the second quarter of 2019 were negatively impacted by the lower revenues and the inclusion of certain acquisition-related expenses including a $249,000 non-cash charge related to the fair value change of our contingent consideration and the incremental operating expenses incurred by CoreBiome and Novosanis. These increased expenses were partially offset by the absence of $2.2 million of transition costs associated with our 2018 executive management changes which did not reoccur in the second quarter of 2019.

OPERATING INCOME BY SEGMENT

We evaluate performance of our operating segments based on revenue and operating income. Reportable segments have no inter-segment revenue and inter-segment expenses are eliminated in consolidation, including the fees associated with an intercompany service agreement between OSUR and DNAG. For this reason, the intercompany service fees were not reflected in our prior year segment results discussion. However, beginning in 2019 the intercompany service fees have been included in each segments results in order to more accurately reflect the results of each segment. 2018 results have be modified to confirm to this presentation.

OSUR Segment

OSUR's gross profit percentage was 59% in the second quarter of 2019 compared to 55% in the second quarter of 2018. The positive impact of lower royalty expense in the second quarter of 2019 resulting from the expiration of the associated license agreement in 2018 and an improved product mix associated with an increase in higher gross profit percentage product sales was partially offset by a decrease in other revenues that contribute 100% to the gross profit percentage.

Research and development expenses decreased 18% to $2.8 million in the second quarter of 2019 from $3.5 million in the second quarter of 2018 due to the elimination of spending for the development of our Zika project which was completed in early 2019 and lower spending related to our Ebola product which is approaching the end phases of the project, partially offset by increased staffing costs and consulting expenses. Sales and marketing expenses remained consistent at $5.0 million in the second quarter of 2019 and 2018. General and administrative expenses decreased 46% to $4.1 million in the second quarter of 2019 compared to $7.7 million in the second quarter of 2018 largely due to the absence of $2.2 million of transition costs associated with executive management changes which occurred in the second quarter of 2018 and did not reoccur in the second quarter of 2019, a reversal of stock-based compensation expense associated with performance stock grants, and an increase in fees for intercompany services provided by OSUR to DNAG which reduced general and administrative expenses.

All of the above contributed to OSUR's second quarter 2019 operating income of $14,000, which included non-cash charges of $844,000 for depreciation and amortization and $403,000 for stock-based compensation.

DNAG Segment

DNAG's gross profit percentage was 70% in the second quarter of 2019 compared to 64% in the second quarter of 2018. This increase was attributable to improved product mix associated with an increase in higher gross profit percentage product sales partially offset by the decline in other revenues which contribute 100% to the gross profit percentage and lower margins generated by CoreBiome and Novosanis.

Research and development expenses increased 112% to $1.7 million in the second quarter of 2019 from $803,000 in the second quarter of 2018 due to higher staffing costs, higher lab supply and consulting costs in support of bioinformatics and new product initiatives, and the inclusion of research and development expense incurred by CoreBiome and Novosanis. Sales and marketing expenses increased 10% to $2.6 million in the second quarter of 2019 from $2.4 million in the second quarter of 2018 largely due to the inclusion of CoreBiome and Novosanis expenses, partially offset by lower staffing costs. General and administrative expenses increased 218% to $3.1 million in the second quarter of 2019 compared to $982,000 in the second quarter of 2018 largely due to an increase in fees for intercompany services provided by OSUR to DNAG, the inclusion of CoreBiome and Novosanis general and administrative expenses, and increased staffing and consulting costs.

All of the above contributed to DNAG's second quarter 2019 operating income of $5.3 million, which included non-cash charges of $249,000 for the change in the fair value of acquisition-related contingent consideration, $1.0 million for depreciation and amortization, and $212,000 for stock-based compensation.

CONSOLIDATED INCOME TAXES

We continue to believe the full valuation allowance established in 2008 against OSUR's total U.S. deferred tax asset is appropriate as the facts and circumstances necessitating the allowance have not changed. For the three months ended June 30, 2019, $9,000 of state income tax expense was recorded as compared to $0 for the three months ended June 30, 2018. For the three months ended June 30, 2019, foreign tax expense of $1.4 million was recorded as compared to income tax expense of $2.2 million recorded for the three months ended June 30, 2018. The decrease in the foreign income tax expense was directly related to the decrease in income before taxes generated by DNAG and the results generated by Novosanis.

Six months ended June 30, 2019 compared to June 30, 2018

CONSOLIDATED NET REVENUES

The table below shows a breakdown of total consolidated net revenues (dollars in thousands) generated by each of our business segments for the six months ended June 30, 2019 and 2018.

	Six Months Ended June 30,				
	Dollars			Percentage of Total Net Revenues	
	2019	2018	% Change	2019	2018
OSUR	$ 37,713	$ 41,583	(9) %	55 %	48 %
DNAG	27,886	35,553	(22)	40	42
Net product revenues	65,599	77,136	(15)	95	90
Other	3,349	8,476	(60)	5	10
Net revenues	$ 68,948	$ 85,612	(19) %	100 %	100 %

Consolidated net product revenues decreased 15% to $65.6 million in the first six months of 2019 from $77.1 million in the same period of 2018 due to lower sales of our genomics and OraQuick® HIV products. Partially offsetting these decreases were higher sales of our microbiome and OraQuick® HCV products and higher cryosurgical systems sales. Other revenues in the first six months of 2019 were $3.3 million compared to $8.5 million in the same period of 2018. Other revenues in the first half of 2019 included $2.2 million in royalty income earned under a litigation settlement agreement and $1.1 million in research and development funding, reimbursement of certain costs under our charitable support agreement with Gates Foundation, and grant revenue. Other revenues in the first half of 2018 consisted of $3.7 million in royalty income and $4.8 million in research and development funding and cost reimbursement from Gates Foundation.

Consolidated net revenues derived from products sold to customers outside of the United States were $20.5 million and $22.6 million, or 30% and 26% of total net revenues, during the six months ended June 30, 2019 and 2018, respectively. Because the majority of our international sales are denominated in U.S. dollars, the impact of fluctuating foreign currency exchange rates was not material to our total consolidated net revenues.

Net Revenues by Segment

OSUR Segment

The table below shows a breakdown of total net revenues (dollars in thousands) generated by our OSUR segment for the six months ended June 30, 2019 and 2018.

	Six Months Ended June 30,				
	Dollars			Percentage of Total Net Revenues	
Market	2019	2018	% Change	2019	2018
Infectious disease testing	$ 25,686	$ 30,090	(15) %	67 %	65 %
Risk assessment testing	5,934	6,316	(6)	15	14
Cryosurgical systems	6,093	5,177	18	16	11
Net product revenues	37,713	41,583	(9)	98	90
Other	892	4,782	(81)	2	10
Net revenues	$ 38,605	$ 46,365	(17) %	100 %	100 %

Infectious Disease Testing Market

Sales to the infectious disease testing market decreased 15% to $25.7 million for the six months ended June 30, 2019 from $30.1 million for the six months ended June 30, 2018. This decrease resulted from lower sales of our OraQuick® HIV products partially offset by higher sales of our OraQuick® HCV product.

The table below shows a breakdown of our total net OraQuick® HIV and HCV product revenues (dollars in thousands) during the six months ended June 30, 2019 and 2018.

	Six Months Ended June 30,		
Market	2019	2018	% Change
Domestic HIV	$ 8,765	$ 10,234	(14) %
International HIV	9,423	13,067	(28)
Net HIV revenues	18,188	23,301	(22)
Domestic HCV	3,930	3,358	17
International HCV	2,440	2,138	14
Net HCV revenues	6,370	5,496	16
Net OraQuick® revenues	$ 24,558	$ 28,797	(15) %

Domestic OraQuick® HIV sales decreased 14% to $8.8 million for the six months ended June 30, 2019 from $10.2 million for the six months ended June 30, 2018. This decrease was primarily the result of reduced sales of our professional product due to price competition and competition from fourth generation automated HIV immunoassays performed in a laboratory and customer ordering patterns.

International sales of our OraQuick® HIV test during the first half of 2019 decreased 28% to $9.4 million for the six months ended June 30, 2019 from $13.1 million for the six months ended June 30, 2018. This decrease was largely due to the timing of orders of our OraQuick® HIV Self-Test placed by our customers in Africa, partially offset by higher sales of this product in Asia and Europe. Product revenues in the first half of 2019 and 2018 included approximately $1.8 million and $2.7 million, respectively, of support payments under the charitable support agreement with the Gates Foundation.

Domestic OraQuick® HCV sales increased 17% to $3.9 million in the first half of 2019 from $3.4 million in the first half of 2018 primarily due to increased government funding that allowed for expansion of existing HCV programs and the addition of new programs as well as due to customer ordering patterns.

International OraQuick® HCV sales increased 14% to $2.4 million in the first six months of 2019 from $2.1 million in the first six months of 2018, due to the continued expansion in Asia.

Risk Assessment Market

Sales to the risk assessment market slightly decreased 6% to $5.9 million in the first half of 2019 compared to $6.3 million in the first half of 2018 due to the continued reduction in pre-employment drug screening as employers move to more questionnaire-based evaluations for new employees.

Cryosurgical Market

Sales of our cryosurgical products increased 18% to $6.1 million in the first six months of 2019 from $5.2 million in the first six months of 2018 primarily due to higher sales in the international over-the-counter market.

Other revenues

Other revenues in the first half of 2019 decreased 81% to $892,000 from $4.8 million in the first half of 2018. Revenue associated with funding of our research and development efforts decreased to $774,000 in the first half of 2019 compared to $3.5 million in the first half of 2018 as a result of the completion of our contract with the Biomedical Advanced Research Development Authority (“BARDA”) associated with the development of our Zika product and due to lower spend on the development of our Ebola product as the project reaches completion. During 2018, because of difficulties in completing development and optimizing our Zika test and because of significant uncertainty regarding the commercial demand for this product, the scope of the work covered by this contract was reduced and substantially completed in the first quarter of 2019. Other revenues in the first halves of 2019 and 2018 also included $118,000 and $1.3 million 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 the agreement included in product revenues.

DNAG Segment

Molecular Collection Systems

Sales of our molecular collection systems products decreased 23% to $30.3 million in the first six months of 2019 from $39.2 million in the first six months of 2018.

Market	Six Months Ended June 30, 2019		2018		% Change
Genomics	$	22,269	$	32,456	(31) %
Microbiome		5,300		3,097	71
Other product revenues		317		-	N/A
Net molecular collection systems product and service revenues	$	27,886	$	35,553	(22)
Other		2,457		3,694	(33)
Net molecular collection systems revenues	$	30,343	$	39,247	(23) %

Sales of our genomics products decreased 31% in the first half of 2019 compared to the first half of 2018, largely due to lower customer demand, primarily from a large consumer genomics customer that changed its promotional tactics resulting in a change in purchasing patterns.

Microbiome sales increased 71% to $5.3 million in the first half of 2019 compared to $3.1 million in the first half of 2018 largely due to the inclusion of laboratory service revenues generated by our newly acquired subsidiary, CoreBiome, and increased product sales to two large clinical research organizations.

Other product revenues represent sales of our Colli-Pee product sold by our newly acquired subsidiary, Novosanis.

Other revenues in the first half of 2019 decreased 33% to $2.5 million from $3.7 million in the first half of 2018 largely as a result of lower royalty income partially offset by funded research and development and grant revenues recognized by Novosanis and CoreBiome. Royalty income decreased to $2.2 million in the first six months of 2019 compared to $3.7 million in 2018.

CONSOLIDATED OPERATING RESULTS

Consolidated gross profit percentage was 63% for the first half of 2019 compared to 59% for the first half of 2018. Gross profit percentage in the first half of 2019 benefited from improved product mix associated with an increase in higher gross profit percentage product sales and lower royalty expense, partially offset by the decrease in other revenues and the lower margins generated by CoreBiome and Novosanis.

Consolidated operating income for the first half of 2019 was $1.5 million, a $3.6 million decline from the $5.1 million of operating income reported in the first half of 2018. Our results in the first half of 2019 were negatively impacted by the lower revenues and the inclusion of certain acquisition-related expenses including a $1.5 million non-cash charge related to the fair value change of our contingent consideration and $597,000 of transaction costs and the incremental operating expenses incurred by CoreBiome and Novosanis. These increased expenses were partially offset by the absence of $8.6 million of transition costs associated with our 2018 executive management changes which did not reoccur in 2019.

OPERATING INCOME (LOSS) BY SEGMENT

We evaluate performance of our operating segments based on revenue and operating income. Reportable segments have no inter-segment revenue and inter-segment expenses are eliminated in consolidation, including the fees associated with an intercompany service agreement between OSUR and DNAG. For this reason, the intercompany service fees were not reflected in our prior year segment results discussion. However, beginning in 2019 the intercompany service fees have been included in each segments results in order to more accurately reflect the results of each segment. 2018 results have be modified to confirm to this presentation.

OSUR Segment

OSUR's gross profit percentage was 57% in the first half of 2019 compared to 55% in the first half of 2018. The positive impact of lower royalty expense in the first half of 2019 resulting from the expiration of the associated license agreement in 2018 and an improved product mix associated with an increase in higher gross profit percentage product sales was partially offset by a decrease in other revenues that contribute 100% to the gross profit percentage.

Research and development expenses decreased 18% to $5.5 million in the first half of 2019 from $6.8 million in the first half of 2018 due to the elimination of spending for the development of our Zika project which was completed in early 2019 and lower spending related to our Ebola product which is approaching the end phases of the project, partially offset by increased staffing costs and consulting expenses. Sales and marketing expenses decreased 3% to $9.6 million in the first half of 2019 from $9.9 million in the first half of 2018 due to lower staffing, advertising, and commission costs, partially offset by higher consulting expenses. General and administrative expenses decreased 49% to $10.2 million in the first half of 2019 compared to $20.1 million in the first half of 2018 largely due to the absence of $8.6 million of transition costs associated with executive management changes which occurred in the first half of 2018 and did not reoccur in 2019, a reversal of stock compensation expense associated with performance stock grants, and an increase in fees for intercompany services provided by OSUR to DNAG which reduced general and administrative expenses.

All of the above contributed to OSUR's operating loss of $3.5 million in the first half of 2019, which included non-cash charges of $1.7 million for depreciation and amortization and $1.5 million for stock-based compensation.

DNAG Segment

DNAG's gross profit percentage was 70% in the first half of 2019 compared to 63% in the first half of 2018. This increase was attributable to improved product mix associated with an increase in higher gross profit percentage product sales partially offset by the decline in other revenues which contribute 100% to the gross profit percentage and the lower margins generated by CoreBiome and Novosanis.

Research and development expenses increased 114% to $3.4 million in the first half of 2019 from $1.6 million in the first half of 2018 due to higher staffing costs, higher lab supply costs, and the inclusion of research and development expense incurred by CoreBiome and Novosanis. Sales and marketing expenses increased 7% to $5.3 million in the first half of 2019 from $5.0 million in the first half of 2018 largely due to the inclusion of CoreBiome and Novosanis expenses, partially offset by lower staffing costs. General and administrative expenses increased 208% to $6.0 million in the first half of 2019 compared to $1.9 million in the first half of 2018 largely due to an increase in fees for intercompany services provided by OSUR to DNAG, the inclusion of CoreBiome and Novosanis general and administrative expenses, and increased staffing, consulting, and legal costs.

All of the above contributed to DNAG's operating income of $5.0 million in the first half of 2019 which included non-cash charges of $1.5 million for the change in the fair value of acquisition-related contingent consideration, $1.9 million for depreciation and amortization, and $367,000 for stock-based compensation.

CONSOLIDATED INCOME TAXES

We continue to believe the full valuation allowance established in 2008 against OSUR's total U.S. deferred tax asset is appropriate as the facts and circumstances necessitating the allowance have not changed. For the six months ended June 30, 2019, $12,000 of state income tax expense was recorded as compared to $0 in the six months ended June 30, 2018. For the six months ended June 30, 2019, a foreign tax expense of $1.4 million was recorded as compared to income tax expense of $4.2 million recorded for the six months ended June 30, 2018. The decrease in the foreign income tax expense was directly related to the decrease in income before taxes generated by DNAG and the results generated by Novosanis.

Liquidity and Capital Resources

	June 30, 2019	December 31, 2018
	(In thousands)	
Cash and cash equivalents	$ 72,567	$ 88,438
Available for sale securities	114,001	112,886
Working capital	179,307	191,332

Our cash and cash equivalents and available-for-sale securities decreased to $186.6 million at June 30, 2019 from $201.3 million at December 31, 2018. Our working capital decreased to $179.3 million at June 30, 2019 from $191.3 million at December 31, 2018.

During the first half of 2019, we generated $4.7 million in cash from operating activities. Our net income of $1.1 million included non-cash charges for depreciation and amortization expense of $3.6 million, the change in the estimated fair value of acquisition-related contingent consideration of $1.5 million, and stock-based compensation expense of $1.8 million, as well as other non-cash benefits of $89,000. Additional sources of cash included a $6.2 million decrease in accounts receivable as a result of the collection of large outstanding balances, a $632,000 decrease in prepaid expenses and other assets and a $301,000 increase in deferred revenue. Offsetting these sources of cash were a decrease in accrued expenses and other liabilities of $8.3 million largely due to the submission of tax payments to the Canadian taxing authorities and payment of our 2018 management incentive bonuses and an increase in inventory of $2.3 million in order to meet contractual obligations associated with our HCV raw materials.

Net cash used in investing activities was $18.4 million for the six months ended June 30, 2019, which reflects $55.3 million used to purchase investments, $13.2 million to acquire CoreBiome and Novosanis, and $5.5 million to acquire property and equipment, partially offset by $55.6 million in proceeds from the maturities and redemptions of investments.

Net cash used in financing activities was $4.4 million for the six months ended June 30, 2019, which resulted from $3.7 million used for the repurchase of common stock to satisfy withholding taxes related to the vesting of restricted shares and $724,000 to pay-off loans which were assumed in the acquisition of Novosanis.

On March 29, 2019, we terminated our credit agreement with a commercial bank, which was initially entered into on September 30, 2016 (as amended in December 2017) and had a maturity date of September 30, 2019. The credit agreement was terminated because of our strong cash position and the availability of alternative financing sources, which, if needed would be more suited to our business needs. There were no borrowings outstanding at December 31, 2018 or at the time of termination of the credit agreement.

Our current balances of cash and cash equivalents and available-for-sale securities are expected to be sufficient to fund our current and foreseeable operating and capital needs. 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, $81.6 million or 44% of our $186.6 million in cash, cash equivalents 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, 2018 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, 2018. As of June 30, 2019, there were no significant changes to this information, including the absence of any off-balance sheet arrangements, except for our obligation under the CoreBiome and Novosanis purchase agreements, which may require us to pay up to an additional $32.4 million of contingent consideration over the next three years based on the achievement of certain performance criteria as defined under the agreements, including meeting certain revenue targets, the execution of a large customer contract, and the development of certain new technology.

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, 2018 filed with the SEC. During the first six months of 2019, there were no material changes in our critical accounting policies, other than those associated with our business combinations which are described below.

Business Combinations and Contingent Consideration

Acquired businesses are accounted for using the acquisition method of accounting, which requires that the purchase price be allocated to the net assets acquired at their respective fair values. Any excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill. Amounts allocated to contingent consideration are recorded to the balance sheet at the date of acquisition based on their relative fair values. The purchase price allocation requires us to make significant estimates and assumptions, especially at the acquisition date, with respect to intangible assets. Although we believe the assumptions and estimates we have made are reasonable, they are based in part on historical experience and information obtained from the management of the acquired companies and are inherently uncertain.

We account for contingent consideration in accordance with applicable guidance provided within the business combination accounting rules. As part of our consideration for the CoreBiome and Novosanis acquisitions, we are contractually obligated to pay certain consideration resulting from the outcome of future events. Therefore, we are required to update our underlying assumptions each reporting period, based on new developments, and record such contingent consideration liabilities at fair value until the contingency is resolved. Changes in the fair value of the contingent consideration liabilities are recognized each reporting period and included in our consolidated statements of operations. Our estimates of fair value are based on assumptions we believe to be reasonable, but the assumptions are uncertain and involve significant judgment by management. Updates to these assumptions could have a significant impact on our results of operations in any given period and any updates to the fair value of the contingent consideration could differ materially from the previous estimates.

Examples of critical estimates used in valuing certain intangible assets and contingent consideration include:

- future expected cash flows from sales and acquired developed technologies;
- the acquired company's trade name and customer relationships as well as assumptions about the period of time the acquired trade name and customer relationships will continue to be used in the combined company's portfolio;
- the probability of meeting the future events; and
- discount rates used to determine the present value of estimated future cash flows.

These estimates are inherently uncertain and unpredictable, and if different estimates were used the purchase price for the acquisition could be allocated to the acquired assets and liabilities differently from the allocation that we have made. In addition, unanticipated events and circumstances may occur, which may affect the accuracy or validity of such estimates, and if such events occur we may be required to record a charge against the value ascribed to an acquired asset or an increase in the amounts recorded for assumed liabilities.

We assess the recoverability of our long-lived assets, which includes property, plant and equipment and intangible assets, by determining whether the carrying value of such assets can be recovered through the sum of undiscounted future cash flows generated from the use and eventual disposition of the asset. If indicators of impairment exists, we measure the amount of such impairment by comparing the carrying value of the assets to the fair value of these assets, which is generally determined based on the present value of the expected future cash flows associated with the use of the assets. Expected future cash flows reflect our assumptions about selling prices, volumes, costs and market conditions over a reasonable period of time.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

As of June 30, 2019, we did not have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. Sales denominated in foreign currencies comprised 4.2% of our total revenues for the six months ended June 30, 2019. We do have foreign currency exchange risk related to our operating subsidiaries in Canada and in Belgium. The principal foreign currencies in which we conduct business are the Canadian dollar and the EURO. Fluctuations in the exchange rate between the U.S. dollar and these foreign currencies could affect year-to-year comparability of operating results and cash flows. Our foreign subsidiaries had net assets, subject to translation, of $125.7 million in U.S. Dollars, which are included in the Company’s consolidated balance sheet as of June 30, 2019. A 10% unfavorable change in the Canadian-to-U.S. dollar and EURO-to-U.S. dollar exchange rates would have decreased our comprehensive income by approximately $11.1 million in the six months ended June 30, 2019.

Item 4. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures. The Company’s management, with the participation of the Company’s Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company’s disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) as of June 30, 2019. Based on that evaluation, the Company’s management, including such officers, concluded that the Company’s disclosure controls and procedures were effective as of June 30, 2019 to provide reasonable assurance that material information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act of 1934 was accumulated and communicated to the Company’s management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure and was recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission.

(b) Changes in Internal Control Over Financial Reporting. There was no change in the Company’s internal control over financial reporting that occurred during the three months ended June 30, 2019 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

Except as provided below, 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, 2018.

Changes in the Genomics Market May Adversely Affect our Business.

The genomics market has been the largest component of our overall molecular business segment for some time and the major driver of this market has been ancestry testing which offers products and services to consumers to provide them with genealogical information. The ancestry market is maturing and sales to this market have declined in recent periods. Our genomics revenues have recently been reduced, primarily due to a change in promotional strategies and purchasing patterns by our largest customer which serves the consumer ancestry and genetic testing market. This trend in the ancestry testing market is continuing and is expected to continue to adversely affect our revenues and results of operations.

In an effort to increase our molecular revenues, we have devoted increasing time and attention to expanding sales internationally, including in the Asia-Pacific and other markets. While we believe these new markets represent large growth opportunities, there is no assurance that we will be successful in capitalizing on these opportunities or that we will be able to increase our international product sales consistent with our expectations. Factors that include, but are not limited to, the market acceptance of our products, available funding, cost containment strategies implemented by customers, increasing competition and regulatory constraints could limit sales of our genomics products into these international markets. To the extent that we are unsuccessful or limited in expanding our business in the Asia-Pacific or other new markets, our revenues and results of operations could be negatively affected.

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

Period	Total number of shares purchased		Average price paid per Share	Total number of shares purchased as part of publicly announced plans or programs	Maximum number (or approximate dollar value) of shares that may yet be repurchased under the plans or programs (1, 2)
April 1, 2019 - April 30, 2019	2,929	(3)	$ 9.60	—	11,984,720
May 1, 2019 - May 31, 2019	8,224	(3)	9.88	—	11,984,720
June 1, 2019 - June 30, 2019	—	(3)	—	—	11,984,720
	11,153			—	

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

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

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

Item 3. DEFAULTS UPON SENIOR SECURITIES

None

Item 4. MINE SAFETY DISCLOSURES

Not applicable

Item 5. OTHER INFORMATION

None

Item 6. EXHIBITS

Exhibit Number	Exhibit
10.1*	Description of OraSure Technologies, Inc. 2019 Incentive Plan is incorporated by reference to Item 5.02 to the Company's Current Report on Form 8-K filed May 8, 2019.
10.2*	Description of Non-Employee Director Compensation Policy, as amended, is incorporated by reference to Item 5.02 to the Company's Current Report on Form 8-K filed May 23, 2019.
31.1**	Certification of Stephen S. Tang required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.*
31.2**	Certification of Roberto Cuca required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.*
32.1**	Certification of Stephen S. Tang required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
32.2**	Certification of Roberto Cuca required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
101.INS	XBRL Instance Document – the Instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Management contract or compensation plan arrangement.

**Filed herewith

SIGNATURES

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

ORASURE TECHNOLOGIES, INC.

	/s/ Roberto Cuca
Date: August 7, 2019	Roberto Cuca
	Chief Financial Officer
	(Principal Financial Officer)
	/s/Michele M. Miller
Date: August 7, 2019	Michele M. Miller
	Vice President, Finance and Controller
	(Principal Accounting Officer)

Exhibit 31.1

Certification

I, Stephen S. Tang, certify that:

1. I have reviewed this report on Form 10-Q of OraSure Technologies, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d – 15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within the entity, particularly during the period in which this report is being prepared;
   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:
   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 7, 2019

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

Exhibit 31.2

Certification

I, Roberto Cuca, certify that:

1. I have reviewed this report on Form 10-Q of OraSure Technologies, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d – 15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within the entity, particularly during the period in which this report is being prepared;
    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:
    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 7, 2019

/s/ Roberto Cuca
Roberto Cuca
Chief Financial Officer
(*Principal Financial Officer*)

Exhibit 32.1

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

In connection with the Quarterly Report of OraSure Technologies, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Stephen S. Tang, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

/s/ Stephen S. Tang

Stephen S. Tang
President and Chief Executive Officer

August 7, 2019

Exhibit 32.2

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

In connection with the Quarterly Report of OraSure Technologies, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Roberto Cuca, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

/s/ Roberto Cuca

Roberto Cuca
Chief Financial Officer

August 7, 2019