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, 2020.

OR

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

For the transition period from _____ to _____ .

Commission File Number 001-16537

ORASURE TECHNOLOGIES, INC.

(Exact Name of Registrant as Specified in Its Charter)

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

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 1, 2020, the registrant had 71,558,443 shares of common stock, $.000001 par value per share, outstanding.

PART I. FINANCIAL INFORMATION

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Item 1. FINANCIAL STATEMENTS

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

	June 30, 2020	December 31, 2019
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 173,874	$ 75,715
Short-term investments	82,666	80,623
Accounts receivable, net of allowance for doubtful accounts of $3,915 and $2,666	25,918	36,948
Inventories	27,707	23,155
Prepaid expenses	2,745	2,433
Other current assets	5,054	5,676
Total current assets	317,964	224,550
Noncurrent Assets:		
Property, plant and equipment, net	33,763	30,339
Operating right-of-use assets, net	4,938	4,996
Finance right-of-use assets, net	1,656	1,951
Intangible assets, net	15,221	14,674
Goodwill	35,244	36,201
Long-term investments	9,222	33,420
Other noncurrent assets	2,819	3,164
Total noncurrent assets	102,863	124,745
TOTAL ASSETS	**$ 420,827**	**$ 349,295**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 9,057	$ 9,567
Deferred revenue	4,917	3,713
Accrued expenses and other current liabilities	14,406	14,288
Finance lease liability	555	613
Operating lease liability	1,093	1,032
Acquisition-related contingent consideration obligation	560	3,500
Total current liabilities	30,588	32,713
Noncurrent Liabilities:		
Finance lease liability	1,154	1,372
Operating lease liability	4,109	4,206
Other noncurrent liabilities	2,507	2,960
Deferred income taxes	712	899
Total noncurrent liabilities	8,482	9,437
TOTAL LIABILITIES	39,070	42,150
Commitments and contingencies (Note 9)		
STOCKHOLDERS' EQUITY		
Preferred stock, par value $.000001, 25,000 shares authorized, none issued	—	—
Common stock, par value $.000001, 120,000 shares authorized, 71,408 and 61,731 shares issued and outstanding	—	—
Additional paid-in capital	499,394	401,814
Accumulated other comprehensive loss	(17,282)	(12,136)
Accumulated deficit	(100,355)	(82,533)
Total stockholders' equity	381,757	307,145
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 420,827**	**$ 349,295**

See accompanying notes to the consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
NET REVENUES:				
Products and services	$ 28,337	$ 37,267	$ 59,223	$ 65,599
Other	922	1,559	1,632	3,349
	29,259	38,826	60,855	68,948
COST OF PRODUCTS AND SERVICES SOLD	11,995	13,808	27,460	25,850
Gross profit	17,264	25,018	33,395	43,098
OPERATING EXPENSES:				
Research and development	6,924	4,535	12,568	8,906
Sales and marketing	10,121	7,687	17,490	14,982
General and administrative	10,280	7,262	20,334	16,192
Change in the estimated fair value of acquisition-related contingent consideration	(660)	249	450	1,544
	26,665	19,733	50,842	41,624
Operating income (loss)	(9,401)	5,285	(17,447)	1,474
OTHER INCOME	216	524	1,646	1,048
Income (loss) before income taxes	(9,185)	5,809	(15,801)	2,522
INCOME TAX EXPENSE	1,309	1,411	2,021	1,382
NET INCOME (LOSS)	$ (10,494)	$ 4,398	$ (17,822)	$ 1,140
INCOME (LOSS) PER SHARE:				
BASIC	$ (0.16)	$ 0.07	$ (0.28)	$ 0.02
DILUTED	$ (0.16)	$ 0.07	$ (0.28)	$ 0.02
SHARES USED IN COMPUTING INCOME (LOSS) PER SHARE:				
BASIC	64,745	61,709	63,335	61,621
DILUTED	64,745	62,128	63,335	62,191

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,	
	2020	2019	2020	2019
NET INCOME (LOSS)	$ (10,494)	$ 4,398	$ (17,822)	$ 1,140
OTHER COMPREHENSIVE INCOME (LOSS)				
Currency translation adjustments	3,726	2,476	(5,495)	4,708
Unrealized gain (loss) on marketable securities	791	186	349	683
COMPREHENSIVE INCOME (LOSS)	$ (5,977)	$ 7,060	$ (22,968)	$ 6,531

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,	
	2020	**2019**
OPERATING ACTIVITIES:		
Net income (loss)	$ (17,822)	$ 1,140
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Stock-based compensation	4,048	1,848
Depreciation and amortization	4,600	3,610
Provision for doubtful accounts	1,365	140
Unrealized foreign currency loss	5	365
Interest expense on finance leases	39	13
Deferred income taxes	(146)	(467)
Change in the estimated fair value of acquisition-related contingent consideration	450	1,544
Payment of acquisition-related contingent consideration	(496)	—
Changes in assets and liabilities		
Accounts receivable	9,311	6,035
Inventories	(4,693)	(2,298)
Prepaid expenses and other assets	369	632
Accounts payable	(605)	81
Deferred revenue	1,311	301
Accrued expenses and other liabilities	80	(8,283)
Net cash provided by (used in) operating activities	(2,184)	4,661
INVESTING ACTIVITIES:		
Purchases of investments	(66,309)	(55,317)
Proceeds from maturities and redemptions of investments	87,616	55,624
Purchases of property and equipment	(6,037)	(5,513)
Proceeds from escrow associated with business acquisitions	126	—
Acquisition of businesses, net of cash acquired	—	(13,217)
Purchase of patent and product rights	(2,250)	—
Net cash provided by (used in) investing activities	13,146	(18,423)
FINANCING ACTIVITIES:		
Repayments of loans	—	(724)
Cash payments for lease liabilities	(354)	(124)
Payment of acquisition-related contingent consideration	(3,004)	—
Issuance of common stock in connection with public offering, net	95,036	—
Proceeds from exercise of stock options	560	169
Repurchase of common stock	(2,064)	(3,704)
Net cash provided by (used in) financing activities	90,174	(4,383)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	(2,977)	2,274
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	98,159	(15,871)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	75,715	88,438
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 173,874	$ 72,567
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for income taxes	$ 1,557	$ 6,097
Non-cash investing and financing activities		
Accrued property and equipment purchases	$ 704	$ 490
Unrealized gain on marketable securities	$ 349	$ 683

See accompanying notes to the consolidated financial statements.

1. The Company

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 products and services business, or "DNAG business" consists of the manufacture and sale of 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 and bioinformatics services.

Our OSUR diagnostic products include tests for diseases including HIV and Hepatitis C 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. Our HIV product is also sold in a consumer-friendly format in the over-the-counter ("OTC") market in the U.S. and as a self-test to individuals in a number of other countries. We also previously manufactured and sold medical devices used for the removal of benign skin lesions by cryosurgery or freezing. We sold the assets associated with our cryosurgical systems business to a third party in August 2019.

Our DNAG business is operated by our subsidiaries, DNA Genotek Inc. ("DNAG"), CoreBiome Inc. ("CoreBiome"), Novosanis NV ("Novosanis"), and Diversigen, Inc. ("Diversigen"). 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. CoreBiome and Diversigen provide laboratory and bioinformatics services. 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 infection markets. We also sell research use only sample collection products into the microbiome market and we offer our customers a suite of genomics and microbiome services, 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 accompanying interim unaudited consolidated financial statements include the accounts of OraSure Technologies, Inc. ("OraSure") and its wholly-owned subsidiaries, DNAG, CoreBiome, Novosanis and Diversigen. 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 unaudited financial statements, 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, 2019. Results of operations for the three and six months ended June 30, 2020 are not necessarily indicative of the results of operations expected for the full year.

Summary of Significant Accounting Policies. There have been no changes to the Company's significant accounting policies described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019 that have had a material impact on the consolidated financial statements and related notes except as discussed herein.

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 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.

We record an allowance for credit loss for our available-for-sale securities when a decline in investment market value is due to credit-related factors. When evaluating an investment for impairment, we review factors such as the severity of the impairment, changes in underlying credit ratings, forecasted recovery, the Company's intent to sell or the likelihood that it would be required to sell the investment before its anticipated recovery in market value and the probability that the scheduled cash payments will continue to be made. As of June 30, 2020, we determined that the decline in the market value of our available-for-sale investment was not due to credit-related factors and as such no allowance for credit-loss was necessary.

The following is a summary of our available-for-sale securities as of June 30, 2020 and December 31, 2019:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
June 30, 2020				
Guaranteed investment certificates	$ 23,571	$ —	$ —	$ 23,571
Corporate bonds	68,082	420	(185)	68,317
Total available-for-sale securities	$ 91,653	$ 420	$ (185)	$ 91,888
December 31, 2019				
Guaranteed investment certificates	$ 24,632	$ —	$ —	$ 24,632
Corporate bonds	89,525	271	(385)	89,411
Total available-for-sale securities	$ 114,157	$ 271	$ (385)	$ 114,043
At June 30, 2020, maturities of our available-for-sale securities were as follows:				
Less than one year	$ 82,581	$ 270	$ (185)	$ 82,666
Greater than one year	$ 9,072	$ 150	$ —	$ 9,222

Fair Value of Financial Instruments. As of June 30, 2020 and December 31, 2019, 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 2 instruments as of June 30, 2020 and December 31, 2019.

Included in cash and cash equivalents at June 30, 2020 and December 31, 2019, was $111,378 and $1,624 invested in government money market funds. These funds have investments in government securities and are measured as Level 1 instruments.

We offer a nonqualified deferred compensation plan for certain eligible employees and members of our Board of Directors. The assets of the plan are held in the name of the Company at a third-party financial institution. Separate accounts are maintained for each participant to reflect the amounts deferred by the participant and all earnings and losses on those deferred amounts. The assets of the plan are held in mutual funds. The fair value of the plan assets as of June 30, 2020 and December 31, 2019 was $3,352 and $3,519, 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 both current assets and noncurrent assets with the same amount included in accrued expenses and other noncurrent liabilities in the accompanying consolidated balance sheets.

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, 2020	December 31, 2019
Raw materials	$ 14,554	$ 14,168
Work in process	850	643
Finished goods	12,303	8,344
	$ 27,707	$ 23,155

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, 2020 and December 31, 2019 was $50,970 and $46,882, respectively.

Intangible Assets. Intangible assets consist of customer relationships, 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, 2020 and December 31, 2019 was $24,205 and $23,420, respectively. The change in intangibles from $14,674 as of December 31, 2019 to $15,221 as of June 30, 2020 is a result of the acquisition of patent and product rights of $2,250 offset by foreign currency translation losses of $176 and $1,527 in amortization expense.

Goodwill. Goodwill represents the excess of the purchase price over the fair value of the net tangible and identifiable intangible assets acquired. All goodwill has been allocated to our DNAG segment. 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 decrease in goodwill from $36,201 as of December 31, 2019 to $35,244 as of June 30, 2020 is a result of a purchase price adjustment related to one of our acquisitions of $126 and a decrease of $831 associated with foreign currency translation.

Leases. In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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 did 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 (Loss) Per Share. Basic earnings (loss) per share is computed by dividing net income (loss) by the weighted-average number of shares of common stock outstanding during the period. Diluted earnings (loss) per share is computed in a manner similar to basic earnings (loss) per share except that the weighted-average number of shares outstanding is increased to include incremental shares from the assumed vesting or exercise of dilutive securities, such as common stock options, unvested restricted stock or performance stock units, unless the impact is antidilutive. The number of incremental shares is calculated by assuming that outstanding stock options were exercised and unvested restricted shares and performance stock units were vested, and the proceeds from such exercises or vesting were used to acquire shares of common stock at the average market price during the reporting period. Basic and dilutive computations of net loss per share are the same in periods in which a net loss exists as the dilutive effects of excluded items would be anti-dilutive.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net income (loss)	$ (10,494)	$ 4,398	$ (17,822)	$ 1,140
Weighted-average shares of common stock outstanding:				
Basic	64,745	61,709	63,335	61,621
Dilutive effect of stock options, restricted stock, and performance stock units	—	419	—	570
Diluted	64,745	62,128	63,335	62,191
Earnings (loss) per share:				
Basic	$ (0.16)	$ 0.07	$ (0.28)	$ 0.02
Diluted	$ (0.16)	$ 0.07	$ (0.28)	$ 0.02

For the three and six months ended June 30, 2020, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 1,078 and 704 shares, respectively, were excluded from the computation of diluted earnings (loss) per share as their inclusion would have been anti-dilutive.

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

Transaction gains and losses resulting from exchange rate changes on transactions denominated in currencies other than a 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 income were $(200) and $(317) for the three months ended June 30, 2020 and 2019, respectively. Net foreign exchange gains (losses) were $493 and $(926) for the six months ended June 30, 2020 and 2019.

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, 2020 consists of $17,517 of currency translation adjustments and $235 of net unrealized gains on marketable securities, which represents the fair market value adjustment for our investment portfolio. Accumulated other comprehensive loss at December 31, 2019 consists of $12,022 of currency translation adjustments and $114 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 requires a credit loss to be recognized when it is probable. We adopted this guidance in the first quarter of 2020 and the impact of the adoption was not material to the Company's consolidated financial statements as credit losses are not expected to be significant based on historical collection trends, the financial condition of payment partners, and external market factors. The Company will continue to actively monitor the impact of the recent coronavirus (COVID-19) pandemic on expected credit losses. In addition, the new guidance requires us to record an allowance for credit loss when a decline in investment market value is due to credit-related factors. As of January 1, 2020, there was no material decline in the market value of available-for-sale investments due to credit-related factors.

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. 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 adopted this guidance in the first quarter of 2020 and the impact of the adoption was not material to the Company's consolidated financial statements.

In August 2018, the FASB issued guidance related to fair value measurement disclosures. This guidance removes the requirement to disclose the amount of and reasons for transfers between Levels 1 and 2 of the fair value hierarchy, the policy for determining that a transfer has occurred, and valuation processes for Level 3 fair value measurements. Additionally, this guidance modifies the disclosures related to the measurement uncertainty for recurring Level 3 fair value measurements (by removing the requirement to disclose sensitivity to future changes) and the timing of liquidation of invested assets (by removing the timing requirement in certain instances). The guidance also requires new disclosures for Level 3 financial assets and liabilities, including the amount and location of unrealized gains and losses recognized in other comprehensive income(loss) and additional information related to significant unobservable inputs used in determining Level 3 fair value measurements. We adopted this guidance in the first quarter of 2020 and the impact of the adoption was not material to the Company's consolidated financial statements.

3. Business Combinations

CoreBiome and Novosanis

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. See Note 3 set forth in the Company's audited financial statements included as part of our Annual Report on Form 10-K for the fiscal year ended December 31, 2019 for additional information on the CoreBiome and Novosanis acquisitions.

During the six months ended June 30, 2019, we incurred a total of $597 of acquisition-related costs in connection with these acquisitions, 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 operations for the six months ended June 30, 2019.

Pursuant to our acquisition agreements, we were to 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 calculated 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 obligation changed from $4,350 as of the acquisition date to $5,898 as of June 30, 2019 as a result of changes in our estimated revenue forecasts. The fair value of the contingent consideration obligation changed from $3,612 as of December 31, 2019 to $560 as of June 30, 2020. This change is a result of a $3,500 payment made in the first quarter of 2020, changes in our estimated revenue forecasts and an amendment to one of the agreements. Pursuant to the amendment, which was entered into in March 2020, the terms of the contingent consideration provisions associated with one of the acquisitions were modified and are expected to be paid during the first quarter of 2021. As of June 30, 2020, we may pay up to an additional $22,500 of contingent consideration through July 2021.

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. Effective as of January 4, 2019, the financial results of CoreBiome and Novosanis are included in our DNAG segment.

Diversigen

On November 8, 2019, the Company acquired all of the outstanding stock of Diversigen pursuant to the terms of a merger agreement. We began operating this entity as of the November 8, 2019 closing date. The aggregate purchase price for this transaction was $12,000, 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 an escrow account for a limited period after closing, pursuant to indemnification obligations under the merger agreement noted above. See Note 3 set forth in the Company's audited financial statements included as part of our Annual Report on Form 10-K for the fiscal year ended December 31, 2019 for additional information on the Diversigen acquisition.

During the six months ended June 30, 2020 and 2019, we did not incur any acquisition related costs associated with this transaction, including investment banking fees and accounting, legal and other professional fees.

Pursuant to the merger agreement, we were to pay up to an additional $1,500 of contingent consideration in 2020 based on the achievement of certain 2019 revenue metrics as defined under the agreements which did not occur.

Revenues from Diversigen primarily consist of microbiome laboratory services that provide metagenomics sequencing, bioinformatics and statistical analysis for the study of the microbiome. Effective as of November 8, 2019, the financial results of Diversigen are included in our DNAG segment.

Unaudited Pro Forma Financial Information

The unaudited pro forma results presented below include the results of the CoreBiome, Diversigen and Novosanis acquisitions as if they had been consummated as of January 1, 2019. 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, 2019.

	Three Months ended June 30, 2019	Six Months ended June 30, 2019
Revenue	$ 39,710	$ 70,758
Net income (loss)	3,687	(230)
Net income (loss) per share, basic and diluted	0.06	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,	
	2020	2019	2020	2019
Infectious disease testing	$ 8,737	$ 13,348	$ 23,400	$ 25,686
Risk assessment testing	1,533	3,097	4,533	5,934
Cryosurgical systems	-	3,518	-	6,093
Genomics	6,471	13,943	14,863	21,791
Microbiome	853	2,057	2,430	3,446
COVID-19	8,472	-	8,866	-
Laboratory services	2,222	1,196	5,053	2,332
Other product revenue	49	108	78	317
Net product and services revenues	28,337	37,267	59,223	65,599
Royalty income	727	1,114	1,172	2,198
Other non product revenues	195	445	460	1,151
Other revenues	922	1,559	1,632	3,349
Net revenues	$ 29,259	$ 38,826	$ 60,855	$ 68,948

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,	
	2020	2019	2020	2019
United States	$ 21,912	$ 27,902	$ 43,528	$ 48,467
Europe	3,069	2,990	5,874	5,421
Other regions	4,278	7,934	11,453	15,060
	$ 29,259	$ 38,826	$ 60,855	$ 68,948

Customer and Vendor Concentrations. One of our customers accounted for 12% of our accounts receivable as of June 30, 2020. Another customer accounted for 19% of our accounts receivable as of December 31, 2019. We had no significant customer concentrations (greater than 10%) in our net consolidated revenues for the three and six months ended June 30, 2020 and for the six months ended June 30, 2019. One of our customers accounted for approximately 13% of our net consolidated revenues for the three months ended June 30, 2019.

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 product. 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, 2020 and December 31, 2019 includes customer prepayments of $3,124 and $1,904, respectively. Deferred revenue as of June 30, 2020 and December 31, 2019 also includes $1,793 and $1,809, 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 and other current liabilities

	June 30, 2020	December 31, 2019
Payroll and related benefits	$ 8,803	$ 6,088
Professional fees	1,824	2,769
Other	3,779	5,431
	$ 14,406	$ 14,288

6. Leases

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, 2020, we are the lessee in all agreements. Our leases have remaining lease terms of 1 to 7 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		Six Months Ended	
	2020	2019	2020	2019
Operating Lease Cost	$ 322	$ 232	$ 634	$ 463
Finance Lease Cost				
Amortization of right-of use assets	163	113	326	152
Interest on lease liabilities	19	9	39	13
Total Finance Lease Cost	$ 182	$ 122	$ 365	$ 165

Supplemental cash flow information related to leases is as follows:

	Six Months Ended	
	2020	2019
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 630	$ 458
Operating cash flows from financing leases	39	13
Financing cash flows from financing leases	354	124
Non-cash activity:		
Right-of-use assets obtained in exchange for operating lease obligations	498	240
Right-of-use assets obtained in exchange for finance lease obligations	46	1,249

Supplemental balance sheet information related to leases is as follows:

	June 30, 2020	December 31, 2019
Operating Leases		
Right-of-use assets	$ 4,938	$ 4,996
Current lease liabilities	1,093	1,032
Non-current lease liabilities	4,109	4,206
Total operating lease liabilities	$ 5,202	$ 5,238
Finance Leases		
Right-of-use assets	$ 1,656	$ 1,951
Current lease liabilities	555	613
Non-current lease liabilities	1,154	1,372
Total finance lease liabilities	$ 1,709	$ 1,985

Weighted Average Remaining Lease Term	
Weighted-average remaining lease term—operating leases	4.87
Weighted-average remaining lease term—finance leases	3.08
Weighted Average Discount Rate	
Weighted-average discount rate—operating leases	4.26%
Weighted-average discount rate—finance leases	4.32%

As of June 30, 2020, minimum lease payments by period are expected to be as follows:

	Finance	Operating
2020 (excluding the six months ended June 30, 2020)	$ 333	$ 677
2021	566	1,302
2022	566	1,284
2023	336	870
2024	24	891
Thereafter	3	839
Total Minimum Lease Payments	1,828	5,863
Less: imputed interest	(119)	(661)
Present Value of Lease Liabilities	$ 1,709	$ 5,202

7. Stockholders' Equity

Reconciliation of the changes in stockholders' equity for the three and six months ended June 30, 2020 and 2019

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balance at December 31, 2019	61,731	$ —	$ 401,814	$ (12,136)	$ (82,533)	$ 307,145
Common stock issued upon exercise of options	6	—	30	—	—	30
Vesting of restricted stock and performance stock units	486	—	—	—	—	—
Purchase and retirement of common shares	(197)	—	(1,408)	—	—	(1,408)
Stock-based compensation	—	—	1,376	—	—	1,376
Net loss	—	—	—	—	(7,328)	(7,328)
Currency translation adjustments				(9,221)		(9,221)
Unrealized loss on marketable securities	—	—	—	(442)	—	(442)
Balance at March 31, 2020	62,026	$ —	$ 401,812	$ (21,799)	$ (89,861)	$ 290,152
Common stock issued upon exercise of options	71	—	530	—	—	530
Vesting of restricted stock and performance stock units	161	—	—	—	—	—
Purchase and retirement of common shares	(50)	—	(656)	—	—	(656)
Issuance of common stock in connection with public offering, net of commissions and expenses of $6,200	9,200	—	95,036	—	—	95,036
Stock-based compensation	—	—	2,672	—	—	2,672
Net loss	—	—	—	—	(10,494)	(10,494)
Currency translation adjustments				3,726		3,726
Unrealized gain on marketable securities	—	—	—	791	—	791
Balance at June 30, 2020	71,408	$ —	$ 499,394	$ (17,282)	$ (100,355)	$ 381,757

	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)
Stock-based compensation	—	—	1,231	—	—	1,231
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)
Stock-based compensation	—	—	616	—	—	616
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

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, 2020 and 2019 was $468 and $635 respectively.

Compensation cost of $2,556 and $1,527 related to restricted shares was recognized during the six months ended June 30, 2020 and 2019, respectively. In connection with the vesting of restricted shares during the six months ended June 30, 2020 and 2019, we purchased and immediately retired 247 and 288 shares with aggregate values of $2,064 and $3,704, 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 $1,024 and $(315) related to PSUs was recognized during the six months ended June 30, 2020 and 2019, respectively.

Public Offering

On June 1, 2020, we entered into an underwriting agreement with J.P. Morgan Securities LLC, Citigroup Global Markets Inc. and Evercore Group LLC, as representatives of several underwriters, relating to the issuance and sale of 8,000 shares of our common stock. The price to the public in the offering was $11.00 per share. Under the terms of the underwriting agreement, we also granted the underwriters an option, exercisable for 30 days, to purchase up to an additional 1,200,000 shares of common stock. On June 3, 2020, we announced the full exercise by the underwriters of their option to purchase these additional shares.

The offering was made pursuant to an effective registration statement on Form S-3 (File No. 333-228877) we had previously filed with the SEC, and a prospectus supplement thereunder. The net proceeds from the offering were approximately $95,000 after deducting underwriting discounts and offering expenses paid by the Company.

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, 2020 and 2019.

8. Income Taxes

During the three and six months ended June 30, 2020, we recorded income tax expense of $1,309 and $2,021, which primarily consists of foreign tax expense. During the three and six months ended June 30, 2019, we recorded income tax expense of $1,411 and $1,382, which also primarily consists of a foreign tax expense.

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, 2020 and December 31, 2019 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, 2020 and December 31, 2019 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, 2020.

9. Commitments and Contingencies

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.

10. 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 "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. 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. Financial results of CoreBiome, Novosanis and Diversigen are included in our DNAG segment. Our cryosurgical systems business was included in our OSUR segment and the impact of the sale of that business in August 2019 is reflected in the results presented below.

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

The following table summarizes operating segment information for the three and six months ended June 30, 2020 and 2019, and asset information as of June 30, 2020 and December 31, 2019:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net revenues:				
OSUR	$ 10,427	$ 20,372	$ 28,219	$ 38,605
DNAG	18,832	18,454	32,636	30,343
Total	$ 29,259	$ 38,826	$ 60,855	$ 68,948
Operating income (loss):				
OSUR	$ (13,523)	$ 14	$ (21,165)	$ (3,485)
DNAG	4,122	5,271	3,718	4,959
Total	$ (9,401)	$ 5,285	$ (17,447)	$ 1,474
Depreciation and amortization:				
OSUR	$ 886	$ 844	$ 1,747	$ 1,666
DNAG	1,517	1,040	2,853	1,944
Total	$ 2,403	$ 1,884	$ 4,600	$ 3,610
Capital expenditures:				
OSUR	$ 2,630	$ 1,616	$ 3,448	$ 3,545
DNAG	812	1,269	2,589	1,968
Total	$ 3,442	$ 2,885	$ 6,037	$ 5,513

	June 30, 2020	December 31, 2019
Total assets:		
OSUR	$ 260,017	$ 163,943
DNAG	160,810	185,352
Total	$ 420,827	$ 349,295

11. Subsequent Events

On July 22, 2020, the Company acquired all of the outstanding stock of UrSure, Inc. (“UrSure”), pursuant to the terms of a merger agreement. Based in Boston, UrSure is developing and commercializing products that measure adherence to HIV medications including pre-exposure prophylaxis or PrEP, the daily medication to prevent HIV. This includes laboratory-based tests that can measure levels of the medication in a patient’s urine or blood, as well as several additional point of care products in development.

This transaction supports OraSure’s strategy of expanding its core offerings to include additional diagnostic products, particularly point-of-care tests that complement its current infectious disease portfolio and pipeline.

The initial aggregate purchase price of this transaction was approximately $3,100, 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 an escrow account for a limited period after closing, pursuant to indemnification obligations under the merger agreement. The merger agreement also includes contingent payments to be paid based on the future performance of UrSure through a specified period of time defined under the agreement. During the six months ended June 30, 2020, we incurred a total of $343 of acquisition related costs, including accounting, legal, and other professional fees, related to the acquisition, all of which were expensed and reported as a component of general and administrative expense in the consolidated statement of operations for the six months ended June 30, 2020.

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; impact of increased or different risks arising from the acquisition of companies located in foreign countries; 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; the impact of the novel coronavirus ("COVID-19") pandemic on our business and our ability to successfully develop new products, validate the expanded use of existing collector products and commercialize such products for COVID-19 testing; 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 contracting with the U.S. government; 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, 2019, 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. Readers are cautioned not to place undue reliance on the forward-looking statements. 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 "DNAG" business consists of the manufacture and sale of kits that are used to collect, stabilize, transport and store biological samples of genetic material for molecular testing. 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 and bioinformatics services. The DNAG segment also includes genomic and microbiome laboratory testing and analytical services.

Our OSUR diagnostic products include tests for diseases including HIV and Hepatitis C 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. Our HIV product is also sold in a consumer-friendly format in the OTC and public health markets in the U.S. and as a self-test to individuals in a number of other countries. We also previously manufactured and sold medical devices used for the removal of benign skin lesions by cryosurgery or freezing. These cryosurgical products were sold in both professional and OTC markets in North America, Europe, Central and South America, and Australia. We sold the assets associated with our cryosurgical systems business to a third party in August 2019.

Our DNAG business is operated by our subsidiaries, DNAG, CoreBiome, Novosanis and Diversigen. 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 biological sample types for genetic and microbiome applications. Our products are used for academic research and commercial applications, including ancestry, disease risk management, lifestyle and animal testing. Included in the disease risk management area are pharmacogenomics testing, hereditary disease screening, prenatal or cancer screening, population health initiatives and other molecular testing in DNA or RNA for the diagnosis of acute disease. CoreBiome and Diversigen provide the laboratory testing and bioinformatics services. 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 infection markets. We also sell research use only sample collection products into the microbiome market and we offer our customers a suite of genomics and microbiome services, 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.

Recent Developments

Impact of COVID-19

In March 2020, the World Health Organization declared the novel coronavirus ("COVID-19") a global pandemic. This contagious disease outbreak, which has continued to spread, and any related adverse public health developments, has adversely affected workforces, economies, and financial markets globally, leading to an economic downturn. It is not possible for us to predict the duration or magnitude of the outbreak's effects on our business or results of operations at this time.

During the first six months of 2020, traditional HIV and HCV testing programs and drug testing in the workplace market was reduced or terminated as a result of the various "stay-at-home" orders and social distancing guidelines issued by federal, state and local governments to contain the spread of the COVID-19 pandemic in the United States. On the international front, during the first six months of 2020, we experienced some delays with international shipments due to a reduction of customs and transportation personnel, a reduced number of air flights and shipping congestion. In our molecular segment, clinical and research work during the first half of the year, particularly in the academic market, has reduced demand for our products. These trends had a material impact on our results of operations during the first half of 2020 and we believe they will continue to have a material and adverse impact on the revenues of certain parts of our business for an indeterminate time period, depending on the duration and severity of the COVID-19 pandemic. While we generated additional revenues from sales of our molecular collection devices related to COVID-19 testing during the second quarter of 2020, the degree to which these and other opportunities will offset these negative trends in future periods cannot be predicted with certainty.

Despite the expected negative impacts from COVID-19, we also believe there are potentially significant opportunities for increased revenues as a result of the pandemic. In the U.S., public health customers are purchasing increased quantities of our OraQuick® In-Home HIV Test in order to permit continued HIV testing while allowing clients and patients to adhere to "stay-at-home" and social distancing requirements. In addition, we are seeing increased demand for our molecular collection products from customers who conduct both saliva and blood-based testing. As it becomes increasingly difficult to collect blood in clinics or healthcare settings, these customers are increasingly relying on the saliva collection alternative. As described below, we are also developing a new pan-SARS-coronavirus antigen self-test and a new SARS-CoV-2 antibody laboratory test and are working to validate the use of a number of our existing molecular collection products for use in COVID-19 testing. If we are successful in these efforts, we believe these new products and FDA Emergency Use Authorizations ("EUAs") for the expanded, emergency use of our existing products could result in significant additional revenues that could potentially offset or exceed the lost revenues expected in

other parts of our business as a result of the COVID-19 pandemic, although such efforts will require significant capital expenditures and additional research and development costs, the extent of which will depend on the timing and success of such efforts. However, the degree to which such additional revenues will offset the lost revenues from other parts of our business cannot be predicted with certainty and, even if our efforts are successful, there is no assurance as to whether we will be able to generate any additional revenue or whether it may be generated in subsequent periods.

COVID-19 Product Development

In April 2020, we were awarded a contract for $710,310 in funding from the U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response's Biomedical Advanced Research and Development Authority ("BARDA") to develop a pan-SARS-coronavirus rapid in-home self-test that uses oral fluid samples and that will be based on our OraQuick® platform which currently supports HIV, HCV, and Ebola testing. This support from BARDA will enable us to complete development and file for EUA allowing for an in-home self-test to debut into the U.S. market. Although originally designed for use with oral fluid, this test has been modified to use a self-collected lower nostril sample, which can be easily and comfortably collected, in order to achieve the best possible accuracy. The final design of this product is nearing completion and human clinical testing of the product has been started. We expect to submit an application for EUA and, assuming our application is approved, to commercially launch the product in the fourth quarter of 2020.

In addition to a rapid pan-SARS-coronavirus antigen self-test, we are developing a lab-based oral fluid microplate SARS-CoV-2 antibody enzyme-linked immunosorbent assay (ELISA). In June 2020, OraSure received $629,217 in funding from BARDA to support the development of this test. The final design of this product has been finalized and we expect to submit our application for EUA, and commercially launch the product in the fourth quarter of 2020 if authorization is received.

We are also actively engaged with several laboratories and researchers to demonstrate the effectiveness of our existing products for use with coronavirus testing. Recent publications show that the coronavirus can be detected successfully in saliva. The stabilization solution in our molecular collection products can accommodate a very broad spectrum of microbiome activity spanning bacteria to viruses and we are collecting data on the usability of our kits for this purpose. Although we understand that the current standard for collecting samples for SARS-CoV-2 testing is with a nasopharyngeal or oropharyngeal swab, we believe that oral samples collected using devices from our product lines for liquid saliva or oral swab samples could be a suitable alternative. Unlike nasopharyngeal and oropharyngeal swabs which cannot be self-administered easily, our products are optimized for self-collection. That means healthcare providers, retailers, and online vendors could ship our kits directly to an individual's home, eliminating unnecessary trips to hospitals, doctors' offices and testing facilities. Self-collection would support the social distancing guidelines already in place in many communities, reduce the burden on testing sites and healthcare facilities, and provide wider access to testing.

Moreover, the chemistry in our products stabilizes nucleic acids, including RNA, which is the nucleic acid used by most labs for COVID-19 testing. The usability and form factor of these products are conducive for use in at-home or clinic settings. Should the data support the use of our existing products for COVID-19 diagnostics, additional avenues of sample collection will be enabled. We expect to receive this data in the near future as this validation requires paired sampling from infected patients (which could include data generated by third parties).

In May 2020, our ORAcollect®•RNA kit was included as the collection device for anterior nares (nasal) samples under an EUA granted to Biocerna LLC for use with its PCR-based SARS-CoV-2 assay. More recently, our OMNIgene®•ORAL saliva collection device was included in an EUA granted by the FDA to P23 Labs for use with its TaqPath SARS-CoV-2 assay. This EUA permits individuals to self-collect saliva specimens at home for the detection of SARS-CoV-2. In June 2020, our Oragene®•Dx oral saliva collection kit was included in an EUA granted to Phosphorus Diagnostics for the detection of SARS-CoV-2 using the Phosphorus COVID-19 RT-qPCR test. Finally, in July 2020 our OMNIgene® ORAL saliva collection device was included in an EUA granted to Clinical Reference Laboratory (CRL), for use with CRL Rapid Response™, a saliva-based SARS-CoV-2 RT-PCR test. Several other laboratories are pursuing EUAs for the inclusion of our specimen collection devices for use with their SARS-CoV-2 assays. We believe that one or more of our collection products will be included in additional EUAs requested by these other laboratories.

UrSure Acquisition

On July 22, 2020, the Company acquired all of the outstanding stock of UrSure, Inc. ("UrSure"), pursuant to the terms of a merger agreement. Based in Boston, UrSure is developing and commercializing products that measure adherence to HIV medications including pre-exposure prophylaxis or PrEP, the daily medication to prevent HIV. This includes laboratory-based tests that can measure levels of the medication in a patient's urine or blood, as well as several additional point of care products in development. This transaction supports OraSure's strategy of expanding its product offerings to include additional diagnostic products, particularly point-of-care tests that complement its current infectious disease portfolio and pipeline.

Public Offering

In June 2020, the Company completed the issuance and sale of 9,200,000 shares of its common stock. The price to the public in the offering was $11.00 per share, with net proceeds from the offering equaling approximately $95.0 million after deducting underwriting discounts and offering expenses paid by the Company.

Current Consolidated Financial Results

During the six months ended June 30, 2020, our consolidated net revenues decreased 12% to $60.9 million, compared to $68.9 million for the six months ended June 30, 2019. Net product and services revenues during the six months ended June 30, 2020 decreased 10% when compared to the same period of 2019, primarily due to lower sales of our genomics, domestic HIV, HCV, risk assessment, and microbiome products. Also contributing to the decrease in revenues was the absence of cryosurgical sales as a result of the divestiture of our cryosurgical systems business in August 2019. Partially offsetting these decreases were the inclusion of product revenues associated with COVID-19, higher laboratory services revenues and higher international sales of our OraQuick® HIV Self-Test. Other revenues for the six months ended June 30, 2020 were $1.6 million compared to $3.3 million in the same period of 2019. This decline was largely due to lower royalty income and lower research and development funding.

Our consolidated net loss for the six months ended June 30, 2020 was $17.8 million, or $0.28 per share on a fully diluted basis, compared to consolidated net income of $1.1 million, or $0.02 per share on a fully diluted basis, for the six months ended June 30, 2019. Results for the six months ended June 30, 2020 included a $450,000 million non-cash pre-tax charge associated with the change in the fair value of acquisition-related contingent consideration and $343,000 of acquisition related transaction costs associated with the UrSure acquisition, which together accounted for approximately $0.01 per share. Results in the first half of 2019 included a $1.5 million 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 during the first six months of 2019 by approximately $0.03.

Cash used in operating activities during the six months ended June 30, 2020 was $2.2 million. Cash provided by operating activities during the six months ended June 30, 2019 was $4.7 million. As of June 30, 2020, we had $265.8 million in cash, cash equivalents, and available-for-sale securities, compared to $189.8 million at December 31, 2019.

Results of Operations

Three months ended June 30, 2020 compared to June 30, 2019

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, 2020 and 2019.

	Three Months Ended June 30,				
	Dollars			Percentage of Total Net Revenues	
	2020	2019	% Change	2020	2019
OSUR	$ 10,270	$ 19,963	(49) %	35 %	51 %
DNAG	18,067	17,304	4	62	45
Net product and services revenues	28,337	37,267	(24)	97	96
Other	922	1,559	(41)	3	4
Net revenues	$ 29,259	$ 38,826	(25) %	100 %	100 %

Consolidated net product and services revenues decreased 24% to $28.3 million in the second quarter of 2020 from $37.3 million in the comparable period of 2019. Lower sales of our genomics, OraQuick® HIV, OraQuick® HCV, risk assessment, and microbiome products and the absence of cryosurgical systems revenues due to the sale of our cryosurgical systems business in August 2019 were partially offset by the inclusion of product sales related to COVID-19 testing and higher laboratory services revenues. Net revenues for the three months ended June 30, 2020 included $8.5 million of COVID-19 related product revenues. Other revenues in the second quarter of 2020 decreased 41% to $922,000 from $1.6 million in the second quarter of 2019 due to lower royalty income and lower research and development funding.

Consolidated net revenues derived from products sold to customers outside of the United States were $7.3 million and $10.9 million, or 25% and 28% of total net revenues, in the second quarters of 2020 and 2019, 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 2020 and 2019.

	Three Months Ended June 30,				
	Dollars			Percentage of Total Net Revenues	
Market	2020	2019	% Change	2020	2019
Infectious disease testing	$ 8,737	$ 13,348	(35) %	84 %	66 %
Risk assessment testing	1,533	3,097	(51)	15	15
Cryosurgical systems	—	3,518	(100)	—	17
Net product revenues	10,270	19,963	(49)	99	98
Other	157	409	(62)	1	2
Net revenues	$ 10,427	$ 20,372	(49) %	100 %	100 %

Infectious Disease Testing Market

Sales to the infectious disease testing market decreased 35% to $8.7 million in the second quarter of 2020 from $13.3 million in the second quarter of 2019. This decrease resulted from lower world-wide OraQuick® HIV and HCV product sales.

The table below shows a breakdown of our total net OraQuick® HIV and HCV product revenues (dollars in thousands) during the second quarters of 2020 and 2019.

	Three Months Ended June 30,		
Market	2020	2019	% Change
Domestic HIV	$ 3,197	$ 4,460	(28) %
International HIV	3,883	5,422	(28)
Net HIV revenues	7,080	9,882	(28)
Domestic HCV	757	2,102	(64)
International HCV	641	983	(35)
Net HCV revenues	1,398	3,085	(55)
Net OraQuick® revenues	$ 8,478	$ 12,967	(35) %

Domestic OraQuick® HIV sales decreased 28% to $3.2 million for the three months ended June 30, 2020 from $4.5 million for the three months ended June 30, 2019. This decrease was primarily the result of the decline in HIV testing at public health agencies, hospitals and physician offices due to the COVID-19 pandemic.

International sales of our OraQuick® HIV tests decreased 28% to $3.9 million for the three months ended June 30, 2020 from $5.4 million for the three months ended June 30, 2019. This decrease was primarily due to the timing of orders of our OraQuick® HIV Self-Test in Africa largely caused by shipping-delays.

Domestic OraQuick® HCV sales decreased 64% to $757,000 in the second quarter of 2020 from $2.1 million in the second quarter of 2019. International OraQuick® HCV sales decreased 35% to $641,000 in the second quarter of 2020 from $1.0 million in the second quarter of 2019. The declines in HCV sales in both the domestic and international markets were due to the closure of testing programs as a result of the COVID-19 pandemic.

Risk Assessment Market

Sales to the risk assessment market decreased 51% to $1.5 million in the second quarter of 2020 compared to $3.1 million in the second quarter of 2019 due to unemployment and reductions in workplace and insurance testing programs resulting from the COVID-19 pandemic.

Cryosurgical Systems Market

In August 2019, we sold our cryosurgical systems line of business and as such have stopped recording revenues associated with that business since the third quarter of 2019.

Other revenues

Other revenues in the second quarter of 2020 decreased 62% to $157,000 from $409,000 of other revenues recorded in the second quarter of 2019 largely due to lower research and development funding as a result of the wind-down of our development efforts on our rapid Ebola test.

DNAG Segment

The table below shows a breakdown of our total net revenues (dollars in thousands) during the second quarters of 2020 and 2019.

	Three Months Ended June 30,		
Market	**2020**	**2019**	**% Change**
Genomics	$ 6,471	$ 13,943	(54) %
Microbiome	853	2,057	(59)
COVID-19	8,472	—	—
Laboratory services	2,222	1,196	86
Other product revenues	49	108	(55)
Net molecular product and services revenues	$ 18,067	$ 17,304	4
Other	765	1,150	(33)
Net molecular product and services revenues	$ 18,832	$ 18,454	2 %

Sales of our genomics products decreased 54% to $6.5 million in the second quarter of 2020 compared to $13.9 million in the second quarter of 2019, largely due to the timing of orders placed by one of our largest genomics customer and the reduction in genomics testing due to the COVID-19 pandemic.

Microbiome sales decreased 59% to $853,000 in the second quarter of 2020 compared to $2.1 million in the second quarter of 2019 largely due to the timing of orders placed by our customers and reduced demand caused by the COVID-19 pandemic.

During the second quarter of 2020, we sold $8.5 million of sample collection devices for use in the collection and transport of samples for COVID-19 molecular testing. There were no similar sales in 2019.

Laboratory services revenues increased 86% to $2.2 million in the second quarter of 2020 compared to $1.2 million in the second quarter of 2019, due to the inclusion of revenues generated by Diversigen which was acquired in the fourth quarter of 2019, partially offset by a decline in laboratory testing due to the inability of our customers to collect samples due to the COVID-19 pandemic.

Other revenues in the second quarter of 2020 decreased 33% to $765,000 from $1.2 million in the second quarter of 2019 largely as a result of lower royalty income under a litigation settlement agreement.

CONSOLIDATED OPERATING RESULTS

Consolidated gross profit percentage was 59% for the second quarter of 2020 compared to 64% for the second quarter of 2019. The decrease in gross profit percentage in the second quarter of 2020 was primarily due to lower labor utilization as we increased our manufacturing headcount with full-time and temporary employees to prepare for expected product production increases for the remainder of the year, a less favorable overall product mix, and the decline in other revenues which contribute 100% to our gross profit percentage.

Consolidated operating loss for the second quarter of 2020 was $9.4 million, a $14.7 million decline from $5.3 million of operating income reported in the second quarter of 2019. Results in the second quarter of 2020 were negatively impacted by the decrease in revenues, the lower gross profit percentage, and increased operating expenses.

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.

OSUR Segment

OSUR’s gross profit percentage was 42% in the second quarter of 2020 compared to 59% in the second quarter of 2019. This decrease is largely due to lower labor utilization as we increased our manufacturing headcount with full-time and temporary employees to prepare for expected product production increases for the remainder of the year, a less favorable product mix, the absence of higher margin cryosurgical system revenues due to the sale of our cryosurgical systems business in August 2019, and the decline in other revenues which contribute 100% to our gross profit percentage.

Research and development expenses increased 52% to $4.3 million in the second quarter of 2020 from $2.8 million in the second quarter of 2019 largely due to increased spending associated with COVID-19 product development. Sales and marketing expenses increased 31% to $6.6 million in the second quarter of 2020 from $5.0 million in the second quarter of 2019, due to higher staffing costs associated with the retirement of a

senior executive who previously led our Infectious Disease Business Unit, the on-boarding costs of his successor and an increase in our reserve for uncollectible accounts largely associated with one of our distributors located in Africa. These increases were partially offset by lower spending on market research studies, and lower travel and trade show costs due to the COVID-19 pandemic. General and administrative expenses increased 69% to $6.9 million in the second quarter of 2020 compared to $4.1 million in the second quarter of 2019 largely due to increased staffing costs, higher legal fees, and the inclusion of the $195,000 in acquisition related transaction costs associated with the UrSure acquisition.

All of the above contributed to OSUR's second quarter 2020 operating loss of $13.5 million, which included non-cash charges of $886,000 for depreciation and amortization and $2.2 million for stock-based compensation.

DNAG Segment

DNAG's gross profit percentage was 68% in the second quarter of 2020 compared to 70% in the second quarter of 2019. This decrease is attributable to the decline in other revenues which contribute 100% to our gross profit percentage and a less favorable overall product mix.

Research and development expenses increased 54% to $2.6 million in the second quarter of 2020 from $1.7 million in the second quarter of 2019 due to higher staffing costs, increased spending related to COVID-19 product development, and the inclusion of research and development expenses incurred by Diversigen. Sales and marketing expenses increased 33% to $3.5 million in the second quarter of 2020 from $2.6 million in the second quarter of 2019 largely due to increased staffing cost, higher bad debt expense, and expenses incurred by Diversigen not included in the second quarter of 2019. General and administrative expenses increased 6% to $3.3 million in the second quarter of 2020 from $3.1 million in the second quarter of 2019 due to expenses incurred by Diversigen not included in the second quarter of 2019 and increased amortization expense, partially offset by lower consulting costs.

All of the above contributed to DNAG's second quarter 2020 operating income of $4.1, which included a non-cash benefit of $660,000 for the change in the fair value of acquisition-related contingent consideration, $1.5 million for depreciation and amortization, and $453,000 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, 2020 and 2019, $9,000 of state income tax expense was recorded. For the three months ended June 30, 2020, foreign tax expense of $1.3 million was recorded compared to foreign tax expense of $1.4 million recorded for the three months ended June 30, 2019.

Six months ended June 30, 2020 compared to June 30, 2019

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, 2020 and 2019.

	Six Months Ended June 30,				
	Dollars			Percentage of Total Net Revenues	
	2020	2019	% Change	2020	2019
OSUR	$ 27,933	$ 37,713	(26) %	46 %	55 %
DNAG	31,290	27,886	12	51	40
Net product revenues	59,223	65,599	(10)	97	95
Other	1,632	3,349	(51)	3	5
Net revenues	$ 60,855	$ 68,948	(12) %	100 %	100 %

Consolidated net product and services revenues decreased 10% to $59.2 million for the six months ended June 30, 2020 from $65.6 million for the comparable period of 2019. Lower sales of our genomics, domestic HIV, HCV, risk assessment, and microbiome products and the absence of cryosurgical sales as a result of the divestiture of our cryosurgical systems business in August 2019 were partially offsetting by the inclusion of product revenues associated with COVID-19 testing, higher laboratory services revenues and higher international sales of our OraQuick® HIV Self-Test. Other revenues for the six months ended June 30, 2020 were $1.6 million compared to $3.3 million in the same period of 2019. This decline is largely due to lower royalty income and lower research and development funding.

Consolidated net revenues derived from products sold to customers outside of the United States were $17.3 million and $20.5 million, or 28% and 30% of total net revenues, in the first six months of 2020 and 2019, 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, 2020 and 2019.

	Six Months Ended June 30,				
	Dollars			Percentage of Total Net Revenues	
Market	2020	2019	% Change	2020	2019
Infectious disease testing	$ 23,400	$ 25,686	(9) %	83 %	67 %
Risk assessment testing	4,533	5,934	(24)	16	15
Cryosurgical systems	—	6,093	(100)	—	16
Net product revenues	27,933	37,713	(26)	99	98
Other	286	892	(68)	1	2
Net revenues	$ 28,219	$ 38,605	(27) %	100 %	100 %

Infectious Disease Testing Market

Sales to the infectious disease testing market decreased 9% to $23.4 million for the six months ended June 30, 2020 from $25.7 million for the six months ended June 30, 2019. This decrease resulted from lower domestic sales of our OraQuick® HIV products and lower world-wide sales of our OraQuick® HCV products partially offset by higher international sales of our OraQuick® HIV products.

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, 2020 and 2019.

	Six Months Ended June 30,		
Market	2020	2019	% Change
Domestic HIV	$ 7,414	$ 8,765	(15) %
International HIV	10,832	9,423	15
Net HIV revenues	18,246	18,188	—
Domestic HCV	2,251	3,930	(43)
International HCV	1,738	2,440	(29)
Net HCV revenues	3,989	6,370	(37)
Net OraQuick® revenues	$ 22,235	$ 24,558	(9) %

Domestic OraQuick® HIV sales decreased 15% to $7.4 million for the six months ended June 30, 2020 from $8.8 million for the six months ended June 30, 2019. This decrease was primarily the result of the decline in domestic HIV testing in public health clinics, hospitals and doctors' offices due to the COVID-19 pandemic partially offset by higher sales of our over-the-counter product as a result of a stocking order at a new retailer in the first quarter and increased at-home testing as a result of the COVID-19 pandemic.

International sales of our OraQuick® HIV tests increased 15% to $10.8 million for the six months ended June 30, 2020 from $9.4 million for the six months ended June 30, 2019. This increase was largely due to higher sales of our OraQuick® HIV Self-Test in Africa, Latin America and certain parts of Europe.

Domestic OraQuick® HCV sales decreased 43% to $2.3 million for the six months ended June 30, 2020 from $3.9 million for the six months ended June 30, 2019. International OraQuick® HCV sales decreased 29% to $1.7 million for the six months ended June 30, 2020 from $2.4 million for the six months ended June 30, 2019. The declines in HCV sales in both the domestic and international markets are due to the closure of testing programs due to the COVID-19 pandemic.

Risk Assessment Market

Sales to the risk assessment market decreased 24% to $4.5 million for the six months ended June 30, 2020 compared to $5.9 million for the six months ended June 30, 2019 due to unemployment and reductions in workplace and insurance testing programs resulting from the COVID-19 pandemic.

Cryosurgical Systems Market

In August 2019, we sold our cryosurgical systems line of business and as such have stopped recording revenues associated with that business since the third quarter of 2019.

Other revenues

Other revenues for the six months ended June 30, 2020 decreased 68% to $286,000 from $892,000 for the six months ended June 30, 2019. Revenue associated with funding of our research and development efforts declined to $242,000 for the six months ended June 30, 2020 from $773,000 for the six months ended June 30, 2019 as a result of the wind-down of efforts to develop our rapid Ebola test. Other revenues for the six months ended June 30, 2020 also included $42,000 in reimbursement of certain costs under our charitable support agreement with the Gates Foundation compared to $118,000 for the six months ended June 30, 2019.

DNAG Segment

The table below shows a breakdown of total net revenues (dollars in thousands) generated by our DNAG segment for the six months ended June 30, 2020 and 2019.

	Six Months Ended June 30,		
Market	**2020**	**2019**	**% Change**
Genomics	$ 14,863	$ 21,791	(32) %
Microbiome	2,430	3,446	(29)
COVID-19	8,866	—	—
Laboratory services	5,053	2,332	117
Other product revenues	78	317	(75)
Net molecular product and services revenues	$ 31,290	$ 27,886	12
Other	1,346	2,457	(45)
Net molecular product and services revenues	$ 32,636	$ 30,343	8 %

Sales of our genomics products decreased 32% to $14.9 million for the six months ended June 30, 2020 compared to $21.8 million for the six months ended June 30, 2019, largely due to the timing of orders placed by one of our largest genomics customer and the reduction in genomics testing due to the COVID-19 pandemic.

Microbiome sales decreased 29% to $2.4 million for the six months ended June 30, 2020 compared to $3.4 million for the six months ended June 30, 2019 largely due to the timing of orders placed by one of our customers and reduced demand caused by the COVID-19 pandemic.

During the first six months of 2020, we sold $8.9 million of sample collection devices for use in the collection and transport of samples for COVID-19 molecular testing. There were no similar sales in 2019.

Laboratory services revenues increased 117% to $5.0 million for the six months ended June 30, 2020 compared to $2.3 million for the six months ended June 30, 2019, due to the inclusion of revenues generated by Diversigen which was acquired in the fourth quarter of 2019, partially offset by a decline in laboratory testing due to the inability of our customers to collect samples as a result of the COVID-19 pandemic.

Other revenues for the six months ended June 30, 2020 decreased 45% to $1.3 million from $2.5 million for the six months ended June 30, 2019 largely as a result of lower royalty income under a litigation settlement agreement.

CONSOLIDATED OPERATING RESULTS

Consolidated gross profit percentage was 55% for the six months ended June 30, 2020 compared to 63% for the six months ended June 30, 2019. The decrease in gross profit percentage in the first half of 2020 was primarily due to a less favorable product mix, lower labor utilization as we increased our manufacturing headcount with full-time and temporary employees to prepare for expected product production increases for the remainder of the year, increased international freight costs, the decline in other revenues which contribute 100% to our gross profit percentage, and increased scrap and spoilage expense.

Consolidated operating loss for the six months ended June 30, 2020 was $17.4 million, an $18.9 million decline from the $1.5 million of operating income reported for the six months ended June 30, 2019. Results in the six months ended June 30, 2020 were negatively impacted by the decrease in revenues, the lower gross profit percentage, and increased operating expenses.

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.

OSUR Segment

OSUR's gross profit percentage was 43% for the six months ended June 30, 2020 compared to 57% for six months ended June 30, 2019. This decrease is largely due to lower labor utilization as we increased our manufacturing headcount with full-time and temporary employees to prepare for expected product production increases for the remainder of the year, increased international freight costs, a less favorable sales mix, the absence of higher margin cryosurgical system revenues due to the sale of our cryosurgical systems business in August 2019, and the decline in other revenues which contribute 100% to our gross profit percentage.

Research and development expenses increased 41% to $7.8 million in the six months ended June 30, 2020 from $5.5 million in the six months ended June 30, 2019, largely due to increased spending associated with COVID-19 product development and higher staffing costs. Sales and marketing expenses increased 16% to $11.2 million in the six months ended June 30, 2020 from $9.6 million in the six months ended June 30, 2019, due to higher staffing costs associated with the retirement of a senior executive who previously led our Infectious Disease Business Unit and the on-boarding costs of his successor and an increase in our reserve for uncollectible accounts largely associated with one of our distributors located in Africa. These increases were partially offset by lower spending on market research studies and lower travel and trade show costs due to the COVID-19 pandemic. General and administrative expenses increased 40% to $14.3 million in the six months ended June 30, 2020 compared to $10.2 million in the six months ended June 30, 2019 largely due to higher staffing and legal fees and the inclusion of the $343,000 in acquisition related transaction costs associated with the UrSure acquisition.

All of the above contributed to OSUR's 2020 operating loss of $21.2 million in the first half of 2020, which included non-cash charges of $1.7 million for depreciation and amortization and $3.3 million for stock-based compensation.

DNAG Segment

DNAG's gross profit percentage was 65% for the six months ended June 30, 2020 compared to 70% for the six months ended June 30, 2019. This decrease is attributable to the decline in other revenues which contribute 100% to our gross profit and percentage and a less favorable overall product mix.

Research and development expenses increased 42% to $4.8 million in the six months ended June 30, 2020 from $3.4 million in the six months ended June 30, 2019 due to higher staffing costs and the inclusion of research and development expenses incurred by Diversigen. Sales and marketing expenses increased 17% to $6.3 million in the six months ended June 30, 2020 from $5.3 million in the six months ended June 30, 2019 largely due to increased staffing costs and expenses incurred by Diversigen not included in the first half of 2019. General and administrative expenses largely remained flat at $6.1 million in the six months ended June 30, 2020 compared to $6.0 million in the same period of 2019.

All of the above contributed to DNAG's operating income of $3.7 million in the first half of 2020, which included a non-cash charge of $450,000 for the change in the fair value of acquisition-related contingent consideration, $2.9 million for depreciation and amortization, and $753,000 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, 2020, $18,000 of state income tax expense was recorded as compared to $12,000 in the six months ended June 30, 2019. For the six months ended June 30, 2020, foreign tax expense of $2.0 million was recorded as compared to income tax expense of $1.4 million recorded for the six months ended June 30, 2019.

Liquidity and Capital Resources

	June 30, 2020	December 31, 2019
	(In thousands)	
Cash and cash equivalents	$ 173,874	$ 75,715
Available for sale securities	91,888	114,043
Working capital	287,376	191,837

Our cash and cash equivalents and available-for-sale securities increased to $265.8 million at June 30, 2020 from $189.8 million at December 31, 2019. Our working capital increased to $287.4 million at June 30, 2020 from $191.8 million at December 31, 2019.

During the first six months of 2020, we used $2.2 million in cash for operating activities. Our net loss of $17.8 million included non-cash charges for depreciation and amortization expense of $4.6 million, stock-based compensation expense of $4.0 million, a provision for doubtful accounts of $1.4 million, a charge for the change in the estimated fair value of acquisition-related contingent consideration of $450,000 and other non-cash benefits of $102,000. Cash used in operating activities also included a $496,000 contingent consideration payment which represents the excess of the total contingent consideration payment made during the first quarter of 2020 over the fair value of the liability estimated at the time of acquisition. Sources of cash generated from our working capital accounts included a $9.3 million decrease in accounts receivable as a result of the collection of large outstanding balances, a $1.3 million increase in deferred revenue associated with customer prepayments, and a $369,000 decrease in prepaid expenses and other assets. Offsetting these sources of cash were an increase in inventory of $4.7 million to meet anticipated demand to support COVID-19 testing programs and a decrease in accounts payable of $605,000 due to the payment of vendor invoices that were outstanding at the end of 2019.

Net cash provided by investing activities was $13.1 million for the six months ended June 30, 2020, which reflects $87.6 million in proceeds from the maturities and redemptions of investments partially offset by $66.3 million used to purchase investments, $6.0 million used to acquire property and equipment, and $2.3 million used to purchase patent and product rights.

Net cash provided by financing activities was $90.2 million for the six months ended June 30, 2020, which largely resulted from the proceeds from the issuance of common stock in connection with a public offering of $95.0 million offset, in part, by $3.0 million used for payment of our contingent consideration obligation and $2.1 million used for the repurchase of common stock to satisfy withholding taxes related to the vesting of restricted shares awarded to our employees.

We expect current balances of cash and cash equivalents and available-for-sale securities 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, $71.6 million or 27% of our $265.8 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, 2019 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, 2019. As of June 30, 2020, there were no significant changes to this information.

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, 2019 filed with the SEC. During the first six months of 2020, there were no material changes to our critical accounting policies.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

As of June 30, 2020, 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 5.9% of our total revenues for the six months ended June 30, 2020. 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 $117.8 million in

U.S. Dollars, which are included in the Company's consolidated balance sheet as of June 30, 2020. 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 $9.8 million in the six months ended June 30, 2020.

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, 2020. 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, 2020 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, 2020 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

The risk factors set forth in this report update, and should be read together with, the risk factors discussed in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2019.

Economic volatility and disruption, including those related to the COVID-19 pandemic, could adversely affect our business, financial performance, results of operations, cash flow and financial condition or those of our customers and suppliers.

Global and U.S. markets and economies have experienced extreme volatility and disruption following the global outbreak of COVID-19 that began in December 2019. Many economists and major investment banks have expressed concern that the continued spread of the virus globally has led or will lead to a world-wide economic downturn. Volatile economic conditions may occur again or continue in the future.

Although the severity and duration of the COVID-19 pandemic cannot be reasonably estimated at this time, impacts that we may experience include, but are not limited to:

- a slowdown or stoppage in the supply chain of the raw materials and components used to manufacture our products;
- interruptions or delays in international shipment of our products to our distributors and customers;
- interruptions in normal operations of certain end use customers that could result in reductions in demand for our products;
- disruptions to our operations, including a shutdown of our facilities or product lines; restrictions on our operations and sales, marketing and distribution efforts; and interruptions to our research and development, manufacturing, clinical/regulatory and other important business activities;
- shutdown or interruption of our manufacturing facilities due to contamination and costs incurred to clean and disinfect a facility following contamination;
- inefficiencies and increased costs in our production and shipping processes due to premium pay for manufacturing and certain other employees as well as social distancing and personal protective equipment requirements;
- limitations on employee resources and availability, including due to sickness, government restrictions, the desire of employees to avoid contact with large groups of people or mass transit disruptions;
- a fluctuation in foreign currency exchange rates or interest rates could result from market uncertainties;
- an increase in exposure to credit losses for customers adversely affected by the COVID-19 pandemic; and
- an increase in regulatory restrictions or continued market volatility could hinder our ability to execute strategic business activities, including acquisitions.

These conditions could adversely affect our financial performance and condition or those of our customers and suppliers. These circumstances could also adversely affect our access to liquidity needed to conduct or expand our business or conduct future acquisitions or make other discretionary investments. Many of our customers rely on public funding provided by federal, state and local governments, and this funding has been and may continue to be reduced or deferred as a result of economic conditions or other factors. These circumstances may adversely impact our customers and suppliers, which, in turn, could adversely affect their ability to purchase and/or distribute our products or supply us with necessary equipment, raw materials or components. Any or all of these effects would have an adverse effect on our operations, business, financial condition and results of operations.

The duration of the COVID-19 pandemic is unknown, and it is difficult to predict the full extent of potential impacts the pandemic will have in the future on our business, operations, and financial results, or on our customers, suppliers, logistics providers, or on the global economy as a whole. It is uncertain how materially the COVID-19 pandemic will affect our global operations, particularly if the effects continue or get worse over an extended period of time. Even with the improvement of economic conditions, it may take time for our customers and suppliers to establish new

budgets and return to normal purchasing and shipping patterns. We cannot predict the reoccurrence of any economic slowdown or the strength or sustainability of an economic recovery.

Terrorist attacks, natural disasters, public health crises or other catastrophic events outside of our control may adversely affect our business.

Terrorist attacks, natural disasters, public health crises or other catastrophic events outside of our control, including pandemics, and subsequent governmental responses to these events, could cause economic instability. These actions could adversely affect economic conditions both within and outside the United States and reduce demand for our products. For example, the COVID-19 outbreak has led to, and for an unknown period of time will continue to lead to, disruptions in local, regional, national and global markets and economies affected thereby, including the United States. This outbreak has resulted in, and until fully resolved is likely to continue to result in, among other things: (i) restrictions on travel, government mandated social distancing measures, and the temporary closure of many corporate offices, retail stores, and manufacturing facilities and factories; (ii) significant disruption to the business of many companies, including our customers and suppliers, as well as layoffs of employees; (iii) reduction or termination by public health and other customers of infectious disease testing programs, including for HIV and HCV, and a reallocation of personnel and monetary resources from these programs to programs intended to address COVID-19; (iv) reduction or termination of clinical and research studies by academic and other entities that use our molecular collection products and laboratory services; and (v) rapidly evolving proposals and actions by state and federal governments to address the problems being experienced by markets, businesses and the economy in general, which may have unintended consequences or may not adequately address such problems. These events have disrupted, and threaten to continue to disrupt, our normal operation, the operations of our customers and suppliers and eliminate, reduce or delay our customers' ability to purchase and use our products and our suppliers' ability to provide raw materials and finished products. Despite our efforts to manage and mitigate the impact of these events on us, it is impossible to predict the precise nature and consequences of these events, or of any political or policy decisions and regulatory changes occasioned by emerging events or uncertainty under applicable laws or regulations that impact us. It is clear that these types of events are impacting and will, for at least some time, continue to impact our product development and operation and in many instances the impact may be adverse and may be material. Any potential impact to our results of operations will depend to a large extent on future developments and new information that could emerge regarding the duration and severity of the COVID-19 pandemic and the actions taken by authorities and other entities to contain the spread or treat its impact, all of which are beyond our control. These potential impacts, while uncertain, could adversely affect our business and results of operation.

Various types of disasters, including earthquakes, fires, floods, riots, acts of terrorism and pandemics, may also affect our manufacturing facilities and computer systems, and increase our cybersecurity risks. Although we have business interruption insurance, our facilities, including some pieces of manufacturing equipment and our computer systems, may be difficult to replace and could require substantial replacement lead-time. In the event our existing manufacturing facilities or computer systems are affected by man-made or natural disasters, including pandemics, we may have difficulty operating our business and may be unable to manufacture products for sale or meet customer demands or sales projections. If our manufacturing operations were curtailed or shut down entirely, it would seriously harm our business. Moreover, we may incur incremental costs following an unforeseen event which could adversely affect our results of operation.

If our essential employees who are unable to telework become ill or otherwise incapacitated, our operations may be adversely impacted.

As a medical device manufacturer, we fall within a "critical essential infrastructure" sector, specifically the "Healthcare/Public Health" sector, and are considered exempt under various stay at home/shelter in place orders. Accordingly, our employees may continue to work because of the importance of our operations to the health and well-being of citizens in the states in which we operate. Consistent with these Stay at Home Orders, we have implemented telework policies wherever possible for appropriate categories of "nonessential" employees. "Essential" employees that are unable to telework continue to work at our facilities, and we have implemented appropriate safety measures, including social distancing, face covering and increased sanitation standards. We are following guidance from the Center for Disease Control and the Occupational Safety and Health Administration regarding suspension of nonessential travel, self-isolation recommendations for employees returning from certain geographic areas, confirmed reports of any COVID-19 diagnosis among our employees, and the return of such employees to our workplace. Pursuant to updated guidance from the Equal Employment Opportunity Commission, we are engaging in limited and appropriate inquiries of employees regarding potential COVID-19 exposure, based on the direct threat that such exposure may present to our workforce. We continue to address other unique situations that arise among our workforce due to the COVID-19 pandemic on a case-by-case basis. While we believe that we have taken appropriate measures to ensure the health and wellbeing of our "essential" employees, there can be no assurances that our measures will be sufficient to protect our employees in our workplace or that they may otherwise be exposed to COVID-19 outside of our workplace. If a number of our essential employees become ill, incapacitated or are otherwise unable to continue working during the current or any future epidemic, our operations may be adversely impacted.

The use of third party supply sources for critical components of our products could adversely affect our business.

We currently purchase certain critical components of our products from sole supply sources or other third-party suppliers. For example, the biological antigens and antibodies, nitrocellulose and certain other components required to make our OraQuick HIV, HCV and Ebola products are currently purchased from sole source suppliers. Our OraSure QuickFlu® test and the fully automated high-throughput drug assays sold with our Intercept i2® device are manufactured and supplied by sole source suppliers and the conjugates used in our MICROPLATE oral fluid drugs-of-abuse assays are obtained from third-party suppliers. We have contracted with a third party in Thailand for the assembly of OraQuick® HIV device and the OraQuick® HIV Self-Test in order to supply certain international markets. In addition, our subsidiary, DNAG, uses two third-party manufacturers to supply virtually all of its products, including its Oragene® line of collection kits. Many of the raw materials and components used in its products are also purchased from third parties, a critical one of which is obtained from a sole source supplier.

The COVID-19 pandemic and the measures taken to contain the spread of the virus, could disrupt the normal operations of our third-party suppliers. Our third-party suppliers may not have the personnel, raw materials, capacity, or capability to manufacture our products according to our schedule and specifications. To the extent any such production and distribution interruption or closures occur and continue for an extended period of time, the impact on our supply chain could have a material adverse effect on our results of operations. If our third-party suppliers are unable or unwilling to supply or manufacture a required component or product or if they make changes to a component, product or manufacturing process or do not supply materials meeting our specifications, we may need to find another source and/or manufacturer. This could require that we perform additional development work and it may be difficult to find such an alternate supply source in a reasonable time period or on commercially reasonable terms, if at all. We may also need to obtain FDA or other regulatory approvals for the use of an alternative component or for changes to our products or manufacturing process. Completing that development and obtaining such approvals could require significant time and expense and such approvals may not occur at all. The availability of critical components and products from sole supply sources or other third parties could also reduce our control over pricing, quality and timely delivery. These events could either disrupt our ability to manufacture and sell certain of our products into one or more markets or completely prevent us from doing so, and could increase our costs. Any such event could have a material adverse effect on our results of operations, cash flow and business.

Marketing of our COVID-19 tests and collection kits under EUAs from FDA is subject to certain limitations and we are required to maintain compliance with the terms of the EUA, among other things, and the continuance of the EUAs is subject to government discretion.

On February 4, 2020, the U.S. Department of Health and Human Services ("HHS") Secretary Alex Azar issued a declaration that the threat to public health posed by COVID-19 justifies the emergency use of unapproved in vitro diagnostics for the detection or diagnosis of SARS-CoV-2. Under Section 564 of the Food, Drug, and Cosmetic Act ("FDCA"), because HHS has issued this declaration, the FDA Commissioner is authorized to issue EUAs to permit certain developers of SARS-CoV-2 diagnostics to begin offering the tests for detection and diagnosis of COVID-19 without having completed the normally applicable FDA review and clearance or approval process for marketing authorization (with the related standards that would apply to demonstrate safety and effectiveness). The issuance of an EUA reflects an FDA conclusion that based on the totality of scientific evidence available to the FDA, it is reasonable to believe that the product may be effective in diagnosing COVID-19, and that the known potential benefits of the product outweigh the known and potential risks, and there is no adequate, approved, and available alternative to the emergency use of the product.

In May 2020, our ORAcollect®•RNA kit was included as the collection device for anterior nares (nasal) samples under an EUA granted to Biocerna LLC for use with its PCR-based SARS-CoV-2 assay. More recently, our OMNIgene®•ORAL saliva collection device was included in an EUA granted by the FDA to P23 Labs for use with its TaqPath SARS-CoV-2 assay. This EUA permits individuals to self-collect saliva specimens at home for the detection of SARS-CoV-2. In June 2020 our Oragene®● Dx oral saliva collection kit was included in an EUA granted to Phosphorus Diagnostics for the detection of SARS-CoV-2 using the Phosphorus COVID-19 RT-qPCR test. Finally, in July 2020 our OMNIgene® ORAL saliva collection device was included in an EUA granted to Clinical Reference Laboratory (CRL) for use with the CRL Rapid Response™, a saliva-based SARS-CoV-2 RT-PCR test. Several other laboratories are pursuing the inclusion of our specimen collection devices for use with their SARS-CoV-2 assays. Although there are certain regulatory requirements the FDA has waived for the duration of the EUA, we remain subject to specific conditions of the authorization, including ensuring appropriate labeling as approved by FDA specifically for purposes of the EUA, maintaining records of distribution to authorized laboratories, collecting data on occurrences of any false positives or false negatives, and tracking any adverse events.

As with other FDA-regulated products, issues could emerge during the course of the marketing and use of our products under an EUA that could impact our ability to continue the sale and distribution of these products (for example, compliance or product performance issues). The applicable EUAs remain effective only until the HHS declaration is terminated or revoked, and FDA may also revoke an EUA if it determines the criteria for issuance are no longer met or other circumstances make such revocation appropriate to protect the public health or safety. If that were to occur then in order market our diagnostic products or collection kits for the purpose of detecting COVID-19, we would be required to obtain the necessary regulatory clearances or approvals and be subject to the full and usual regulatory obligations for device manufacturers, including the Quality System Regulation under 21 CFR Part 820.

Our future success depends upon market acceptance of our existing and future products and service offerings.

We believe successful new product and service introductions provide a significant competitive advantage because customers make an investment of time in selecting and learning to use a new product or service and are reluctant to switch thereafter. Our future success will depend, in part, on the market acceptance, and the timing of such acceptance, of new products such as our in-home antigen pan-SARS-coronavirus self-test ("Coronavirus Self-Test"), laboratory-based SARS-CoV-2 antibody test ("Coronavirus Antibody Test"), OraQuick® HIV Self-Test, OraQuick® Ebola test and OMNIgene® • GUT product offerings, and other new products or technologies that may be developed or acquired. In addition, our future revenues will depend on market acceptance of new uses for our saliva collection products, including for COVID-19 testing, and our new service offerings, such as the microbiome laboratory testing and analytical services we provide through CoreBiome and Diversigen. To commercially market new uses of our products and to achieve market acceptance, we will likely be required to undertake clinical studies to validate the new uses for our products and substantial marketing efforts and spend significant funds to complete product development and clinical studies and inform potential customers and the public of the existence and perceived benefits of these products and services. In addition, governmental funding may be needed to help complete development, obtain required regulatory approvals, clearances or EUAs and create market acceptance and expand the use of these products and services.

There may be limited evidence on which to evaluate the market reaction to products and services that may be developed and our marketing efforts for new products and services or products with new uses may not be successful. The market for microbiome products and services is in its early

stages and its future development and acceptance by our customers is uncertain. It is also possible that governmental funding may be limited for new products, such as our Coronavirus Self-Test and Coronavirus Antibody Test or the new sample collection and stabilization products being commercialized by DNAG. Also, we are still in the process of developing the Coronavirus Self-Test and Coronavirus Antibody Test and validating the use of existing products for pan-SARS-coronavirus testing, and it is uncertain whether we will be successful in our development and validation efforts or whether these products will prove effective, receive applicable regulatory approvals, clearances or EUAs and gain widespread acceptance in the marketplace. As such, there can be no assurance that any products or services will obtain significant market acceptance and fill the market need that is perceived to exist on a timely basis, or at all. In addition, it is possible that our expenses to develop and market any such products, including, without limitation our Coronavirus Self-Test and Coronavirus Antibody Test, will exceed any benefit in revenues, which may be short-lived, or that other products that compete with ours achieve commercial acceptable earlier than we do.

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, 2020 - April 30, 2020	838	(3)	$ 9.27	—	11,984,720
May 1, 2020 - May 31, 2020	19,035	(3)	16.04	—	11,984,720
June 1, 2020 - June 30, 2020	30,091		11.37	—	11,984,720
	49,964			—	

(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
1.1	Underwriting Agreement among the Company and J.P. Morgan Securities LLC, Citigroup Global Markets Inc. and Evercore Group L.L.C., as representatives of the underwriters named therein, dated as of June 2, 2020 is incorporated by reference to the Company's Current Report on Form 8-K filed June 4, 2020.
10.1	Retirement Agreement dated as of May 1, 2020 between OraSure Technologies, Inc. and Anthony Zezzo II is incorporated by reference to the Company's Current Report on Form 8-K filed May 5, 2020.*
10.2 †	Employment Agreement dated as of May 11, 2020, between OraSure Technologies, Inc. and Lisa Nibauer.*
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	Inline 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	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
Exhibit 104	Cover Page from the Company's Quarterly Report on Form 10-Q for the Quarter Ended June 30, 2020 has been formatted in Inline XBRL

* 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 6, 2020

Roberto Cuca
Chief Financial Officer
(Principal Financial Officer)

/s/Michele M. Miller

Date: August 6, 2020

Michele M. Miller
Vice President, Finance and Controller
(Principal Accounting Officer)

Exhibit 10.2

EMPLOYMENT AGREEMENT

This Employment Agreement (this "**Agreement**") is entered into as of May 11, 2020 (the "**Effective Date**"), between Lisa A. Nibauer ("**Employee**") and OraSure Technologies, Inc. ("**OraSure**" or the "Company").

WHEREAS, the parties wish to set forth the terms of their relationship and to enter into this Agreement and a confidentiality agreement of even date herewith (the "Confidentiality Agreement").

NOW, THEREFORE, in consideration of the mutual promises made herein, intending to be legally bound, the parties hereby agree as follows:

1. **Services.**

1.1 **Employment.** Subject to the terms hereof, the Company agrees to employ Employee as the Company's Executive Vice President, Business Unit Leader, Infectious Disease (the "**Position**"), and Employee hereby accepts such employment in accordance with the terms and conditions of this Agreement. Employee shall begin her employment with the Company on the Effective Date.

1.2 **Duties.** Upon the Effective Date, Employee shall have such powers and duties that are (a) commensurate with the Position, (b) set forth in Exhibit A attached to this Agreement, and (c) otherwise determined from time to time by the Board of Directors of OraSure (the "**Board of Directors**") or the Chief Executive officer of OraSure (the "**CEO**"). Employee's primary place of work shall be the Company's headquarters, at its present location in Bethlehem, Pennsylvania. Subject to the provisions of Section 6 hereof, Employee's position and duties may be changed and Employee's primary place of work may be relocated from time to time during the Term (as defined below) of this Agreement, and such changes shall not be considered a material change in circumstance that would invalidate the provisions of this Agreement which, in any event, shall survive such change or changes.

1.3 **Outside Activities.** Employee shall obtain the consent of the Board of Directors or the CEO before she engages, either directly or indirectly, in any other professional or business activities that may require an appreciable portion of Employee's time.

1.4 **Direction of Services.** Employee shall at all times report directly to, and discharge her duties in consultation with and under the supervision and direction of, the CEO.

2. **Term.** The initial term of this Agreement shall begin as of the Employment Date and end on the third anniversary of the Employment Date, unless Employee's employment is sooner terminated in accordance with Section 6 below (the "Initial Term"). Thereafter, this Agreement shall automatically renew and Employee's employment shall continue for successive one-year terms (each, a "Renewal Term" and together with the Initial Term, the "Term") unless

the Company gives Employee written notice of the Company's intent not to renew this Agreement at least 90 days before the expiration of the Initial Term or any Renewal Term, or Employee's employment under this Agreement is terminated in accordance with Section 6 below.

3. **Compensation and Expenses.**

3.1 **Salary.** As compensation for services under this Agreement, the Company shall pay to Employee a base salary of $410,000 per annum. Such salary will be subject to review by the Board of Directors on an annual basis and may be increased from time to time in the discretion of the Board of Directors. Any reduction shall be subject to the provisions of Good Reason (as defined below) and Section 6 below. Payment shall be made in accordance with the Company's normal payroll practices as in effect from time to time, less all amounts required by law or authorized by Employee to be withheld or deducted. For all purposes under this Agreement, the term "salary" shall mean the regular annual base salary of Employee payable under this Section 3.1, as increased.

3.2 **Bonus.** In addition to the salary described in Section 3.1 above, Employee shall be entitled to participate in the incentive plan established by OraSure each year for the payment of cash bonuses to senior executive officers of OraSure and its subsidiaries (each, a "**Bonus Plan**"), on such terms as may be approved by the Board of Directors or its compensation committee (the "**Compensation Committee**") in its sole discretion each Bonus Plan. With respect to each Bonus Plan, (a) Employee shall have a target bonus amount as determined by the Board of Directors or Compensation Committee which is at least equal to 40% of Employee's salary and (b) cash bonuses payable to Employee shall be determined in the same manner as the cash bonuses paid to other senior executive officers of the Company under the applicable Bonus Plan with respect to the same time period. Notwithstanding the foregoing, Employee's bonus for performance during 2020 shall not be less than $80.000.

3.3 **Long-Term Incentive Awards.** Employee shall be entitled to participate in the Long-Term Incentive Policy or comparable long-term incentive equity policy or plan that may from time to time be adopted by the Board of Directors or the Compensation Committee, in its sole discretion (an "**LTIP**") and, with respect to each LTIP, (a) Employee shall be entitled to annual awards ranging from between 95% to 155% of her salary (with the target set at a minimum of 125% of her salary), as determined by the Board of Directors or its Compensation Committee and (b) equity awards or other benefits provided to Employee under any such LTIP shall be determined in the same manner as the awards or other benefits provided under such policies or plans to other senior executive officers of the Company with respect to the same time period. All equity awards granted to Employee on or after the Effective Date, including the award provided for in Section 4, shall, to the extent then unvested, immediately vest (i) in the event of a Change of Control (as defined herein) or (ii) in the event Employee's employment is terminated for Good Reason (as defined herein) pursuant to Section 6.4 or without Cause (as defined herein) pursuant to Section 6.5 during a Change of Control Period (as defined herein), and 50% of such awards shall, to the extent then unvested, immediately vest in the event Employee's employment is terminated for death or Disability (as defined herein) pursuant to Section 6.1, Good Reason pursuant to Section 6.4 or without Cause pursuant to Section 6.5 during any period other than a Change of Control Period (as defined herein).

3.4 **Employee Benefits.** Employee shall be entitled to receive or participate in any additional benefits, including without limitation medical and dental insurance programs, qualified and non-qualified profit sharing or pension plans, disability plans, medical reimbursement plans, and life insurance programs, which may from time to time be made available by the Company to other senior executive officers of the Company. The Company may change or discontinue such benefits at any time in its sole discretion; provided that the benefits provided to Employee shall be determined in the same manner as the benefits provided to other senior executive officers of the Company under such plans with respect to the same time period.

3.5 **Expenses.** The Company shall reimburse Employee for all reasonable and necessary expenses incurred in carrying out her duties under this Agreement, subject to compliance with the Company's reasonable policies relating to expense reimbursement. Expenses subject to reimbursement under this Section 3.5 shall include, but not be limited to, the cost of business-related travel, lodging and meals and the fees and expenses incurred by Employee to maintain her membership in professional associations and obtain continuing professional education reasonably required in connection with Employee's performance of her duties under this Agreement. All reimbursements under this Section 3.5 will be made as soon as practicable after submission of any required documentation, in compliance with the Company's reasonable policies relating to expense reimbursement.

3.6 **Fees.** From and after the Employment Date, all compensation earned by Employee, other than pursuant to this Agreement, as a result of services performed on behalf of the Company or as a result of or arising out of any work done by Employee in any way related to the scientific or business activities of the Company shall belong to the Company. Employee shall pay or deliver such compensation to the Company promptly upon receipt. For the purposes of this provision, "compensation" shall include, but is not limited to, all professional and nonprofessional fees, lecture fees, expert testimony fees, publishing fees, royalties, and any related income, earnings, or other things of value; and "scientific or business activities of the Company" shall include, but not be limited to, any project or projects in which the Company is involved and any subject matter that is directly or indirectly researched, tested, developed, promoted, or marketed by the Company.

4. **Onboarding Compensation.** On or as soon as practicable after the Effective Date, Employee shall be granted an equity award under the Company's Stock Award Plan having an aggregate value of $500,000 and consisting of (i) 50% time-vested restricted stock and (ii) 50% performance-vested restricted units. The foregoing award shall contain terms substantially similar to the annual equity awards provided to executives under the LTIP in February 2020 for performance during 2019. In addition, Employee shall receive a sign-on bonus in the amount of $50,000, less applicable withholdings, which shall be paid within thirty (30) days after the Effective Date.

5. **Confidentiality Agreement.** Employee's compliance with the terms of the Confidentiality Agreement is a material requirement of this Agreement. Any breach of the Confidentiality Agreement that is materially detrimental to the Company and that, if capable of being cured, is not cured within 30 days of written notice thereof from the Company to Employee shall constitute a material breach of this Agreement. Notwithstanding the foregoing, (i) nothing in this Agreement or the Confidentiality Agreement shall prohibit the Employee from reporting

possible violations of law or a regulation to any governmental agency or entity or self-regulatory organization or making disclosures that are protected under law, including the whistleblower provisions of U.S. federal law or regulation; and (ii) in accordance with the U.S. Defend Trade Secrets Act of 2016, Employee shall not be held criminally or civilly liable under any U.S. federal or state trade secret law for the disclosure of a trade secret that: (A) is made (i) in confidence to a U.S. federal, state, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

6. **Termination.**

6.1 **Termination Upon Death or Disability.** Employee's employment under this Agreement shall terminate immediately upon Employee's death or Disability. The term "**Disability**" means Employee is (a) unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or can be expected to last for a continuous period of not less than twelve (12) months; or (b) by reason of any medically determinable physical or mental impairment that can be expected to result in death or can be expected to last for a continuous period of not less than twelve (12) months, receiving income replacement benefits for a period of not less than three (3) months under an accident and health plan covering employees of the Company.

6.2 **Termination by Employee.** Employee may terminate her employment under this Agreement by ninety (90) days' written notice to the Company.

6.3 **Termination by the Company for Cause.** Employee's employment under this Agreement may be terminated by the Company at any time for Cause. Only the following actions, failures, or events by or affecting Employee shall constitute "**Cause**" for termination of Employee by the Company: (i) willful and continued failure by Employee to substantially perform her duties provided herein after a written demand for substantial performance is delivered to Employee by the CEO or the Board of Directors, which demand identifies with reasonable specificity the manner in which Employee has not substantially performed her duties, and Employee's failure to comply with such demand within a reasonable time, which shall not be less than thirty (30) days after Employee's receipt of such demand; (ii) the engaging by Employee in gross misconduct or gross negligence materially injurious to the Company, which if capable of being cured, is not cured within 30 days of written notice thereof from the CEO or the Board of Directors to Employee; (iii) the commission of any act in direct competition with or materially detrimental to the best interests of the Company, which if capable of being cured, is not cured within 30 days of written notice thereof from the CEO or the Board of Directors to Employee; or(iv) Employee's conviction of having committed a felony. Notwithstanding the foregoing, Employee shall not be deemed to have been terminated by the Company for Cause unless and until there shall have been delivered to her a copy of a resolution duly adopted by the affirmative vote of not less than a majority of the entire membership of the Board of Directors finding that, in the good faith opinion of the Board of Directors, the Company has Cause for the termination of the employment of Employee as set forth in any of clauses (i) through (iv) above and specifying the particulars thereof in reasonable detail.

6.4 **Termination by Employee With Good Reason.** Employee may terminate her employment under this Agreement for Good Reason; provided that (i) Employee gives written notice to the Board of Directors within sixty (60) days of the event constituting Good Reason; (ii) the Company has not cured the event giving rise to such notice within thirty (30) days of receipt of Employee's notice; and (iii) Employee resigns her employment within thirty (30) days following the expiration of such cure period. The term "**Good Reason**" shall mean any of the following actions that are taken without Employee's prior written consent: (a) a material breach of this Agreement by the Company (or its successor); (b) a material diminution in Employee's base compensation or authority, duties or responsibilities; (c) a material change in Employee's reporting obligation from the CEO to another employee of the Company; or (d) a relocation of Employee's principal worksite that increases Employee's one-way commute by more than 30 miles.

6.5 **Termination by the Company Without Cause.** The Company may terminate Employee's employment under this Agreement without Cause by ninety (90) days' written notice to Employee. In the event the Company fails to renew this Agreement pursuant to Section 2, such failure shall be deemed to be a termination of Employee's employment by the Company without Cause.

6.6 **Definitions.** For purposes of this Agreement, the term "**Change of Control Period**" shall mean the period which begins sixty (60) days prior to the occurrence of a Change of Control and ends eighteen (18) months thereafter. For purposes of this Agreement, the term "**Change of Control**" shall mean a change of control of a nature that would be required to be reported in response to Item 6(e) of Schedule 14A of Regulation 14A pursuant to the U.S. Securities Exchange Act of 1934 (the "**Exchange Act**"); provided, however, that a change of control shall only be deemed to have occurred at such time as (i) any person, or more than one person acting as a group within the meaning of Section 409A of the Internal Revenue Code (the "**Code**") and the regulations issued thereunder, acquires ownership of stock of the Company that, together with stock held by such person or group, constitutes more than fifty percent (50%) of the total fair market value or total voting power of the stock of the Company; (ii) any person, or more than one person acting as a group within the meaning of Code Section 409A and the regulations issued thereunder, acquires (or has acquired during the twelve (12) month period ending on the date of the most recent acquisition) ownership of stock of the Company possessing thirty percent (30%) or more of the total voting power of the Company's stock; (iii) a majority of the members of the Board of Directors is replaced during any twelve (12) month period by directors whose appointment or election is not endorsed by a majority of the members of the Board of Directors before the date of the appointment or election; or (iv) a person, or more than one person acting as a group within the meaning of Code Section 409A and the regulations issued thereunder, acquires (or has acquired during the 12-month period ending on the date of the most recent acquisition) assets from the Company that have a total gross fair market value equal to or more than 40 percent of the total gross fair market value of all the assets of the Company immediately before such acquisition or acquisitions.

6.7 **Compensation Upon Termination.**

6.7.1 **Termination Upon Death or Disability, by Employee (Other Than for Good Reason) or for Cause.**

In the event of a termination of Employee's employment under Sections 6.1, 6.2 or 6.3, all salary and benefits shall cease on the date of termination, subject to the terms of any benefit plans then in force and applicable to Employee, and the Company shall have no further liability or obligation hereunder by reason of such termination, save and except as stated herein. In the event of a termination of Employee's employment under Sections 6.1, 6.2 or 6.3, Employee or her estate, as applicable, shall be paid all salary earned under Section 3.1 through the date of termination on the next regularly scheduled payroll date following the termination date ("**Accrued Salary and Benefits**"). With respect to terminations under Sections 6.1 and 6.2 only, Employee or her estate, as applicable, shall receive, in addition to the foregoing, any bonus that has been approved by the Board of Directors or Compensation Committee prior to the date of termination but not yet paid (the "**Accrued Bonus**"), payable at the time that cash bonuses are or would otherwise be payable to other officers of the Company in respect of such year. In the event of a termination under Sections 6.1 or 6.2 that occurs after June 30 in any given year, Employee or her estate, as applicable, shall receive a prorated portion of any cash bonus, at Employee's target bonus percentage of base salary (subject to adjustment for bonus pool funding as determined by the Board of Directors), for the calendar year in which termination occurs (calculated based on the number of days in the calendar year that have passed prior to Employee's termination), payable at the time that cash bonuses are or would otherwise be payable to other officers of the Company in respect of such year (the "**Prorated Bonus**"). For greater certainty, in the event a termination under Sections 6.1 or 6.2 occurs on or before June 30 in any given year, Employee or her estate, as applicable, shall not receive a Prorated Bonus. The Accrued Salary and Benefits and Prorated Bonus (if any) are herein referred to collectively as the "**Accrued Obligations**."

6.7.2 **Termination Without Cause or Upon Good Reason.** In the event of a termination of Employee's employment under Sections 6.4 or 6.5 of this Agreement, the following shall occur:

(i) shall receive the Accrued Obligations;

(ii) Employee shall receive: (A) if such termination does not occur during a Change of Control Period, a lump sum payment (less applicable withholdings) equivalent to twelve (12) months of Employee's annual salary; or (B) if such termination occurs during a Change of Control Period, a lump sum payment (less applicable withholdings) equivalent to twenty-four (24) months of the Employee's annual salary;

(iii) Employee shall receive, as a component of severance, a cash bonus for the calendar year in which termination occurs equal to Employee's target bonus for such year established pursuant to Section 3.2;

(iv) if Employee validly elects to receive continuation coverage under OraSure's group health plan pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985 ("**COBRA**"), and if such termination is for Good Reason pursuant to Section 6.4 or without Cause pursuant to Section 6.5 and does not occur during a Change of Control Period, the Company shall reimburse Employee for the applicable premium otherwise payable for COBRA continuation coverage for such coverage for a period of twelve (12) months after the date of termination, but only with respect to the portion of such premium that exceeds the monthly amount charged to active employees of the Company for the same coverage. If such termination is for

Good Reason pursuant to Section 6.4 or without Cause pursuant to Section 6.5 and occurs during a Change of Control Period, the Company shall reimburse Employee for the applicable premium otherwise payable for COBRA continuation coverage for such coverage for a period for the shorter of either (x) twenty-four (24) months after the date of termination; or (y) the date Employee is no longer eligible for COBRA, but only with respect to the portion of such premium that exceeds the monthly amount charged to active employees of the Company for the same coverage; and

(v) Employee shall receive accelerated vesting as described in Section 3.3 herein.

The amounts payable under clauses (ii), (iii) and (iv) are collectively referred to as "severance." Subject to Section 6.8, all severance payments will be made (or commence) under this Section 6.7.2 on the 90th day after termination of employment hereunder. As a condition to receipt of severance under this Section 6.7.2, within forty-five (45) days following termination of Employee's employment, Employee shall sign, deliver and not revoke a release agreement, in the form and substance set forth in Exhibit B hereto, releasing all claims related to Employee's employment, other than those that cannot be released as a matter of law. The severance shall be in lieu of and not in addition to any other severance arrangement maintained by the Company, and shall be offset by any monies Employee may owe to the Company. The Company's obligation to pay the amounts stated in clauses (ii), (iii) and (iv) of this Section 6.7.2 shall terminate if, during the period commencing on termination of employment and continuing until all severance payments have been made by the Company, Employee fails to comply with Sections 9 or 13 of this Agreement or with the Confidentiality Agreement.

6.7.3 **Parachute Payment.** In the event that (i) Employee becomes entitled to any payments or benefits hereunder or otherwise from the Company or any of its affiliates which constitute a "parachute payment" as defined in Code Section 280G (the "**Total Payments**") and (ii) Employee is subject to an excise tax imposed under Code Section 4999 (the "**Excise Tax**"), then, if it would be economically advantageous for Employee, the Total Payments shall be reduced by an amount (including zero) that results in the receipt by Employee on an after tax basis (including the applicable U.S. federal, state and local income taxes, and the Excise Tax) of the greatest Total Payments, notwithstanding that some or all of the portion of the Total Payments may be subject to the Excise Tax. If a reduction in Total Payments is required pursuant to the preceding sentence, the reduction will occur in the manner (the "**Reduction Method**") that results in the greatest economic benefit for Employee. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata (the "**Pro Rata Reduction Method**"). Notwithstanding the foregoing, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the Total Payments being subject to taxes pursuant to Code Section 409A (as defined below) that would not otherwise be subject to taxes pursuant to Section 409A, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, will be modified so as to avoid the imposition of taxes pursuant to Section 409A as follows: (A) as a first priority, the modification will preserve to the greatest extent possible, the greatest economic benefit for Employee as determined on an after-tax basis; (B) as a second priority, Payments that are contingent on future events (e.g., being terminated without Cause), will be reduced (or eliminated) before Payments that are not contingent on future events; and (C) as a third priority, Payments that are "deferred compensation" within the meaning of Section 409A will be reduced (or eliminated) before Payments that are not deferred compensation within the meaning

of Section 409A. All calculations hereunder shall be performed by a nationally recognized independent accounting firm selected by the Company, with the full cost of such firm being borne by the Company. Any determinations made by such firm shall be final and binding on Employee and the Company.

6.8 **Section 409A.** This Agreement is intended to comply with Section 409A of the Internal Revenue Code of 1986, as amended ("**Code Section 409A**") (to the extent applicable) and the parties hereto agree to interpret, apply and administer this Agreement in the least restrictive manner necessary to comply therewith and without resulting in any increase in the amounts owed hereunder by the Company. Notwithstanding any other provision of this Agreement to the contrary, if Employee is a "specified employee" within the meaning of Section 409A of the Internal Revenue Code, as amended (the "**Code**") at the time of Employee's termination of employment and any payment under this Section 6 would otherwise subject Employee to any tax, interest or penalty imposed under Code Section 409A (or any regulation promulgated thereunder) if the payment or benefit would commence as set forth in this Section 6, then the payment due under this Section 6 shall not be made (or commence) until the first day which is at least six (6) months after the date of the Employee's termination of employment. All payments, which would have otherwise been required to be made to Employee over such six (6) month period, shall be paid to Employee in one lump sum payment as soon as administratively feasible after the first day which is at least six months after the date of Employee's termination of employment with the Company. For purposes of the application of Code Section 409A, each payment in a series of payments will be deemed a separate payment. Notwithstanding anything herein to the contrary, except to the extent any expense, reimbursement or in-kind benefit provided to the Employee does not constitute "nonqualified deferred compensation" within the meaning of Code Section 409A, and its implementing regulations and guidance, (i) the amount of expenses eligible for reimbursement or in-kind benefits provided to the Employee during any calendar year will not affect the amount of expenses eligible for reimbursement or in-kind benefits provided to the Employee in any other calendar year, (ii) the reimbursements for expenses for which the Employee is entitled to be reimbursed shall be made on or before the last day of the calendar year following the calendar year in which the applicable expense is incurred and (iii) the right to payment or reimbursement or in-kind benefits hereunder may not be liquidated or exchanged for any other benefit.

7. **Indemnification.** The Company agrees that if Employee is made a party (or is threatened to be made a party to) any action, suit, or proceeding, whether civil, criminal, administrative, or investigative (a "**Proceeding**"), by reason of her service (including past service) as an officer, director, employee, agent, or the like of the Company, or is or was serving at the request of the Company as an officer, director, employee, agent, or the like of another entity, including, without limitation, as a fiduciary of an employee benefit plan sponsored or established by the Company (any such service for a subsidiary, affiliate, joint venture or other entity in which the Company has an ownership or other financial interest, or as a fiduciary of any employee benefit plan sponsored by the Company or any such other entity, shall be presumed to be at the request of the Company), whether or not the basis of such Proceeding is an act or omission alleged to have occurred while Employee was acting in an official capacity as a director, officer, employee, agent, or the like, then Employee shall be indemnified and held harmless by the Company to the fullest extent authorized by applicable law (including for all reasonable attorneys' fees and costs incurred

by Employee), and such indemnification shall continue even if Employee has ceased to be a director, officer, employee, agent, or the like of the Company for any reason.

8. **Insurance.** During the Term and for a period of six (6) years thereafter (regardless of the reason for the termination of Employee's employment), the Company shall maintain suitable directors and officers insurance coverage for Employee in her respective roles and shall name Employee as an additional insured under such insurance policies, which policies shall be no less favorable to Employee than such insurance policies that cover OraSure's directors during such time period.

9. **Non-Competition.** In consideration of the severance payable hereunder, during the Term and for a period of one (1) year thereafter, Employee agrees that, unless she obtains written agreement from the CEO or the Board of Directors, Employee covenants to not:

(a) recruit, solicit, or hire any executive or employee of the Company;

(b) induce or solicit any current or prospective customer, client, or supplier of the Company to cease being a customer, client or supplier or divert Company business
away from any customer, client, or supplier of the Company; or

(c) own, manage, control, work for, or provide services to any entity which competes with the Company in the market for rapid point-of-care, oral fluid diagnostic testing in the United States (the "Protected Business"); provided, however, that this Section 9: (i) shall not prevent Employee from accepting a position with and working for any other entity which competes with the Company in the Protected Business, if such business is diversified, Employee is employed in a department, division or other unit of the business that is not engaged in the Protected Business and Employee does not, directly or indirectly, provide any assistance, services, advice, consultation or information with respect to rapid point-of-care, oral fluid diagnostic testing to the department, division or unit of the business engaged in the Business; and (ii) shall not prevent Employee from purchasing or owning less than five percent (5%) of the stock or other securities of any entity, provided that such stock or other securities are traded on any national or regional securities exchange or are actively traded in the over-the-counter market and registered under Section 12(g) of the Securities Exchange Act of 1934, as amended. The parties acknowledge that the non-competition agreement set forth in this Section 9 is intended to replace and supersede the non-competition provision set forth on page 1 of the Confidentiality Agreement executed contemporaneously herewith.

10. **Remedies.** The respective rights and duties of the Company and Employee under this Agreement are in addition to, and not in lieu of, those rights and duties afforded to and imposed upon them by law or at equity.

11. **Severability of Provisions.** The provisions of this Agreement are severable, and if any provision hereof is held invalid or unenforceable, it shall be enforced to the maximum extent permissible, and the remaining provisions of the Agreement shall continue in full force and effect.

12. **Non-Waiver.** Failure by either party at any time to require performance of any provision of this Agreement shall not limit the right of the party failing to require performance to

enforce the provision. No provision of this Agreement may be waived by either party except by a writing signed by that party. A waiver of any breach of a provision of this Agreement shall be construed narrowly and shall not be deemed to be a waiver of any succeeding breach of that provision or a waiver of that provision itself or of any other provision.

13. **Non-Disparagement.** Both during and after her employment, Employee agrees not to disparage the Company or any of the stockholders, directors, officers, or employees of the Company. The Company agrees not to disparage, and will not direct its directors, officers and employees to disparage, Employee. Employee and the Company agree not to make any statement or engage in any conduct that might affect adversely the business or professional reputation of the other party or, in the case of the Company, any of the stockholders, directors, officers or employees of the Company. Any breach of this Section 13 by a director, officer or employee of the Company shall be deemed to be a breach by the Company.

14. **Other Agreements.** Employee represents, warrants and, where applicable, covenants to the Company that:

(a) There are no restrictions, agreements or understandings whatsoever to which Employee is a party which would prevent or make unlawful Employee's execution of this Agreement or Employee's employment hereunder, or which is or would be inconsistent or in conflict with this Agreement or Employee's employment hereunder, or would prevent, limit or impair in any way the performance by Employee of her obligations hereunder;

(b) Employee's execution of this Agreement and Employee's employment hereunder shall not constitute a breach of any contract, agreement or understanding, oral or written, to which Employee is a party or by which Employee is bound; and

(c) Employee is free to execute this Agreement and to be employed by the Company as an employee pursuant to the provisions set forth herein.

15. **Successors and Assigns.** This Agreement shall inure to the benefit of and be binding upon the Company and Employee and their respective successors, executors, administrators, heirs and/or permitted assigns; *provided*, *however*, that neither Employee nor the Company may make any assignments of this Agreement or any interest herein, by operation of law or otherwise, without the prior written consent of the other party, except that, without such consent, the Company may assign this Agreement to any successor to all or substantially all the business or assets of the Company by means of liquidation, dissolution, merger, consolidation, transfer of assets, or otherwise and Employee may transfer this Agreement by will or the laws of descent and distribution. The Company will require any successor (whether direct or indirect, by merger, consolidation, transfer of assets, or otherwise) acquiring all or substantially all of the business and/or assets of the Company (whether such assets are held directly or indirectly) to assume expressly and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform it if no such succession had taken place. As used in this Agreement, "**Company**" shall mean the Company as hereinbefore defined and any successor to its business and/or assets as aforesaid which assumes and agrees to perform this Agreement by operation of law, or otherwise.

16. **Non-exclusivity of Rights.** Nothing in this Agreement shall prevent or limit Employee's continuing or further participation in any benefit, bonus, incentive, stock-based or other plan or program provided by the Company and for which Employee may qualify. Except as otherwise provided herein, amounts and benefits which are vested benefits or which Employee is otherwise entitled to receive at or subsequent to the date of termination shall be payable in accordance with such plan or program.

17. **Entire Agreement; Amendments.** This Agreement and the Confidentiality Agreement contain the entire agreement and understanding of the parties hereto relating to the subject matter hereof and thereof, and supersede all prior and contemporaneous discussions, agreements and understandings of every nature relating to the employment of Employee by the Company. This Agreement may not be changed or modified, except by an agreement in writing signed by each of the parties hereto.

18. **Consent to Suit.** Any legal proceeding arising out of or relating to this Agreement shall be instituted in the United States District Court for the Eastern District of Pennsylvania, or if such court does not have jurisdiction or will not accept jurisdiction, in any court of general jurisdiction in the county in Pennsylvania in which the Company maintains its principal place of business, and Employee and the Company hereby consent to the personal and exclusive jurisdiction of such court and hereby waive any objection that Employee or the Company may have to personal jurisdiction, venue, and any claim or defense of inconvenient forum.

19. **Cooperation.** Employee further agrees that during and after her employment with the Company, subject to reimbursement of her reasonable expenses, she will cooperate fully with the Company and its counsel with respect to any matter (including, without limitation, litigation, investigations, or governmental proceedings) in which the Employee was in any way involved during her employment with the Company. Employee shall render such cooperation in a timely manner on reasonable notice from the Company, so long as the Company, following Employee's termination of employment, exercises commercially reasonable efforts to schedule and limit its need for Employee's cooperation under this paragraph so as not to interfere with Employee's other personal and professional commitments

20. **Counterparts and Facsimiles.** This Agreement may be executed, including execution by facsimile signature, in one or more counterparts, each of which shall be deemed an original, and all of which together shall be deemed to be one and the same instrument.

21. **Governing Law.** This Agreement shall be governed by, and enforced in accordance with, the laws of the Commonwealth of Pennsylvania without regard to the application of the principles of conflicts of laws.

The parties have executed this Employment Agreement as of the date stated above.

ORASURE TECHNOLOGIES, INC.

/s/ Lisa A. Nibauer

By: */s/ Stephen S. Tang*

Lisa A. Nibauer Stephen S. Tang

Title: President and Chief Executive Officer

EXHIBIT A

Specific Duties of Employee as
Executive Vice President, Business Unit Leader, Infectious Disease

Employee, as the Executive Vice President, Business Unit Leader, Infectious Disease of the Company or the surviving entity in the event of a Change of Control, shall have duties commonly performed by the head executive in charge of a company's business and operations, including (i) oversight of the commercial, operational and financial performance of the Company's infectious disease business; (ii) development and implementation of financial and business plans; (iii) development of short and long term business strategies for the infectious disease business; (iv) assisting in identifying and evaluating new products and technologies and product improvements and enhancements to be developed or acquired by the Company or such surviving entity; and (v) assistance to the CEO of OraSure in developing strategic business plans and in planning and evaluating mergers, acquisitions and other strategic matters.

EXHIBIT B

RELEASE AGREEMENT

THIS RELEASE AGREEMENT (the "**Agreement**") is entered into on this __ day of _____, 20__, by and between Lisa A. Nibauer ("**Executive**") and OraSure Technologies, Inc., a Delaware corporation, together with each and every of its predecessors, successors (by merger or otherwise), parents, subsidiaries, affiliates, divisions and related entities, directors, officers, Executives, attorneys and agents, whether present or former (collectively "**OraSure**");

WHEREAS, Executive is entitled to receive severance under an Employment Agreement ("**Employment Agreement**"), dated _____, 2020 between Employee and OraSure; and

WHEREAS, Executive agrees to execute this Agreement as consideration for such severance; and

WHEREAS, capitalized terms not otherwise defined in this Agreement shall have the meanings set forth in the Employment Agreement.

NOW, THEREFORE, the parties agree as follows, in consideration of the mutual covenants and obligations contained herein, and intending to be legally held bound:

1. Employment Termination; Consideration. Executive's employment with OraSure shall terminate on _____ (the "**Termination Date**"). In consideration for Executive's receipt of severance as provided in the foregoing Employment Agreement, Executive is willing to enter into this Agreement and provide the release set forth herein.

2. Executive's Release. Executive, on behalf of Executive, Executive's heirs, executors, successors, assigns and representatives hereby unconditionally and irrevocably releases settles and forever discharges OraSure, together with each and every one of its predecessors, successors (by merger or otherwise), parents, subsidiaries, affiliates, divisions and related entities, and all of their directors, officers, executives, attorneys and agents, and benefit plans (and the administrators, fiduciaries and agents of such plans), whether present or former (collectively the "**Releasees**"), from any and all suits, causes of action, complaints, obligations, demands, or claims of any kind, whether in law or in equity, direct or indirect, known or unknown, suspected or unsuspected (hereinafter "Claims"), which the Executive ever had or now has arising out of or relating to any matter, thing or event occurring up to and including the date of this Agreement. Except as otherwise expressly provided in this Agreement, the Claims released by Executive specifically include, but are not limited to:

a. any and all claims for wages and benefits including, without limitation, salary, stock, options, commissions, royalties, license fees, health and welfare benefits, separation pay, vacation pay, incentives, and bonuses (collectively "wage related claims") other than wage related claims that cannot be released as a matter of law;

b. any and all claims for wrongful discharge, breach of contract (whether express or implied), or for breach of the implied covenant of good faith and fair dealing;

c. any and all claims for alleged employment discrimination on the basis of age, race, color, religion, sex, national origin, veteran status, disability and/or handicap and any and all other claims in violation of any federal, state or local statute, ordinance, judicial precedent or executive order, including but not limited to claims under the following statutes: Title VII of the Civil Rights Act of 1964, as amended, 42 U.S.C. §2000e et seq., the Civil Rights Act of 1866, 42 U.S.C. §1981, the Age Discrimination in Employment Act, 29 U.S.C. §621 et seq., the Older Workers Benefit Protection Act, 29 U.S.C. §626(f) (together with the Age Discrimination in Employment Act, the "**ADEA**"), the Americans with Disabilities Act, 42 U.S.C. §12101 et seq., the Family and Medical Leave Act of 1993, the Fair Labor Standards Act, the Employee Retirement Income Security Act of 1974, or any comparable statute of any other state, country, or locality except as required by law, but excluding claims for vested benefits under OraSure's pension plans;

d. any and all claims under any foreign, federal, state or local statute or law;

e. any and all claims in tort (including but not limited to any claims for misrepresentation, defamation, interference with contract or prospective economic advantage, intentional or negligent infliction of emotional distress, duress, loss of consortium, invasion of privacy and negligence);

f. any and all claims for attorneys' fees and costs; and

g. any and all other claims for damages of any kind.

It is the intention of Executive and OraSure that the language relating to the description of released claims in this Section shall be accorded the broadest possible interpretation. Notwithstanding the foregoing, nothing contained in this paragraph shall apply to, or shall release OraSure from, (i) any obligation of OraSure under this Agreement or the Employment Agreement; (ii) any accrued or vested benefit of Executive pursuant to any employee benefit plan of OraSure, including any benefit not yet due and payable; (iii) any obligation of OraSure under existing stock options, restricted stock or other stock awards; or (iv) any right to indemnification under this Agreement, the By-Laws or Certificate of Incorporation of OraSure or any subsidiary or any insurance policy maintained by the Company or any subsidiary or other entity. Further, Executive does not waive any rights or claims under the ADEA or otherwise that may arise after the date of Executive's execution of this Agreement.

3. Acknowledgment. Executive understands that her release in Section 2 extends to all of the aforementioned Claims and potential Claims which arose on or before the date of this Agreement, whether now known or unknown, suspected or unsuspected, and that this constitutes an essential term of this Agreement. Executive further understands and acknowledges the significance and consequence of this Agreement and of each specific release and waiver, and expressly consents that this Agreement shall be given full force and effect according to each and all of its express terms and provisions, including those relating to unknown and unsuspected

claims, demands, obligations, and causes of action, if any, as well as those relating to any other claims, demands, obligations or causes of action hereinabove specified.

4. Remedies. All remedies at law or in equity shall be available to OraSure for the enforcement of this Agreement. This Agreement may be pleaded as a full bar to the enforcement of any claim that Executive may assert against OraSure in violation of this Agreement.

5. Promise Not To Sue.

a. Executive agrees and covenants not to file, initiate, or join any lawsuit (individually, with others, or as part of a class), in any forum, pleading, raising, or asserting any claim(s) barred or released by this Agreement. If Executive does so, and the action is found to be barred in whole or in part by this Agreement, Executive agrees to pay the attorneys' fees and costs, or the proportions thereof, incurred by the applicable Releasees in defending against those claims that are found to be barred by this Agreement. While this Agreement will serve to release any ADEA claims, the attorneys' fees/cost shifting provision set forth in this paragraph will not apply to any claims challenging the validity of the release contained in this Agreement under the ADEA.

b. Notwithstanding any of the foregoing to the contrary, nothing in this Agreement or otherwise shall prohibit Executive from (a) reporting possible violations of federal law or regulation to any governmental agency or entity or self-regulatory organization (including but not limited to the Department of Justice, the Securities and Exchange Commission, Congress and any agency Inspector General), or making other disclosures that are protected under the whistleblower provisions of federal law or regulations (it being understood that Executive does not need the prior authorization of OraSure to make any such reports or disclosures or to notify OraSure that Executive has made such reports or disclosures), or (b) providing truthful testimony or statements to the extent, but only to the extent, required by applicable law, rule, regulation, legal process or by any court, arbitrator, mediator or administrative, regulatory, judicial or legislative body (including any committee thereof) with apparent jurisdiction (provided, however, that in such event, except as set forth in the foregoing clause (a) above, Executive will give OraSure prompt written notice thereof prior to such disclosure so that OraSure may seek appropriate protection for such information). However, Executive acknowledges and agrees that Executive shall not seek or accept and waives any rights to any relief obtained on Executive's behalf in any proceeding by any government agency (including the Equal Employment Opportunity Commission), private party, class, or otherwise with respect to any claims covered by the release in Section 2 of this Agreement.

6. No Admissions. Neither the execution of this Agreement by the Company, nor the terms hereof, constitute or should be construed to constitute any admission or evidence of any wrongdoing, liability or violation of any federal, state or local law or the common law on the part of the Company.

7. Confidentiality. To the extent not otherwise made public by OraSure and except as permitted by this Section, Executive shall not disclose or publicize the terms or fact of this Agreement, directly or indirectly, to any person or entity, except to Executive's attorney and

spouse, provided that Executive's attorney and spouse agree to keep the information confidential, and to others as required by law. Executive is specifically prohibited from disclosing the facts or terms of this Agreement to any former or present executive of OraSure except as required by law. Executive further agrees that in the event Executive receives a subpoena, order, or other legal process seeking disclosure of the information referred to in this Agreement, within five (5) business days of such receipt then Executive shall immediately notify OraSure's General Counsel of such subpoena, request or order and cooperate with OraSure in any efforts to oppose such disclosure.

8. Non-Disparagement. Executive agrees not to disparage or encourage others to disparage OraSure, as well as any of the other Releasees, their products, missions or businesses or any of the Releasees' officers, directors, attorneys, and employees, and Executive agrees not to initiate any contact with or respond to any inquiry by the press or other media regarding the Releasees. For the purpose of this Agreement, "disparage" includes, without limitation, comments or statements to any person or entity, including but not limited to the press and/or media, employees, contractors, or advisors of OraSure or any entity with which OraSure has a business relationship, which would adversely affect in any manner (a) the conduct of the business of OraSure or any of the Releasees (including but not limited to any business plans or prospects) or (b) the reputation of OraSure, OraSure's officers, directors or any of the Releasees. For the avoidance of doubt, nothing in this Agreement precludes Executive from supplying truthful information to any governmental authority or in response to any lawful subpoena or other legal process.

9. Entire Agreement. This Agreement, together with the terms of the Employment Agreement and the Confidentiality Agreement, contain the entire agreement of the parties with respect to the subject matter hereof, supersede any prior agreements or understandings with respect to the subject matter hereof, and shall be binding upon their respective heirs, executors, administrators, successors and assigns. The Executive agrees that the obligations contained in this Agreement and the other agreements referenced herein are in addition to, and not in lieu of, any obligations Executive may have.

10. Severability. If any term or provision of this Agreement shall be held to be invalid or unenforceable for any reason, the validity or enforceability of the remaining terms or provisions shall not be affected, and such term or provision shall be deemed modified to the extent necessary to make it enforceable.

11. Advice of Counsel; Revocation Period. Executive is hereby advised to seek the advice of counsel. Executive acknowledges that she is acting of her own free will, that she has been afforded a reasonable time to read and review the terms of this Agreement, and that Executive is voluntarily entering into this Agreement with full knowledge and understanding of its provisions and effects. Executive understands and agrees that she is waiving rights or claims, including, but not limited to, possible claims under the ADEA, in exchange for consideration in addition to anything of value to which Executive is already entitled. Executive agrees that this Agreement shall not be deemed void or avoidable by claims of duress, deception, mistake of fact, or otherwise. Nor shall the principle of construction whereby all ambiguities are to be construed against the drafter be employed in the interpretation of this Agreement. There is absolutely no agreement or reservation that is not clearly expressed in this Agreement. This Agreement should not be

construed for or against any party. Executive further acknowledges that she has been given at least twenty-one (21) days within which to consider this Agreement and that if Executive decides to execute this Agreement before the twenty-one (21) day period has expired, Executive does so voluntarily and waives the opportunity to use the full review period. Executive acknowledges and agrees that changes made to this Agreement, whether or not material, do not restart the aforementioned twenty-one (21) day period. Executive also acknowledges that she has seven (7) days following her execution of this Agreement to revoke acceptance of this Agreement, with the Agreement not becoming effective until the revocation period has expired without Executive having revoked. Executive acknowledges that to be effective any revocation must be in writing, signed by the Executive, and received by OraSure prior to the expiration of the revocation date. If Executive chooses to revoke her acceptance of this Agreement, she should provide written notice to:

General Counsel
OraSure Technologies, Inc.
220 East First Street
Bethlehem, Pennsylvania 18015

12. Amendments. Neither this Agreement nor any term hereof may be orally changed, waived, discharged, or terminated, and may be amended only by a written agreement between the parties hereto.

13. Governing Law. This Agreement shall be governed by the laws of the Commonwealth of Pennsylvania, without regard to the conflict of law principles of any jurisdiction.

14. Legally Binding. The terms of this Agreement contained herein are contractual, and not a mere recital.

IN WITNESS WHEREOF, the parties, acknowledging that they are acting of their own free will, have caused the execution of this Agreement as of this day and year written below.

OraSure Technologies, Inc.

By: _____

Name: _____

Title: _____

Dated: _____

_____
Lisa A. Nibauer

Dated: _____

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 6, 2020

/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 6, 2020

/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, 2020 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 6, 2020

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, 2020 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 6, 2020