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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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 November 1, 2020, the registrant had 71,732,752 shares of common stock, $.000001 par value per share, outstanding.

PART I. FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

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

	September 30, 2020	December 31, 2019
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 162,859	$ 75,715
Short-term investments	72,961	80,623
Accounts receivable, net of allowance for doubtful accounts of $3,751 and $2,666	30,638	36,948
Inventories	30,488	23,155
Prepaid expenses	2,527	2,433
Other current assets	3,504	5,676
Total current assets	302,977	224,550
Noncurrent Assets:		
Property, plant and equipment, net	39,056	30,339
Operating right-of-use assets, net	4,682	4,996
Finance right-of-use assets, net	1,462	1,951
Intangible assets, net	18,111	14,674
Goodwill	39,480	36,201
Long-term investments	27,841	33,420
Other noncurrent assets	2,801	3,164
Total noncurrent assets	133,433	124,745
TOTAL ASSETS	**$ 436,410**	**$ 349,295**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 14,377	$ 9,567
Deferred revenue	5,311	3,713
Accrued expenses and other current liabilities	15,147	14,288
Finance lease liability	536	613
Operating lease liability	1,092	1,032
Acquisition-related contingent consideration obligation	764	3,500
Total current liabilities	37,227	32,713
Noncurrent Liabilities:		
Finance lease liability	1,025	1,372
Operating lease liability	3,848	4,206
Acquisition-related contingent consideration obligation	3,176	112
Other noncurrent liabilities	2,493	2,848
Deferred income taxes	749	899
Total noncurrent liabilities	11,291	9,437
TOTAL LIABILITIES	48,518	42,150
Commitments and contingencies (Note 11)		
STOCKHOLDERS' EQUITY		
Preferred stock, par value $.000001, 25,000 shares authorized, none issued	—	—
Common stock, par value $.000001, 120,000 shares authorized, 71,611 and 61,731 shares issued and outstanding	—	—
Additional paid-in capital	502,802	401,814
Accumulated other comprehensive loss	(15,595)	(12,136)
Accumulated deficit	(99,315)	(82,533)
Total stockholders' equity	387,892	307,145
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 436,410**	**$ 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
NET REVENUES:				
Products and services	$ 46,749	$ 35,299	$ 105,972	$ 100,898
Other	1,262	690	2,894	4,039
	48,011	35,989	108,866	104,937
COST OF PRODUCTS AND SERVICES SOLD	17,722	14,343	45,182	40,193
Gross profit	30,289	21,646	63,684	64,744
OPERATING EXPENSES:				
Research and development	8,007	4,619	20,575	13,525
Sales and marketing	7,849	8,955	25,339	23,937
General and administrative	10,108	7,556	30,442	23,748
Change in the estimated fair value of acquisition-related contingent consideration	(60)	(2,387)	390	(843)
Gain on sale of business	—	(10,149)	—	(10,149)
	25,904	8,594	76,746	50,218
Operating income (loss)	4,385	13,052	(13,062)	14,526
OTHER INCOME	314	1,195	1,960	2,243
Income (loss) before income taxes	4,699	14,247	(11,102)	16,769
INCOME TAX EXPENSE	3,659	1,169	5,680	2,551
NET INCOME (LOSS)	$ 1,040	$ 13,078	$ (16,782)	$ 14,218
INCOME (LOSS) PER SHARE:				
BASIC	$ 0.01	$ 0.21	$ (0.25)	$ 0.23
DILUTED	$ 0.01	$ 0.21	$ (0.25)	$ 0.23
SHARES USED IN COMPUTING INCOME (LOSS) PER SHARE:				
BASIC	71,537	61,726	66,088	61,656
DILUTED	72,662	62,143	66,088	62,172

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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
NET INCOME (LOSS)	$ 1,040	$ 13,078	$ (16,782)	$ 14,218
OTHER COMPREHENSIVE INCOME (LOSS)				
Currency translation adjustments	1,953	(1,557)	(3,542)	3,151
Unrealized gain (loss) on marketable securities	(266)	194	83	877
COMPREHENSIVE INCOME (LOSS)	$ 2,727	$ 11,715	$ (20,241)	$ 18,246

See accompanying notes to the consolidated financial statements.

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

	Nine Months Ended September 30,	
	2020	**2019**
OPERATING ACTIVITIES:		
Net income (loss)	$ (16,782)	$ 14,218
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Stock-based compensation	5,913	3,283
Depreciation and amortization	7,051	5,532
Provision for doubtful accounts	1,141	2,083
Unrealized foreign currency (gain) loss	(41)	272
Interest expense on finance leases	56	23
Deferred income taxes	(764)	(291)
Loss on sale of fixed assets	104	145
Gain on sale of business	—	(10,149)
Change in the estimated fair value of acquisition-related contingent consideration	390	(843)
Payment of acquisition-related contingent consideration	(496)	—
Changes in assets and liabilities		
Accounts receivable	5,228	5,730
Inventories	(7,425)	(3,255)
Prepaid expenses and other assets	2,420	1,438
Accounts payable	3,269	(1,042)
Deferred revenue	1,664	348
Accrued expenses and other liabilities	468	(6,654)
Net cash provided by operating activities	2,196	10,838
INVESTING ACTIVITIES:		
Purchases of investments	(90,137)	(92,173)
Proceeds from maturities and redemptions of investments	102,616	91,451
Purchases of property and equipment	(11,234)	(7,961)
Proceeds from escrow associated with business acquisitions	126	—
Proceeds from sale of business	—	12,000
Acquisition of businesses, net of cash acquired	(3,037)	(13,217)
Purchase of patent and product rights	(2,250)	—
Net cash used in investing activities	(3,916)	(9,900)
FINANCING ACTIVITIES:		
Repayments of loans	—	(724)
Cash payments for lease liabilities	(521)	(253)
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	2,115	169
Repurchase of common stock	(2,076)	(3,711)
Net cash provided by (used in) financing activities	91,550	(4,519)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	(2,686)	608
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	87,144	(2,973)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	75,715	88,438
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 162,859	$ 85,465
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for income taxes	$ 3,888	$ 7,470
Non-cash investing and financing activities		
Accrued property and equipment purchases	$ 2,093	$ 477
Unrealized gain on marketable securities	$ 83	$ 877

See accompanying notes to the consolidated financial statements.

1. The Company

Our business consists of two segments: our "OSUR business" primarily 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, infectious disease diagnostics, 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.

The OSUR business includes 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. Our OSUR business includes the operations of UrSure, Inc. ("UrSure"), which was acquired in July 2020. UrSure is developing and commercializing products that measure adherence to HIV medications including pre-exposure prophylaxis or PrEP, the daily medication to prevent HIV. UrSure's products include 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 currently in development. 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"), Diversigen, Inc. ("Diversigen"), CoreBiome Inc. ("CoreBiome") and Novosanis NV ("Novosanis"). DNAG's specimen collection devices provide all-in-one systems for the collection, stabilization, transportation and storage of nucleic acids from human saliva and other sample types for genetic and microbiome applications. CoreBiome and Diversigen provide laboratory and bioinformatics services in the microbiome market. 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, Diversigen, CoreBiome, Novosanis, and UrSure. 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 nine months ended September 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 September 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 September 30, 2020 and December 31, 2019:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
September 30, 2020				
Guaranteed investment certificates	$ 24,019	$ —	$ —	$ 24,019
Corporate bonds	76,814	269	(300)	76,783
Total available-for-sale securities	$ 100,833	$ 269	$ (300)	$ 100,802
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 September 30, 2020, maturities of our available-for-sale securities were as follows:				
Less than one year	$ 72,947	$ 228	$ (214)	$ 72,961
Greater than one year	$ 27,886	$ 41	$ (86)	$ 27,841

Fair Value of Financial Instruments. As of September 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 September 30, 2020 and December 31, 2019.

Included in cash and cash equivalents at September 30, 2020 and December 31, 2019, was $95,254 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 September 30, 2020 and December 31, 2019 was $3,360 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.

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 September 30, 2020 and December 31, 2019 was $51,807 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 September 30, 2020 and December 31, 2019 was $25,393 and $23,420, respectively. The increase in intangibles from $14,674 as of December 31, 2019 to $18,111 as of September 30, 2020 is a result of the developed technology acquired in our acquisition of UrSure of $3,400, the acquisition of patent and product rights of $2,250, and foreign currency translation gains of $148 offset by $2,361 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. Goodwill is not amortized but rather is tested annually for impairment or more frequently if we believe that indicators of impairment exist. Current U.S. generally accepted accounting principles permit us to make a qualitative evaluation about the likelihood of goodwill impairment. If we conclude that it is more likely than not that the carrying value of a reporting unit is greater than its fair value, then we would be required to recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value, provided the impairment charge does not exceed the total amount of goodwill allocated to the reporting unit.

The increase in goodwill from $36,201 as of December 31, 2019 to $39,480 as of September 30, 2020 is a result of the additional goodwill associated with our acquisition of UrSure of $3,739 offset by a purchase price adjustment related to our Diversigen acquisition of $(126), and an adjustment of $(334) associated with foreign currency translation.

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 resulting from foreign currency transactions that are included in other income in our consolidated statements of income were $70 and $50 for the three months ended September 30, 2020 and 2019, respectively. Net foreign exchange gains (losses) were $563 and $(875) for the nine months ended September 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 September 30, 2020 consists of $15,564 of currency translation adjustments and $31 of net unrealized losses on marketable securities, which represents the fair market value adjustment for our investment portfolio. Accumulated other comprehensive loss at December 31, 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

UrSure

On July 22, 2020, the Company acquired all of the outstanding stock of UrSure, Inc. ("UrSure"), pursuant to the terms of a merger agreement. The initial aggregate purchase price of this transaction was $3,000, 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.

Pursuant to our acquisition agreements, we may pay up to an additional $28,000 of contingent consideration over the next four years based on the achievement of certain performance criteria as defined under the agreements, including generating certain revenue dollars, and the development of certain new technology. The Company, with the assistance of an independent valuation specialist, determined the estimated acquisition-date fair value of the acquisition-related contingent consideration of $3,440. 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. There has been no material change in the fair value of the contingent consideration obligation changed from the acquisition date to September 30, 2020.

During the nine months ended September 30, 2020, we incurred a total of $393 of acquisition related costs, including accounting, legal, and other professional fees, all of which were expensed and reported as a component of general and administrative expense in the consolidated statement of income for the nine months ended September 30, 2020.

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

Assets Acquired		
Accounts receivable	$	285
Other current assets		24
Other assets		6
Intangibles		3,400
Goodwill		3,739
Total assets acquired		7,454
Liabilities Assumed		
Current liabilities		212
Deferred tax liability		642
Deferred revenue		123
Total liabilities assumed		977
Net Assets Acquired	$	6,477
Estimated fair value of contingent consideration		(3,440)
Net Cash Paid (net of cash acquired of $111)	**$**	**3,037**

The purchase price was allocated to the tangible assets and identifiable intangible assets acquired and liabilities assumed based on their acquisition-date estimate fair values. The identifiable intangible assets principally included developed technology, which is subject to amortization on a straight-line basis and is being amortized over a ten year estimated useful life.

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

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

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

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

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

Revenues from UrSure primarily consist of grant money received to fund the development of certain new technology. Effective as of July 22, 2020, the financial results of UrSure are included in our OSUR segment.

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. 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. 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 nine months ended September 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 nine months ended September 30, 2019.

Pursuant to our acquisition agreements, we were to pay up to an additional $32,400 of contingent consideration over 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 $3,424 as of September 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 $500 as of September 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 September 30, 2020, we may pay up to an additional $22,500 of contingent consideration through July 2021.

Revenues from CoreBiome primarily consist of fees paid for 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. 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 nine months ended September 30, 2019, we did not incur any acquisition related costs associated with this transaction.

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 fees paid for 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, Novosanis and UrSure 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 September 30,		Nine Months ended September 30,	
	2020	2019	2020	2019
Revenue	$ 48,073	$ 37,695	$ 109,708	$ 105,703
Net income (loss)	1,009	12,340	(17,179)	12,531
Net income (loss) per share, basic and diluted	0.01	0.20	(0.27)	0.20

4. Inventories

	September 30, 2020	December 31, 2019
Raw materials	$ 15,913	$ 14,168
Work in process	1,277	643
Finished goods	13,298	8,344
	$ 30,488	$ 23,155

5. 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net income (loss)	$ 1,040	$ 13,078	$ (16,782)	$ 14,218
Weighted-average shares of common stock outstanding:				
Basic	71,537	61,726	66,088	61,656
Dilutive effect of stock options, restricted stock, and performance stock units	1,125	417	—	516
Diluted	72,662	62,143	66,088	62,172
Earnings (loss) per share:				
Basic	$ 0.01	$ 0.21	$ (0.25)	$ 0.23
Diluted	$ 0.01	$ 0.21	$ (0.25)	$ 0.23

For the nine months ended September 30, 2020, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 917 shares were excluded from the computation of diluted loss per share as their inclusion would have been anti-dilutive. For the three months ended September 30, 2020 and 2019, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 136 and 909 shares, respectively, were excluded from the computation of diluted earnings per share as their inclusion would have been anti-dilutive. For the nine months ended September 30, 2019, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 709 shares were excluded from the computation of diluted earnings per share.

6. Revenues

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Infectious disease testing	$ 13,224	$ 13,588	$ 36,625	$ 39,284
Risk assessment testing	2,316	3,312	6,848	9,246
Cryosurgical systems	—	961	—	7,054
Genomics	8,519	13,647	23,381	35,438
Microbiome	1,828	1,878	4,259	5,325
COVID-19	18,441	—	27,307	—
Laboratory services	2,418	1,617	7,472	3,947
Other product revenue	3	296	80	604
Net product and services revenues	46,749	35,299	105,972	100,898
Royalty income	450	758	1,623	2,956
Other non product revenues	812	(68)	1,271	1,083
Other revenues	1,262	690	2,894	4,039
Net revenues	$ 48,011	$ 35,989	$ 108,866	$ 104,937

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
United States	$ 38,594	$ 26,245	$ 82,125	$ 74,712
Europe	2,789	2,767	8,663	8,188
Other regions	6,628	6,977	18,078	22,037
	$ 48,011	$ 35,989	$ 108,866	$ 104,937

Customer and Vendor Concentrations. We had no significant customer concentrations (greater than 10%) in our accounts receivable at September 30, 2020. One of our customers accounted for 19% of our accounts receivable as of December 31, 2019. One customer accounted for 11% of net consolidated revenues for the three months ended September 30, 2020. Another customer accounted for approximately 17% and 11% of our net consolidated revenues for the three and nine months ended September 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 September 30, 2020 and December 31, 2019 includes customer prepayments of $3,525 and $1,904, respectively. Deferred revenue as of September 30, 2020 and December 31, 2019 also includes $1,786 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 average price.

7. Accrued Expenses and other current liabilities

	September 30, 2020	December 31, 2019
Payroll and related benefits	$ 8,553	$ 6,088
Professional fees	1,293	2,769
Other	5,301	5,431
	$ 15,147	$ 14,288

8. 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 September 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		Nine Months Ended	
	2020	2019	2020	2019
Operating Lease Cost	$ 330	$ 232	$ 964	$ 695
Finance Lease Cost				
Amortization of right-of use assets	150	112	476	264
Interest on lease liabilities	17	10	56	23
Total Finance Lease Cost	$ 167	$ 122	$ 532	$ 287

Supplemental cash flow information related to leases is as follows:

	Nine Months Ended	
	2020	2019
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 965	$ 690
Operating cash flows from financing leases	56	23
Financing cash flows from financing leases	521	253
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:

	September 30, 2020	December 31, 2019
Operating Leases		
Right-of-use assets	$ 4,682	$ 4,996
Current lease liabilities	1,092	1,032
Non-current lease liabilities	3,848	4,206
Total operating lease liabilities	$ 4,940	$ 5,238
Finance Leases		
Right-of-use assets	$ 1,462	$ 1,951
Current lease liabilities	536	613
Non-current lease liabilities	1,025	1,372
Total finance lease liabilities	$ 1,561	$ 1,985

Weighted Average Remaining Lease Term	
Weighted-average remaining lease term—operating leases	4.66
Weighted-average remaining lease term—finance leases	2.87
Weighted Average Discount Rate	
Weighted-average discount rate—operating leases	4.25%
Weighted-average discount rate—finance leases	4.34%

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

	Finance	Operating
2020 (excluding the nine months ended September 30, 2020)	$ 166	$ 330
2021	566	1,311
2022	566	1,294
2023	336	872
2024	25	893
Thereafter	4	841
Total Minimum Lease Payments	1,663	5,541
Less: imputed interest	(102)	(601)
Present Value of Lease Liabilities	$ 1,561	$ 4,940

9. Stockholders' Equity

Reconciliation of the changes in stockholders' equity for the three and nine months ended September 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 issued upon exercise of options	202	—	1,555	—	—	1,555
Vesting of restricted stock and performance stock units	2	—	—	—	—	—
Purchase and retirement of common shares	(1)	—	(12)	—	—	(12)
Stock-based compensation	—	—	1,865	—	—	1,865
Net income	—	—	—	—	1,040	1,040
Currency translation adjustments	—	—	—	1,953	—	1,953
Unrealized loss on marketable securities	—	—	—	(266)	—	(266)
Balance at September 30, 2020	71,611	$ —	$ 502,802	$ (15,595)	$ (99,315)	$ 387,892

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Capital	Loss	Deficit	Total
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
Common stock issued upon exercise of options	—	—	—	—	—	—
Vesting of restricted stock and performance stock units	2	—	—	—	—	—
Purchase and retirement of common shares	(1)	—	(7)	—	—	(7)
Stock-based compensation	—	—	1,436	—	—	1,436
Net income	—	—	—	—	13,078	13,078
Currency translation adjustments	—	—	—	(1,557)	—	(1,557)
Unrealized gain on marketable securities	—	—	—	194	—	194
Balance at September 30, 2019	61,726	$ —	$ 401,014	$ (14,678)	$ (84,971)	$ 301,365

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 nine months ended September 30, 2020 and 2019 was $683 and $894 respectively.

Compensation cost of $3,329 and $2,385 related to restricted shares was recognized during the nine months ended September 30, 2020 and 2019, respectively.

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 employed 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 $1,901 and $4 related to PSUs was recognized during the nine months ended September 30, 2020 and 2019, respectively.

In connection with the vesting of restricted shares and PSU's during the nine months ended September 30, 2020 and 2019, we purchased and immediately retired 248 and 289 shares with aggregate values of $2,076 and $3,711, respectively, in satisfaction of minimum tax withholding obligations.

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 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 nine months ended September 30, 2020 and 2019.

10. Income Taxes

During the three and nine months ended September 30, 2020, we recorded income tax expense of $3,659 and $5,680, respectively, which primarily consists of foreign tax expense. During the three and nine months ended September 30, 2019, we recorded income tax expense of $1,169 and $2,551, 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 September 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 September 30,2020 and December 31, 2019 since the facts and circumstances necessitating the allowance have not changed.

11. 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.

12. Business Segment Information

Our business consists of two segments: our "OSUR" business primarily 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 OSUR segment includes the financial results of UrSure. 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 Diversigen, CoreBiome and Novosanis 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 nine months ended September 30, 2020 and 2019, and asset information as of September 30, 2020 and December 31, 2019:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net revenues:				
OSUR	$ 16,314	$ 17,730	$ 44,533	$ 56,335
DNAG	31,697	18,259	64,333	48,602
Total	$ 48,011	$ 35,989	$ 108,866	$ 104,937
Operating income (loss):				
OSUR	$ (9,951)	$ 8,080	$ (31,116)	$ 4,595
DNAG	14,336	4,972	18,054	9,931
Total	$ 4,385	$ 13,052	$ (13,062)	$ 14,526
Depreciation and amortization:				
OSUR	$ 934	$ 889	$ 2,681	$ 2,555
DNAG	1,517	1,033	4,370	2,977
Total	$ 2,451	$ 1,922	$ 7,051	$ 5,532
Capital expenditures:				
OSUR	$ 2,186	$ 1,796	$ 5,634	$ 5,341
DNAG	3,011	652	5,600	2,620
Total	$ 5,197	$ 2,448	$ 11,234	$ 7,961

	September 30, 2020	December 31, 2019
Total assets:		
OSUR	$ 260,167	$ 163,943
DNAG	176,243	185,352
Total	$ 436,410	$ 349,295

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 collection 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 primarily 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.

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. Our OSUR business includes the operations of UrSure. UrSure is developing and commercializing products that measure adherence to HIV medications including pre-exposure prophylaxis or PrEP, the daily medication to prevent HIV. UrSure's products include 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 currently in development. 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, Diversigen and Novosanis. DNAG's specimen collection devices provide all-in-one systems for the collection, stabilization, transportation and storage of nucleic acids from human saliva and other biological sample types for genetic and microbiome applications and for infectious disease diagnostics. 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 laboratory testing and bioinformatics services in the microbiome market. 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, 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 nine months of 2020, traditional HIV and HCV testing programs and drug testing in the workplace market were 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 nine 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 nine months 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 nine months 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. Although we generated additional revenues from sales of our molecular collection devices related to COVID-19 testing during the second and third quarters 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

The Company has continued to progress development of its OraQuick® Coronavirus Rapid Antigen Self-Test, but additional time is required to finalize the device design and conduct the clinical testing needed to meet FDA requirements applicable to a self-test. The Company is working to finalize the overall device design and usage procedures in order to optimize performance. The Company has also contracted with an external clinical research organization to conduct clinical studies that will be needed to support an EUA submission to the FDA. Subject to regulatory approvals, the Company intends to sequentially introduce its antigen test to the market for three different uses:

- **Professional Test** for use at drive-through sites, physician offices, public health testing sites, and employer/university health centers. In this instance, a physician would prescribe the test and the patient would conduct a self-swab in the presence of a healthcare provider who would then interprets the results.
- **Prescription Self-Test** for use by individual consumers (with prescription) at home or in any location, by employers/universities on- or off-site, or by physicians or public health via remote testing. In this instance, a physician would prescribe the test and the patient would conduct a self-swab at home, or in any location, where they would then interpret their own results.
- **OTC Self-Test** for use by consumers who would purchase online or at retail without prescription, and conduct the test and receive the results themselves anytime, anywhere.

Given the preparations necessary to conduct clinical studies, and subject to availability of specimens, the Company expects an initial EUA submission for the Professional Test in the first quarter of 2021, with an EUA submission for the Prescription Self-Test and an EUA amendment for the OTC Self-Test expected to follow as soon as possible thereafter.

During the third quarter, limit of detection studies for the assay were completed with live coronavirus in a certified third party analytical laboratory, with results comparable to that of another EUA approved, instrument-free, rapid antigen test. The results from the limit of detection comparison provides further confidence that the proprietary chemistries incorporated on OraSure's lateral flow test strip will deliver the analytical sensitivity needed. Although the timing of EUA approval is subject to FDA review, the Company will be prepared to launch the test, subject to authorization, without delay following such approval. Subject to receipt of EUA, this product would test for active COVID-19 infection using nasal samples collected from the lower nostril. Results would be available at the point of collection, with no special instrumentation needed to interpret results.

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 October 2020, the Company submitted an EUA application to the FDA for its SARS-CoV-2 Antibody ELISA test. The OraSure SARS-CoV-2 Antibody ELISA is intended for qualitative detection of total antibodies (including IgM/IgA/IgG) to SARS-CoV-2 in human oral fluid specimens collected with the OraSure Oral Antibody Collection Device. To date, there are no oral fluid antibody tests for COVID-19 authorized for sale in the U.S. The Company plans to commercialize the test in the fourth quarter, subject to receipt of the EUA. Oral sample collection is quick, painless, non-invasive and requires less human contact in comparison to a blood draw, minimizing the need for personal protective equipment and exposure to potentially infected patients. With this test, individuals would use a collection pad to self-collect an oral fluid sample under the observation of a healthcare professional. The sample would then be placed into the OraSure oral antibody collection device buffer for storage and transport, and then later dispensed onto the ELISA microplate for testing in a laboratory. The lab-based antibody test can aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. Antibody tests are well suited for community surveillance and seroprevalence studies to identify people in a population or community that have antibodies against an infectious disease such as COVID-19.

We are also actively engaged with several laboratories and researchers to demonstrate the effectiveness of our existing products for use with COVID-19 testing. Recent publications show that COVID-19 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 to 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 September 2020, the Company's ORAcollect®•RNA (OR-100) collection device was included in two FDA EUAs. The first was granted to MiraDx Inc., which will permit the use of ORAcollect®•RNA along with other collection devices to collect oropharyngeal samples in MiraDx's COVID-19 testing program for essential workers and first responders to help slow, and hopefully prevent, the spread of COVID-19. The second was granted to Quadrant Biosciences Inc. for a COVID-19 laboratory test offered by Quadrant. Under both EUAs, the ORAcollect®•RNA (OR-100) device can be used to collect saliva samples from individuals suspected of COVID-19 by a healthcare professional. There are now six EUAs that include a collection device from the Company's DNA Genotek subsidiary. In October 2020, the Company's DNA Genotek subsidiary received FDA EUAs for the use of its OMNIgene®•ORAL (OM-505, OME-505) and ORAcollect•RNA (OR-100, ORE-100) collection devices in COVID-19 testing. These EUAs will allow for the unsupervised use of the device at-home or in a healthcare setting when used as part of an approved or validated at-home test kit, meaning that patients can safely collect their own sample, without the presence of a healthcare professional, before sending the sample to a lab for analysis. With these FDA authorizations, OMNIgene®•ORAL and ORAcollect•RNA devices can be used for the self-collection, transport and laboratory testing of saliva specimens suspected of containing SARS-CoV-2 ribonucleic acid (RNA). These EUAs follow the CE marking of the devices for in vitro diagnostic use, including for COVID-19 testing, in the European Union.

Current Consolidated Financial Results

During the nine months ended September 30, 2020, our consolidated net revenues increased 4% to $108.9 million, compared to $104.9 million for the nine months ended September 30, 2019. Net product and services revenues during the nine months ended September 30, 2020 increased 5% when compared to the same period of 2019, due to the inclusion of product revenues associated with COVID-19 testing, higher laboratory services revenues and higher international sales of our OraQuick® HIV Self-Test. Partially offsetting these increases were lower sales of our genomics, HCV, risk assessment, domestic HIV and microbiome products and the absence of cryosurgical sales as a result of the divestiture of our cryosurgical systems business in August 2019. Other revenues for the nine months ended September 30, 2020 were $2.9 million compared to $4.0 million in the same period of 2019. This decline was largely due to lower royalty income.

Our consolidated net loss for the nine months ended September 30, 2020 was $16.8 million, or $0.25 per share on a fully diluted basis, compared to consolidated net income of $14.2 million, or $0.23 per share on a fully diluted basis, for the nine months ended September 30, 2019. Results for the nine months ended September 30, 2020 included a $390,000 non-cash pre-tax charge associated with the change in the fair value of acquisition-related contingent consideration and $393,000 of acquisition related transaction costs associated with the UrSure acquisition, which together accounted for approximately $0.01 per share. Results for the nine months ended September 30, 2019 included a pre-tax gain on the sale of our cryosurgical systems business of $10.2 million, $843,000 of non-cash pre-tax income associated with the change in the fair value of acquisition-related contingent consideration and $1.0 million of acquisition-related transaction costs. The combined net impact of these items increased earnings per share by approximately $0.16.

Cash provided by operating activities during the nine months ended September 30, 2020 and 2019 was $2.2 million and $10.8 million, respectively. As of September 30, 2020, we had $263.7 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 September 30, 2020 compared to September 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 September 30, 2020 and 2019.

	Three Months Ended September 30,				
	Dollars			Percentage of Total Net Revenues	
	2020	2019	% Change	2020	2019
OSUR	$ 15,540	$ 17,861	(13) %	32 %	50 %
DNAG	31,209	17,438	79	65	48
Net product and services revenues	46,749	35,299	32	97	98
Other	1,262	690	83	3	2
Net revenues	$ 48,011	$ 35,989	33 %	100 %	100 %

Consolidated net product and services revenues increased 32% to $46.7 million in the third quarter of 2020 from $35.3 million in the comparable period of 2019. Product sales related to COVID-19 testing, higher international sales of our OraQuick® HIV Self-Test and higher laboratory services revenues were partially offset by lower sales of our genomics, risk assessment, HCV, and domestic HIV products and the absence of cryosurgical systems revenues due to the sale of our cryosurgical systems business in August 2019. Net revenues for the three months ended September 30, 2020 included $18.4 million of COVID-19 related product revenues. There were no similar revenues in the comparable period of 2019. Other revenues in the third quarter of 2020 increased 83% to $1.3 million from $690,000 in the third quarter of 2019 due to new funding for COVID-19 development projects and the inclusion of UrSure research and development funding partially offset by lower royalty income.

Consolidated net revenues derived from products sold to customers outside of the United States were $9.4 million and $9.7 million, or 20% and 27% of total net revenues, in the third 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 third quarters of 2020 and 2019.

	Three Months Ended September 30,				
	Dollars			Percentage of Total Net Revenues	
Market	2020	2019	% Change	2020	2019
Infectious disease testing	$ 13,224	$ 13,588	(3) %	81 %	77 %
Risk assessment testing	2,316	3,312	(30)	14	19
Cryosurgical systems	—	961	(100)	—	5
Net product revenues	15,540	17,861	(13)	95	101
Other	774	(131)	—	5	(1)
Net revenues	$ 16,314	$ 17,730	(8) %	100 %	100 %

Infectious Disease Testing Market

Sales to the infectious disease testing market decreased 3% to $13.2 million in the third quarter of 2020 from $13.6 million in the third quarter of 2019. This decrease resulted from lower world-wide HCV product sales and lower domestic OraQuick® HIV sales partially offset by higher international sales of our OraQuick® HIV Self-Test.

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

	Three Months Ended September 30,		
Market	2020	2019	% Change
Domestic HIV	$ 3,909	$ 4,259	(8) %
International HIV	6,865	5,891	17
Net HIV revenues	10,774	10,150	6
Domestic HCV	1,186	1,977	(40)
International HCV	1,033	1,129	(9)
Net HCV revenues	2,219	3,106	(29)
Net OraQuick® revenues	$ 12,993	$ 13,256	(2) %

Domestic OraQuick® HIV sales decreased 8% to $3.9 million for the three months ended September 30, 2020 from $4.3 million for the three months ended September 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, partially offset by higher sales of our over-the-counter ("OTC") in-home HIV test as a result of CDC guidance recommending the use of the OTC product for testing in lieu of in-person testing.

International sales of our OraQuick® HIV tests increased 17% to $6.9 million for the three months ended September 30, 2020 from $5.9 million for the three months ended September 30, 2019. This increase was largely due to higher sales of our OraQuick® HIV Self-Test in Africa.

Domestic OraQuick® HCV sales decreased 40% to $1.2 million in the third quarter of 2020 from $2.0 million in the third quarter of 2019. International OraQuick® HCV sales decreased 9% to $1.0 million in the third quarter of 2020 from $1.1 million in the third 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 30% to $2.3 million in the third quarter of 2020 compared to $3.3 million in the third 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 third quarter of 2020 increased to $774,000 from a net reduction of $131,000 of other revenues recorded in the third quarter of 2019, largely due to new funding for COVID-19 development projects and UrSure research and development funding which was not present in the third quarter of 2019.

DNAG Segment

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

	Three Months Ended September 30,		
Market	2020	2019	% Change
Genomics	$ 8,519	$ 13,647	(38) %
Microbiome	1,828	1,878	(3)
COVID-19	18,441	—	—
Laboratory services	2,418	1,618	49
Other product revenues	3	295	(99)
Net molecular product and services revenues	$ 31,209	$ 17,438	79
Other	488	821	(41)
Net molecular product and services revenues	$ 31,697	$ 18,259	74 %

Sales of our genomics products decreased 38% to $8.5 million in the third quarter of 2020 compared to $13.6 million in the third 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 were largely flat at $1.8 million in the third quarter of 2020 compared to $1.9 million in the third quarter of 2019.

During the third quarter of 2020, we sold $18.4 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 49% to $2.4 million in the third quarter of 2020 compared to $1.6 million in the third 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 resulting from the inability of our customers to collect samples due to the COVID-19 pandemic.

Other revenues in the third quarter of 2020 decreased 41% to $488,000 from $821,000 in the third quarter of 2019 largely as a result of lower royalty income under a litigation settlement agreement.

CONSOLIDATED OPERATING RESULTS

Consolidated gross profit percentage was 63% for the third quarter of 2020 compared to 60% for the third quarter of 2019. Gross profit percentage in the third quarter of 2020 benefited from an improved product mix associated with an increase in higher gross profit percentage product sales.

Consolidated operating income for the third quarter of 2020 was $4.4 million, an $8.7 million decline from $13.1 million of operating income reported in the third quarter of 2019. Results in the third quarter of 2019 included a pre-tax gain on the sale of our cryosurgical systems business of $10.2 million and $2.4 million in non-cash income related to the fair value change acquisition-related contingent consideration. Results in the third quarter of 2020 did not include those comparable items but were positively impacted by increased total revenues and improved product mix partially offset by increased spending associated with COVID-19 product development.

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 44% in the third quarter of 2020 compared to 53% in the third quarter of 2019. This decrease is largely due to a less favorable product mix, higher scrap expense, and the absence of higher margin cryosurgical system revenues due to the sale of our cryosurgical systems business in August 2019, partially offset by the increase in other revenues which contribute 100% to our gross profit percentage.

Research and development expenses increased 134% to $5.7 million in the third quarter of 2020 from $2.4 million in the third quarter of 2019 largely due to spending associated with COVID-19 product development and the inclusion of UrSure expenses not present in the third quarter of 2019. Sales and marketing expenses increased 11% to $4.9 million in the third quarter of 2020 from $4.4 million in the third quarter of 2019, due to COVID-19 project spending and UrSure expenses not present in the third quarter of 2019. General and administrative expenses increased 39% to $6.5 million in the third quarter of 2020 compared to $4.7 million in the third quarter of 2019 largely due to increased staffing costs.

All of the above contributed to OSUR's third quarter 2020 operating loss of $10.0 million, which included non-cash charges of $934,000 for depreciation and amortization and $1.6 million for stock-based compensation.

DNAG Segment

DNAG's gross profit percentage was 73% in the third quarter of 2020 compared to 67% in the third quarter of 2019. This increase is attributable to an increase in higher gross profit percentage product sales.

Research and development expenses increased 6% to $2.3 million in the third quarter of 2020 from $2.2 million in the third quarter of 2019 largely due to the inclusion of research and development expenses incurred by Diversigen not present in the third quarter of 2019. Sales and marketing expenses decreased 35% to $2.9 million in the third quarter of 2020 from $4.5 million in the third quarter of 2019 largely due to a prior period increase in our reserve for uncollectible accounts largely associated with a receivable from a large Chinese genomics customer. General and administrative expenses increased 25% to $3.6 million in the third quarter of 2020 from $2.9 million in the third quarter of 2019 due to expenses incurred by Diversigen not included in the third quarter of 2019, higher staffing costs and increased amortization expense.

All of the above contributed to DNAG's third quarter 2020 operating income of $14.3 million, which included $1.5 million for depreciation and amortization, and $229,000 for stock-based compensation.

CONSOLIDATED INCOME TAXES

We continue to believe the full valuation allowance established against OSUR's total U.S. deferred tax asset is appropriate as the facts and circumstances necessitating the allowance have not changed. For the three months ended September 30, 2020, a federal and state tax benefit of $629,000 was recorded compared to $232,000 of state income tax expense was recorded for the three months ended September 30,2019. For the three months ended September 30, 2020, foreign tax expense of $4.3 million was recorded compared to foreign tax expense of $937,000 recorded for the three months ended September 30, 2019.

Nine months ended September 30, 2020 compared to September 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 nine months ended September 30, 2020 and 2019.

	Nine Months Ended September 30,					
	Dollars			Percentage of Total Net Revenues		
	2020	2019	% Change	2020	2019	
OSUR	$ 43,473	$ 55,573	(22) %	40 %	53 %	
DNAG	62,499	45,325	38	57	43	
Net product revenues	105,972	100,898	5	97	96	
Other	2,894	4,039	(28)	3	4	
Net revenues	$ 108,866	$ 104,937	4 %	100 %	100 %	

Consolidated net product and services revenues increased 5% to $106.0 million for the nine months ended September 30, 2020 from $100.9 million for the comparable period of 2019 due to the inclusion of product revenues associated with COVID-19 testing coupled with higher laboratory services revenues and increased international sales of our OraQuick® HIV Self-Test. These increases were partially offset by lower sales of our genomics, HCV, risk assessment, domestic HIV, and microbiome products and the absence of cryosurgical sales as a result of the divestiture of our cryosurgical systems business in August 2019. Other revenues for the nine months ended September 30, 2020 were $2.9 million compared to $4.0 million in the same period of 2019. This decline was largely due to lower royalty income.

Consolidated net revenues derived from products sold to customers outside of the United States were $26.7 million and $30.2 million, or 25% and 29% of total net revenues, in the first nine 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 nine months ended September 30, 2020 and 2019.

	Nine Months Ended September 30,				
	Dollars			Percentage of Total Net Revenues	
Market	2020	2019	% Change	2020	2019
Infectious disease testing	$ 36,625	$ 39,273	(7) %	82 %	70 %
Risk assessment testing	6,848	9,246	(26)	16	16
Cryosurgical systems	—	7,054	(100)	—	13
Net product revenues	43,473	55,573	(22)	98	99
Other	1,060	762	39	2	1
Net revenues	$ 44,533	$ 56,335	(21) %	100 %	100 %

Infectious Disease Testing Market

Sales to the infectious disease testing market decreased 7% to $36.6 million for the nine months ended September 30, 2020 from $39.3 million for the nine months ended September 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 nine months ended September 30, 2020 and 2019.

	Nine Months Ended September 30,		
Market	2020	2019	% Change
Domestic HIV	$ 11,323	$ 13,024	(13) %
International HIV	17,697	15,313	16
Net HIV revenues	29,020	28,337	—
Domestic HCV	3,437	5,907	(42)
International HCV	2,772	3,569	(22)
Net HCV revenues	6,209	9,476	(34)
Net OraQuick® revenues	$ 35,229	$ 37,813	(7) %

Domestic OraQuick® HIV sales decreased 13% to $11.3 million for the nine months ended September 30, 2020 from $13.0 million for the nine months ended September 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 increased at-home testing as a result of the COVID-19 pandemic.

International sales of our OraQuick® HIV tests increased 16% to $17.7 million for the nine months ended September 30, 2020 from $15.3 million for the nine months ended September 30, 2019. This increase was largely due to higher sales of our OraQuick® HIV Self-Test in Africa, Latin America and Europe.

Domestic OraQuick® HCV sales decreased 42% to $3.4 million for the nine months ended September 30, 2020 from $5.9 million for the nine months ended September 30, 2019. International OraQuick® HCV sales decreased 22% to $2.8 million for the nine months ended September 30, 2020 from $3.6 million for the nine months ended September 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 26% to $6.8 million for the nine months ended September 30, 2020 compared to $9.2 million for the nine months ended September 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 nine months ended September 30, 2020 increased 39% to $1.1 million from $762,000 for the nine months ended September 30, 2019. Revenue associated with funding of our research and development efforts increased to $1.1 million for the nine months ended September 30, 2020 from $558,000 for the nine months ended September 30, 2019 as new grants for COVID-19 funded projects and UrSure research and development funding were partially offset by the wind-down of efforts to develop our rapid Ebola test. Other revenues for the nine months ended September 30, 2020 also included $63,000 in reimbursement of certain costs under our charitable support agreement with the Gates Foundation compared to $203,000 for the nine months ended September 30, 2019.

DNAG Segment

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

	Nine Months Ended September 30,		
Market	**2020**	**2019**	**% Change**
Genomics	$ 23,381	$ 35,449	(34) %
Microbiome	4,259	5,325	(20)
COVID-19	27,307	—	—
Laboratory services	7,472	3,947	89
Other product revenues	80	604	(87)
Net molecular product and services revenues	$ 62,499	$ 45,325	38
Other	1,834	3,277	(44)
Net molecular product and services revenues	$ 64,333	$ 48,602	32 %

Sales of our genomics products decreased 34% to $23.4 million for the nine months ended September 30, 2020 compared to $35.4 million for the nine months ended September 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 20% to $4.3 million for the nine months ended September 30, 2020 compared to $5.3 million for the nine months ended September 30, 2019 largely due to reduced demand caused by the COVID-19 pandemic.

During the first nine months of 2020, we sold $27.3 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 89% to $7.5 million for the nine months ended September 30, 2020 compared to $3.9 million for the nine months ended September 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 nine months ended September 30, 2020 decreased 44% to $1.8 million from $3.3 million for the nine months ended September 30, 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 nine months ended September 30, 2020 compared to 62% for the nine months ended September 30, 2019. The decrease in gross profit percentage 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, increased scrap and spoilage expense, a less favorable product mix, and the decline in other revenues which contribute 100% to our gross profit percentage.

Consolidated operating loss for the nine months ended September 30, 2020 was $13.1 million, a $27.6 million decline from the $14.5 million of operating income reported for the nine months ended September 30, 2019. Results for the nine months ended September 30, 2020 were negatively impacted by the lower gross profit percentage, increased operating expenses related to COVID-19 product development, higher staffing costs, and the inclusion of $393,000 of transaction costs associated with the acquisition of UrSure. The nine months ended September 30, 2020 also included $390,000 of a non-cash charge related to the fair value change of acquisition-related contingent consideration compared to $843,000 of non-cash income in the comparable period of the prior year. Results for the nine months ended September 30, 2019 also included the pre-tax gain on sale of our cryosurgical systems business of $10.2 million.

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 nine months ended September 30, 2020 compared to 56% for nine months ended September 30, 2019. This decrease is largely 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, and increased scrap and spoilage expense.

Research and development expenses increased 69% to $13.5 million in the nine months ended September 30, 2020 from $8.0 million in the nine months ended September 30, 2019, largely due to increased spending associated with COVID-19 product development, higher staffing costs, and the inclusion of UrSure expenses not present in the first nine months of 2019. Sales and marketing expenses increased 15% to $16.1 million in the nine months ended September 30, 2020 from $14.0 million in the nine months ended September 30, 2019, due to an increase in our reserve for uncollectible accounts largely associated with one of our distributors located in Africa, 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 the inclusion of UrSure expenses not present in the third quarter of 2019. These increases were partially offset by lower travel and trade show costs due to the COVID-19 pandemic. General and administrative expenses increased 40% to $20.7 million in the nine months ended September 30, 2020 compared to $14.9 million in the nine months ended September 30, 2019 largely due to increased staffing costs, higher legal fees, and the inclusion of the $393,000 in acquisition related transaction costs associated with the UrSure acquisition.

All of the above contributed to OSUR's 2020 operating loss of $31.1 million in the nine months ended September 30, 2020, which included non-cash charges of $2.7 million for depreciation and amortization and $4.9 million for stock-based compensation.

DNAG Segment

DNAG's gross profit percentage was 69% for both the nine months ended September 30, 2020 and 2019.

Research and development expenses increased 28% to $7.1 million in the nine months ended September 30, 2020 from $5.6 million in the nine months ended September 30, 2019 due to higher staffing costs and the inclusion of research and development expenses incurred by Diversigen not included in the first nine months of 2019. Sales and marketing expenses decreased 7% to $9.2 million in the nine months ended September 30, 2020 from $9.9 million in the nine months ended September 30, 2019 largely due to a prior period increase in our reserve for uncollectible accounts largely associated with a receivable from a large Chinese genomics customer partially offset by increased staffing costs and expenses incurred by Diversigen. General and administrative expenses increased 9% to $9.7 million in the nine months ended September 30, 2020 from $8.9 million in the nine months ended September 30, 2019 due to the inclusion of expenses incurred by Diversigen.

All of the above contributed to DNAG's operating income of $18.1 million in the first nine months of 2020, which included a non-cash charge of $390,000 for the change in the fair value of acquisition-related contingent consideration, $4.4 million for depreciation and amortization, and $982,000 for stock-based compensation.

CONSOLIDATED INCOME TAXES

We continue to believe the full valuation allowance established against OSUR's total U.S. deferred tax asset is appropriate as the facts and circumstances necessitating the allowance have not changed. For the nine months ended September 30, 2020, a federal and state income tax benefit of $612,000 was recorded as compared to $244,000 in the nine months ended September 30, 2019. For the nine months ended September 30, 2020, foreign tax expense of $6.3 million was recorded as compared to income tax expense of $2.3 million recorded for the nine months ended September 30, 2019.

Liquidity and Capital Resources

	September 30, 2020	December 31, 2019
	(In thousands)	
Cash and cash equivalents	$ 162,859	$ 75,715
Available for sale securities	100,802	114,043
Working capital	265,750	191,837

Our cash and cash equivalents and available-for-sale securities increased to $263.7 million at September 30, 2020 from $189.8 million at December 31, 2019. Our working capital increased to $265.8 million at September 30, 2020 from $191.8 million at December 31, 2019.

During the first nine months of 2020, net cash provided by operating activities was $2.2 million. Our net loss of $16.8 million included non-cash charges for depreciation and amortization expense of $7.1 million, stock-based compensation expense of $5.9 million, a provision for doubtful accounts of $1.1 million, a charge for the change in the estimated fair value of acquisition-related contingent consideration of $390,000 and other non-cash benefits of $645,000. 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 $5.2 million decrease in accounts receivable as a result of the collection of large outstanding balances, a $3.3 million increase in accounts payable due to the timing of invoice payments, a $2.4 million decrease in prepaid expenses and other assets due to lower estimated income tax installments and the timing of insurance renewals, a $1.7 million increase in deferred revenue associated with customer prepayments, and a $468,000 decrease in accrued expenses. Offsetting these sources of cash were an increase in inventory of $7.4 million to meet anticipated demand to support COVID-19 testing programs.

Net cash used in investing activities was $3.9 million for the nine months ended September 30, 2020, which reflects $90.1 million used to purchase investments, $11.2 million used to acquire property and equipment, $3.0 million to acquire UrSure, and $2.3 million used to purchase patent and product rights partially offset by $102.6 million in proceeds from the maturities and redemptions of investments.

Net cash provided by financing activities was $91.6 million for the nine months ended September 30, 2020, which largely resulted from the proceeds from the issuance of common stock in connection with a public offering of $95.0 million and proceeds of stock option exercises of $2.1 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, $82.0 million or 31% of our $263.7 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 September 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 nine 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 September 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 nine months ended September 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 $131.7 million in U.S. Dollars, which are included in the Company's consolidated balance sheet as of September 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 $11.3 million in the nine months ended September 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 September 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 September 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 September 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.

On February 6, 2017, DNAG entered into a settlement and license agreement (the "Settlement Agreement") in order to settle certain patent infringement and breach of contract litigation against Ancestry.comDNA, LLC ("Ancestry") and its contract manufacturer. This litigation was related to a saliva DNA collection device sold by Ancestry that was similar to products sold by DNAG. Under the terms of the Settlement Agreement, DNAG and Ancestry agreed to certain procedures for considering whether future versions of Ancestry's saliva DNA collection product are covered by the DNAG patents licensed to Ancestry (the "Licensed Patents") and thus subject to ongoing royalties under the Settlement Agreement. A dispute arose among the parties regarding whether certain new Ancestry products are covered by the Licensed Patents. Pursuant to the terms of the Settlement Agreement, a binding arbitration proceeding was commenced to resolve the dispute. In February 2020, an arbitration panel issued a decision finding that the future Ancestry products do not infringe the DNAG patents asserted in the arbitration and would no longer be subject to the royalties under the Settlement Agreement.

Following the completion of the arbitration, a new patent issued to DNAG that is a continuation of a patent licensed to Ancestry and is thus a Licensed Patent under the Settlement Agreement. DNAG notified Ancestry of this new patent and following discussions between the parties Ancestry initiated a new arbitration proceeding during the third quarter of 2020 with a third party alternative dispute resolution provider pursuant to the Settlement Agreement with respect to the applicability of the new patent to the future Ancestry products and the validity of that patent. Following the initiation of the arbitration by Ancestry, DNAG filed a statement of defense and an objection to the arbitration on the basis that a dispute between the parties has not yet occurred and therefore the alleged dispute is not sufficiently ripe to arbitrate. An arbitration panel has been appointed and the arbitration is expected to be completed during the first half of 2021.

Item 1A. RISK FACTORS

There have been no material changes to the risk factors disclosed in Item 1A, entitled "Risk Factors," in our Annual Report on Form 10-K for the year ended December 31, 2019 and our Quarterly Report on form 10-Q for the quarter ended September 30, 2020.

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

Period	Total number of shares purchased		Average price paid per Share	Total number of shares purchased as part of publicly announced plans or programs	Maximum number (or approximate dollar value) of shares that may yet be repurchased under the plans or programs (1, 2)
July 1, 2020 - July 31, 2020	—		$ —	—	11,984,720
August 1, 2020 - August 31, 2020	600	(3)	13.34	—	11,984,720
September 1, 2020 - September 30, 2020	408	(3)	10.89	—	11,984,720
	1,008			—	

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

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

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

Item 3. DEFAULTS UPON SENIOR SECURITIES

None

Item 4. MINE SAFETY DISCLOSURES

Not applicable

Item 5. OTHER INFORMATION

None

Item 6. EXHIBITS

Exhibit Number	Exhibit
31.1 †	Certification of 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 September 30, 2020 has been formatted in Inline XBRL

† 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: November 4, 2020

Roberto Cuca
Chief Financial Officer
(Principal Financial Officer)

/s/Michele M. Miller

Date: November 4, 2020

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

Exhibit 31.1

Certification

I, Stephen S. Tang, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 5, 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: November 5, 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 September 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

November 5, 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 September 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

November 5, 2020