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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2022.

OR

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

For the transition period from _____ to _____ .

Commission File Number 001-16537

ORASURE TECHNOLOGIES, INC.

(Exact Name of Registrant as Specified in Its Charter)

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

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

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

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

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

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

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

As of August 5, 2022, the registrant had 72,619,055 shares of common stock, $.000001 par value per share, outstanding.

PART I. FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

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

	June 30, 2022	December 31, 2021
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 66,159	$ 116,762
Short-term investments	29,625	36,279
Accounts receivable, net of allowance for doubtful accounts of $3,222 and $3,418	62,886	45,323
Inventories	71,304	53,138
Prepaid expenses	5,477	7,939
Other current assets	31,855	28,990
Total current assets	267,306	288,431
Noncurrent Assets:		
Property, plant and equipment, net	93,697	88,164
Operating right-of-use assets, net	16,451	9,056
Finance right-of-use assets, net	1,887	2,493
Intangible assets, net	12,851	14,343
Goodwill	36,038	40,279
Long-term investments	—	17,009
Other noncurrent assets	1,024	1,215
Total noncurrent assets	161,948	172,559
TOTAL ASSETS	**$ 429,254**	**$ 460,990**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 36,226	$ 28,024
Deferred revenue	2,660	2,936
Accrued expenses and other current liabilities	23,165	33,778
Finance lease liabilities	1,182	939
Operating lease liabilities	2,054	2,181
Acquisition-related contingent consideration obligation	199	206
Total current liabilities	65,486	68,064
Noncurrent Liabilities:		
Finance lease liabilities	1,445	1,952
Operating lease liabilities	14,978	7,202
Acquisition-related contingent consideration obligation	117	354
Other noncurrent liabilities	489	651
Deferred income taxes	2,547	2,234
Total noncurrent liabilities	19,576	12,393
TOTAL LIABILITIES	85,062	80,457
Commitments and contingencies (Note 12)		
STOCKHOLDERS' EQUITY		
Preferred stock, par value $.000001, 25,000 shares authorized, none issued	—	—
Common stock, par value $.000001, 120,000 shares authorized, 72,572 and 72,069 shares issued and outstanding	—	—
Additional paid-in capital	515,928	511,063
Accumulated other comprehensive loss	(12,514)	(10,077)
Accumulated deficit	(159,222)	(120,453)
Total stockholders' equity	344,192	380,533
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 429,254**	**$ 460,990**

See accompanying notes to the consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
NET REVENUES:				
Products and services	$ 79,167	$ 55,741	$ 144,403	$ 112,320
Other	1,064	1,866	3,535	3,869
	80,231	57,607	147,938	116,189
COST OF PRODUCTS AND SERVICES SOLD	52,647	26,934	96,082	47,190
Gross profit	27,584	30,673	51,856	68,999
OPERATING EXPENSES:				
Research and development	9,068	7,682	17,481	16,674
Sales and marketing	11,684	10,420	24,401	19,950
General and administrative	17,579	10,993	36,735	21,181
Loss on impairment	10,542	—	10,542	—
Change in the estimated fair value of acquisition-related contingent consideration	—	(220)	(36)	(1,026)
	48,873	28,875	89,123	56,779
Operating income (loss)	(21,289)	1,798	(37,267)	12,220
OTHER INCOME	1,318	448	1,265	329
Income (loss) before income taxes	(19,971)	2,246	(36,002)	12,549
INCOME TAX EXPENSE (BENEFIT)	(1,169)	3,610	2,767	10,139
NET INCOME (LOSS)	$ (18,802)	$ (1,364)	$ (38,769)	$ 2,410
INCOME (LOSS) PER SHARE:				
BASIC	$ (0.26)	$ (0.02)	$ (0.54)	$ 0.03
DILUTED	$ (0.26)	$ (0.02)	$ (0.54)	$ 0.03
SHARES USED IN COMPUTING INCOME (LOSS) PER SHARE:				
BASIC	72,496	71,983	72,361	71,931
DILUTED	72,496	71,983	72,361	72,683

See accompanying notes to the consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
NET INCOME (LOSS)	$ (18,802)	$ (1,364)	$ (38,769)	$ 2,410
OTHER COMPREHENSIVE INCOME (LOSS)				
Currency translation adjustments	(4,349)	1,403	(2,593)	2,755
Unrealized gain (loss) on marketable securities	82	(122)	156	(101)
COMPREHENSIVE INCOME (LOSS)	$ (23,069)	$ (83)	$ (41,206)	$ 5,064

See accompanying notes to the consolidated financial statements.

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

	Six Months Ended June 30,	
	2022	**2021**
OPERATING ACTIVITIES:		
Net income (loss)	$ (38,769)	$ 2,410
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Stock-based compensation	6,804	2,937
Depreciation and amortization	7,464	5,144
Loss on impairment	10,542	—
Other non-cash amortization	313	380
Provision for doubtful accounts	(152)	747
Inventory reserve	1,989	1,168
Unrealized foreign currency gain	(62)	(364)
Interest expense on finance leases	55	35
Deferred income taxes	361	(218)
Loss on disposal of fixed assets	718	—
Change in the estimated fair value of acquisition-related contingent consideration	(36)	(1,026)
Payment of acquisition-related contingent consideration	—	(142)
Changes in assets and liabilities		
Accounts receivable	(18,646)	3,680
Inventories	(20,385)	(17,233)
Prepaid expenses and other assets	(4,416)	154
Accounts payable	11,942	4,400
Deferred revenue	(252)	(630)
Accrued expenses and other liabilities	(2,959)	(4,914)
Net cash used in operating activities	(45,489)	(3,472)
INVESTING ACTIVITIES:		
Purchases of investments	—	(10,428)
Proceeds from maturities and redemptions of investments	23,017	43,745
Purchases of property and equipment	(25,440)	(22,929)
Purchase of property and equipment under government contracts	(33,803)	—
Proceeds from funding under government contract	33,962	—
Other investing activities	—	(18)
Net cash (used in) provided by investing activities	(2,264)	10,370
FINANCING ACTIVITIES:		
Cash payments for lease liabilities	(392)	(510)
Proceeds from exercise of stock options	15	121
Payment of acquisition-related contingent consideration	(208)	(264)
Repurchase of common stock	(1,954)	(1,877)
Net cash used in financing activities	(2,539)	(2,530)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	(311)	(7,050)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(50,603)	(2,682)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	116,762	160,802
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 66,159	$ 158,120
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for income taxes	$ 9,107	$ 10,329
Non-cash investing and financing activities		
Accrued property and equipment purchases	1,900	896
Accrued property and equipment purchases under government contracts	2,023	—
Unrealized gain (loss) on marketable securities	156	(101)

See accompanying notes to the consolidated financial statements.

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

1. 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, DNA Genotek Inc. ("DNAG"), Diversigen, Inc. ("Diversigen"), and Novosanis NV ("Novosanis"). All intercompany transactions and balances have been eliminated. References herein to "we," "us," "our," or the "Company" mean OraSure and its consolidated subsidiaries, unless otherwise indicated. The 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, 2021. Results of operations for the three and six months ended June 30, 2022 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, 2021 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 purchased with 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. During the six months ended June 30, 2022, we recognized a provision for expected credit losses for our available-for-sale securities of $72.

The following is a summary of our available-for-sale securities as of June 30, 2022 and December 31, 2021:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
June 30, 2022				
Guaranteed investment certificates	$ 24,860	$ —	$ —	$ 24,860
Corporate bonds	5,043	—	(278)	4,765
Total available-for-sale securities	$ 29,903	$ —	$ (278)	$ 29,625
December 31, 2021				
Guaranteed investment certificates	$ 33,249	$ —	$ —	$ 33,249
Corporate bonds	20,473	—	(434)	20,039
Total available-for-sale securities	$ 53,722	$ —	$ (434)	$ 53,288
At June 30, 2022, maturities of our available-for-sale securities were as follows:				
Less than one year	$ 29,903	$ —	$ (278)	$ 29,625
Greater than one year	$ —	$ —	$ —	$ —

Fair Value of Financial Instruments. As of June 30, 2022 and December 31, 2021, the carrying values of cash and cash equivalents, accounts receivable, accounts payable, and accrued expenses approximate their respective fair values based on their short-term nature.

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

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

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

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

All of our available-for-sale debt securities are measured as Level 2 instruments as of June 30, 2022 and December 31, 2021. Our available-for-sale guaranteed investment certificates are measured as Level 1 instruments as of June 30, 2022 and December 31, 2021.

Included in cash and cash equivalents at June 30, 2022 and December 31, 2021, was $5,636 and $1,160 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 and company stock. The fair value of the plan assets as of June 30, 2022 and December 31, 2021 was $1,576 and $1,763, 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.

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 years, while computer equipment, machinery and equipment, and furniture and fixtures are depreciated over two to ten years. Building improvements are amortized over their estimated useful lives. When assets are sold, retired, or discarded, the related property amounts are relieved from the accounts, and any gain or loss is recorded in the consolidated statements of operations. Accumulated depreciation of property, plant and equipment as of June 30, 2022 and December 31, 2021 was $66,468 and $61,157, respectively.

Intangible Assets. Intangible assets consist of customer relationships, patents and product rights, acquired technology and tradenames. Patents and product rights consist of costs associated with the acquisition of patents, licenses, and product distribution rights. Intangible assets are amortized using the straight-line method over their estimated useful lives of five to fifteen years. Accumulated amortization of intangible assets as of June 30, 2022 and December 31, 2021 was $30,988 and $30,412, respectively. The decrease in intangible assets from $14,343 as of December 31, 2021 to $12,851 as of June 30, 2022 was due to $1,120 in amortization expense and foreign currency translation losses of $372.

Impairment of Long-Lived Assets. Long-lived assets, which include property and equipment and definite-lived intangible assets, are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. We assess the recoverability of our long-lived assets by determining whether the carrying value of such assets can be recovered through the sum of the undiscounted future cash flows generated from the use and eventual disposition of the asset. If indicators of impairment exist, we measure the amount of such impairment by comparing the carrying value of the assets to the fair value of these assets, which is generally determined based on the present value of the expected future cash flows associated with the use of the assets. Expected future cash flows reflect our assumptions about selling prices, volumes, costs and market conditions over a reasonable period of time.

During the three months ended June 30, 2022, management decided to move three idle manufacturing cells to storage due to changes in forecasted demand for the products the cells are intended to produce. As a result of this decision, we determined that the carrying values of the equipment is not recoverable and recorded an aggregate pre-tax asset impairment charge of $6,938 during the three months ended June 30, 2022 to write the assets down their estimated fair values. This charge is reported within loss on impairments in the consolidated statement of operations.

We estimated the fair value of the impaired long-lived assets using a market approach, which required us to estimate the value that would be received for the equipment in the principal or most advantageous market for that equipment in an orderly transaction between market participants. Due to the extremely specialized nature of the manufacturing equipment and various market data points, the estimated fair value was not significant. Our fair value estimates were representative of Level 3 measurements within the fair value hierarchy due to the significant level of estimation involved and the lack of transparency as to the inputs used.

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 (loss) in our consolidated statements of operations were $783 and $198 for the three months ended June 30, 2022 and 2021, respectively. Net foreign exchange gains (losses) were $54 and $(379) for the six months ended June 30, 2022 and 2021, respectively.

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

We have defined the Canadian dollar as the functional currency of our Canadian subsidiary, DNAG, and we have defined the Euro as the functional currency of our Belgian subsidiary, Novosanis. The results of operations for those subsidiaries are translated into U.S. dollars, which is the reporting currency of the Company. Accumulated other comprehensive loss at June 30, 2022 consisted of $12,236 of currency translation adjustments and $278 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, 2021 consists of $9,643 of currency translation adjustments and $434 of net unrealized losses on marketable securities, which represents the fair market value adjustment for our investments portfolio.

Recent Accounting Pronouncements.

In March 2020, the FASB issued Accounting Standards Update ("ASU") No. 2020-04, *Reference Rate Reform* (Topic 848) *Facilitation of the Effects of Reference Rate Reform on Financial Reporting*. The purpose of this update is to provide optional guidance for a limited time to ease the potential burden in accounting for (or recognizing the effects of) reference rate reform on financial reporting. The amendments provide optional expedients and exceptions for applying GAAP to contracts, hedging relationships, and other transactions affected by reference rate reform if certain criteria are met. The amendments in this ASU were effective upon issuance and could be applied prospectively through December 31, 2022. The FASB issued a proposed amendment to the ASU in April 2022 which, if approved, will extend the date for prospective application to December 31, 2024. Management has evaluated this ASU and concluded that it will not have a material impact on the Company's Consolidated Financial Statements.

2. Government Capital Contracts

In September 2021, we entered into an agreement for $109,000 in funding from the U.S. Department of Defense (the "DOD"), in coordination with the Department of Health and Human Services, to build additional manufacturing capacity in the United States for our InteliSwab® COVID-19 Rapid Tests as part of the nation's pandemic preparedness plan. Funding will be paid to the Company based on achievement of milestones through March 2024 for the design, acquisition, installation, qualification and acceptance of the manufacturing equipment, as set forth in the agreement. In accordance with the milestone payment schedule, 15% of the total will not be funded until the completion of the final equipment validation, which is scheduled to occur in late 2023 or early 2024. We began making payments to vendors for the capital project during the fourth quarter of 2021 and began receiving funds from the DOD in January 2022.

Additionally, during 2021, we received $531 in funding from the Commonwealth of Pennsylvania, acting through the Department of Community and Economic Development, for the purchase of machinery and equipment as part of an expansion of manufacturing operations in Pennsylvania. All related purchases were completed in 2021.

Activity for these capital contracts is accounted for pursuant to International Accounting Standard ("IAS") 20, Accounting for Government Grants and Disclosure of Government Assistance. Funding earned in relation to capital-related costs incurred for government contracts is recorded as a reduction to the cost of property, plant and equipment and reflected within investing activities in the consolidated statements of cash flows; and associated unpaid liabilities and government proceeds receivable are considered non-cash changes in such balances within the operating section of the consolidated statements of cash flows. Amounts earned in excess of our expected cost of the project for project management are recognized straight-line in other income over the term of the government contract. We recognized $561 and $1,123 of such income for the three and six months ended June 30, 2022, respectively, which is reported as other income (loss) in our consolidated statement of operations.

The balances corresponding to government contracts included in our consolidated balance sheet are as follows:

	June 30, 2022	December 31, 2021
Other current assets:		
Billed receivables	$ —	$ 9,913
Unbilled receivables	15,748	9,716
Total other current assets	15,748	19,629
Property, plant and equipment, net:		
Cost of assets, cumulative	47,321	11,495
Reduction for funding earned to date, not yet received	(12,828)	(10,964)
Reduction for funding received to date	(34,493)	(531)
Total property, plant and equipment, net	—	—
Accrued expenses and other current liabilities	(620)	(8,103)

3. Inventories

	June 30, 2022	December 31, 2021
Raw materials	$ 37,292	$ 33,168
Work in process	2,348	2,252
Finished goods	31,664	17,718
	$ 71,304	$ 53,138

4. Earnings (Loss) Per Share

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Net income (loss)	$ (18,802)	$ (1,364)	$ (38,769)	$ 2,410
Weighted-average shares of common stock outstanding:				
Basic	72,496	71,983	72,361	71,931
Dilutive effect of stock options, restricted stock, and performance stock units	—	—	—	752
Diluted	72,496	71,983	72,361	72,683
Earnings (loss) per share:				
Basic	$ (0.26)	$ (0.02)	$ (0.54)	$ 0.03
Diluted	$ (0.26)	$ (0.02)	$ (0.54)	$ 0.03

For the three months ended June 30, 2022, three months ended June 30, 2021 and six months ended June 30, 2022, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 226, 603, and 381 shares, respectively, were excluded from the computation of diluted loss per share. For the six months ended June 30, 2021, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 604 shares were excluded from the computation of diluted earnings per share as their inclusion would have been anti-dilutive.

5. Revenues

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
COVID-19 [1]	$ 43,378	$ 12,070	$ 74,411	$ 40,215
Genomics [1]	15,486	19,498	30,578	30,316
HIV	10,357	10,944	18,523	19,722
HCV	3,691	4,300	6,948	6,668
Substance abuse	2,630	2,629	5,191	4,591
Microbiome [1]	1,832	2,447	3,822	4,198
Laboratory services	1,204	3,114	2,938	5,611
Other product and service revenues	589	739	1,992	999
Net product and services revenues	79,167	55,741	144,403	112,320
Royalty income	642	875	1,326	2,136
Other non-product revenues	422	991	2,209	1,733
Other revenues	1,064	1,866	3,535	3,869
Net revenues	$ 80,231	$ 57,607	$ 147,938	$ 116,189

[1] 2021 COVID-19, Genomics and Microbiome revenues were reclassified to reflect the correct classification of the product line sales. The reclassification increased (decreased) the product line revenues for the three months ended June 30, 2021 by $490, $(84) and $(406), respectively. The reclassification increased (decreased) the product line revenues for the six months ended June 30, 2021 by $1,073, $(330) and $(743), respectively.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
United States	$ 70,320	$ 47,601	$ 128,307	$ 96,700
Europe	2,436	3,325	6,722	7,877
Other regions	7,475	6,681	12,909	11,612
	$ 80,231	$ 57,607	$ 147,938	$ 116,189

Customer and Vendor Concentrations. At June 30, 2022, one non-commercial customer accounted for 48% of our accounts receivable and another commercial customer accounted for 10% of our accounts receivable. No customers accounted for more than 10% of our accounts receivable as of December 31, 2021. One non-commercial customer accounted for 56% and 39% of net consolidated revenues for the three and six months ended June 30, 2022. One customer accounted for 14% of net consolidated revenues for the three months ended June 30, 2021. Another customer accounted for 10% and 14%, respectively, of net consolidated revenues for the three and six months ended June 30, 2021.

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. Third-party suppliers also manufacture certain products. Our inability to have a timely supply of any of these components and products could have a material adverse effect on our business, as well as our financial condition and results of operations.

Deferred Revenue. We record deferred revenue when funds are received prior to the recognition of the associated revenue. Deferred revenue as of June 30, 2022 and December 31, 2021 includes customer prepayments of $1,746 and $1,843, respectively. Deferred revenue as of June 30, 2022 and December 31, 2021 also includes $914 and $1,093, 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.

6. Goodwill

The following table represents the changes in goodwill by operating segment for the six months ended June 30, 2022:

	June 30, 2022	
	Diagnostics	Molecular Solutions
Balance as of January 1	$ 3,604	$ 36,675
Impairment	(3,604)	—
Change related to foreign currency translation	—	(637)
Balance as of June 30	$ —	$ 36,038

We perform an annual goodwill impairment assessment as of July 31 each year by comparing the estimated fair values of our reporting units to their respective carrying values. A more frequent evaluation is performed if an event occurs or circumstances change between annual tests that could more likely than not reduce the fair value of a reporting unit below its carrying amount.

During the three months ended June 30, 2022, we determined that a triggering event occurred in relation to the depressed market price of the Company's common stock and corresponding significant decline in our market capitalization. As a result, we performed an interim goodwill impairment test and concluded that the carrying value of our Diagnostics reporting unit exceeded its estimated fair value and the goodwill balance for that segment was fully impaired. Thus, we recognized a pre-tax impairment charge of $3.6 million during the three months ended June 30, 2022, which is reported in loss on impairments in our condensed consolidated statement of operations.

We estimated fair values of both of our reporting units using a combined income-based approach and market-based approach. Our income approach utilized projected future cash flows that were discounted at a rate of 22% for the Diagnostic reporting unit and 20% for the Molecular Solutions reporting unit based on a weighted-average cost of capital analysis that reflected current market conditions. The market comparable approach primarily considered earnings, revenue and other multiples of comparable companies and applied those multiples to certain key drivers of the reporting units. This market approach utilized a revenue multiple weighted by year for the Diagnostics reporting unit and both a revenue and EBITDA multiple for the Molecular Solutions reporting unit. We assigned a weight of 75% to the results of our income-based approach and 25% to the results from the market-based approach for estimation of the reporting units' fair value. Our fair value estimates utilize significant unobservable inputs and thus represent Level 3 fair value measurements.

7. Accrued Expenses and other current liabilities

	June 30, 2022	December 31, 2021
Payroll and related benefits	$ 11,636	$ 15,570
Commitment to purchase under government contract	—	8,103
Deferred income for government contract	620	—
Professional fees	3,799	3,335
Sales tax payable	1,807	2,227
Other	5,303	4,543
	$ 23,165	$ 33,778

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 June 30, 2022, we are the lessee in all agreements. Our leases have remaining lease terms of 1 to 11 years, some of which include options to extend the leases based on agreed upon terms, and some of which include options to terminate the leases within 1 year.

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

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

The components of lease expense are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating lease cost	$ 811	$ 499	$ 1,510	$ 919
Variable and short-term lease cost	152	—	227	—
Finance lease cost:				
Amortization of right-of use assets	306	212	691	339
Interest on lease liabilities	23	21	55	35
Total finance lease cost	329	233	746	374
Total lease cost	$ 1,292	$ 732	$ 2,483	$ 1,293

Supplemental cash flow information related to leases is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Cash paid for amounts included in the measurement of lease liabilities:				
Operating cash flows from operating leases	$ 1,027	$ 416	$ 2,213	$ 824
Operating cash flows from financing leases	23	21	55	35
Financing cash flows from financing leases	239	228	392	510
Non-cash activity:				
Right-of-use assets obtained in exchange for operating lease obligations	5,131	7,205	8,797	7,834
Right-of-use assets obtained in exchange for finance lease obligations	-	—	117	—

Supplemental balance sheet information related to leases is as follows:

	June 30, 2022	December 31, 2021
Operating Leases		
Right-of-use assets	$ 16,451	$ 9,056
Lease liabilities:		
Current lease liabilities	2,054	2,181
Non-current lease liabilities	14,978	7,202
Total operating lease liabilities	$ 17,032	$ 9,383
Finance Leases		
Right-of-use assets	$ 1,887	$ 2,493
Lease liabilities:		
Current lease liabilities	1,182	939
Non-current lease liabilities	1,445	1,952
Total finance lease liabilities	$ 2,627	$ 2,891
Weighted Average Remaining Lease Term		
Weighted-average remaining lease term—operating leases	7.73 years	5.26 years
Weighted-average remaining lease term—finance leases	1.82 years	2.21 years
Weighted Average Discount Rate		
Weighted-average discount rate—operating leases	4.27%	3.90%
Weighted-average discount rate—finance leases	3.52%	3.57%

As of June 30, 2022, minimum lease payments by period are expected to be as follows:

	Finance	Operating
2022 (excluding the six months ended June 30, 2022)	$ 710	$ 1,496
2023	1,283	1,879
2024	740	2,969
2025	19	2,619
2026	11	2,422
Thereafter	—	9,021
Total minimum lease payments	2,763	20,406
Less: imputed interest	(136)	(3,374)
Present value of lease liabilities	$ 2,627	$ 17,032

9. Stockholders' Equity

Reconciliation of the changes in stockholders' equity for the three and six months ended June 30, 2022 and 2021

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balance at December 31, 2021	72,069	$ —	$ 511,063	$ (10,077)	$ (120,453)	$ 380,533
Common stock issued upon exercise of options	2	—	15	—	—	15
Vesting of restricted stock and performance stock units	352	—	—	—	—	—
Purchase and retirement of common shares	(116)	—	(1,049)	—	—	(1,049)
Stock-based compensation	—	—	3,524	—	—	3,524
Net loss	—	—	—	—	(19,967)	(19,967)
Currency translation adjustments	—	—	—	1,756	—	1,756
Unrealized gain on marketable securities	—	—	—	74	—	74
Balance at March 31, 2022	72,307	$ —	$ 513,553	$ (8,247)	$ (140,420)	$ 364,886
Vesting of restricted stock and performance stock units	407	—	—	—	—	—
Purchase and retirement of common shares	(142)	—	(905)	—	—	(905)
Stock-based compensation	—	—	3,280	—	—	3,280
Net loss	—	—	—	—	(18,802)	(18,802)
Currency translation adjustments	—	—	—	(4,349)	—	(4,349)
Unrealized gain on marketable securities	—	—	—	82	—	82
Balance at June 30, 2022	72,572	$ —	$ 515,928	$ (12,514)	$ (159,222)	$ 344,192

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Capital	Loss	Deficit	Total
Balance at December 31, 2020	71,738	$ —	$ 505,123	$ (9,097)	$ (97,455)	$ 398,571
Common stock issued upon exercise of options	11	—	92	—	—	92
Vesting of restricted stock and performance stock units	318	—		—	—	—
Purchase and retirement of common shares	(111)	—	(1,730)	—	—	(1,730)
Stock-based compensation	—	—	1,464	—	—	1,464
Net income	—	—	—	—	3,774	3,774
Currency translation adjustments	—	—	—	1,352	—	1,352
Unrealized gain on marketable securities	—	—	—	21	—	21
Balance at March 31, 2021	71,956	$ —	$ 504,949	$ (7,724)	$ (93,681)	$ 403,544
Common stock issued upon exercise of options	3	—	29	—	—	29
Vesting of restricted stock and performance stock units	64	—	—	—	—	—
Purchase and retirement of common shares	(15)	—	(147)	—	—	(147)
Stock-based compensation	—	—	1,473	—	—	1,473
Net loss	—	—	—	—	(1,364)	(1,364)
Currency translation adjustments	—	—	—	1,403	—	1,403
Unrealized loss on marketable securities	—	—	—	(122)	—	(122)
Balance at June 30, 2021	72,008	$ —	$ 506,304	$ (6,443)	$ (95,045)	$ 404,816

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 expense related to stock options for the six months ended June 30, 2022 and 2021 was $879 and $521, respectively.

The following table summarizes the stock option activity for the six months ended June 30, 2022:

	Options
Outstanding on January 1, 2022	1,410
Granted	589
Exercised	(2)
Expired	(20)
Forfeited	(173)
Outstanding on June 30, 2022	1,804

Compensation expense of $5,071 and $2,066 related to restricted shares was recognized during the six months ended June 30, 2022 and 2021, respectively.

The following table summarizes time-vested restricted stock award and restricted stock unit activity for the six months ended June 30, 2022:

	Units
Issued and unvested, January 1, 2022	701
Granted	2,782
Vested	(571)
Forfeited	(249)
Issued and unvested, June 30, 2022	2,663

We grant performance-based restricted stock units ("PSUs") to certain executives. Vesting of these PSUs is dependent upon achievement of certain 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. If the one-year target is achieved, the PSUs will then vest three years from grant date. 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 expense of $854 and $350 related to PSUs was recognized during the six months ended June 30, 2022 and 2021, respectively.

The following table summarizes the PSU activity for the six months ended June 30, 2022:

	Units
Issued and unvested, January 1, 2022	622
Granted [(1)]	532
Performance adjustment [(2)]	36
Vested	(188)
Forfeited	(171)
Issued and unvested, June 30, 2022	831

[(1)] Grant activity for all PSUs disclosed at target

[(2)] Reflects the performance adjustment based on actual performance measured at the end of the performance period

Stock Repurchase Program

On August 5, 2008, our Board of Directors approved a share repurchase program pursuant to which we are permitted to acquire up to $25,000 of our outstanding common shares. No shares were purchased and retired during the six months ended June 30, 2022 and 2021.

10. Transition costs

On December 31, 2021, the Company's Board of Directors approved the termination of Stephen S. Tang, the Company's former President and Chief Executive Officer, without cause under his existing employment agreement with the Company, with such termination effective as of March 31, 2022. On January 2, 2022, Dr. Tang and the Company entered into a transition agreement ("Transition Agreement") providing for the terms of the cessation of Dr. Tang's employment with the Company, including the cessation of his service as President and Chief Executive Officer of the Company and as a member of the Board. Dr. Tang's service to the Company in all capacities ended on March 31, 2022.

Pursuant to the Transition Agreement, Dr. Tang received severance of $1,569, which was accrued in the consolidated financial statements at December 31, 2021 and paid in April 2022. Additionally, in accordance with his Transition Agreement, certain of his unvested time-vesting restricted stock awards and unvested PSUs that were outstanding at March 31, 2022 vested on April 8, 2022. His remaining unvested time-vesting restricted stock awards and PSUs were forfeited on March 31, 2022. These payments, rights and benefits are substantially similar to the severance benefits contemplated by his previous employment agreement in respect to a termination without cause thereunder. In aggregate, we recognized a net $128 and $1,508 of expense in relation to Dr. Tang's stock compensation during the three and six months ended June 30, 2022, respectively.

On April 1, 2022 the Company's Board of Directors appointed Nancy J. Gagliano, M.D., M.B.A., to serve as the Company's Interim Chief Executive Officer. In connection therewith, the Company and Dr. Gagliano entered into an employment agreement, dated as of March 21, 2022 (the "Employment Agreement"). Pursuant to the Employment Agreement, on April 1, 2022, Dr. Gagliano began receiving a monthly base salary of $56 per month and was also granted a one-time award of fully vested shares of the Company's common stock with a grant date fair value of $100. Additionally, she was granted a one-time restricted stock unit award with a grant date fair value of $670 scheduled to vest in twelve equal monthly installments starting in April through her employment term, of which $168 vested during the three months ended June 30, 2022 and the remainder was forfeited when her employment ceased in June 2022.

On May 20, 2022, the Company entered into an employment agreement with Carrie Eglinton Manner, and in connection therewith, the Company's Board of Directors appointed Ms. Eglinton Manner as the Company's President and Chief Executive Officer, effective June 4, 2022 (the "Effective Date"). Pursuant to the Employment Agreement, Ms. Eglinton Manner's initial annual base salary is $700 and she will participate in the Company's annual incentive plan with a target annual incentive amount of at least 100% of her annual base salary. Additionally, she received inducement grants comprised of (i) a restricted stock unit award with a grant date fair value of $4,000, which vests on the second anniversary of the Effective Date (ii) a restricted stock award with a grant date fair value of $1,600, which vests annually starting on the first anniversary of the Effective Date and (iii) a PSU award with a grant date fair value of $1,600, which will be subject to the same vesting and performance conditions as are applicable to the 2022 performance-based restricted stock unit awards granted to the Company's other executive officers.

11. Income Taxes

During the three and six months ended June 30, 2022, we recorded an income tax expense (benefit) of $(1,169) and $2,767, respectively. Tax expense for 2022 includes $1,702 of withholding tax due on the repatriation of $65,000 of unremitted earnings from Canada to the United States. The remaining tax expense for the first half of 2022 is comprised of U.S. state income taxes of $400 and foreign taxes of $665. During the three and six months ended June 30, 2021, we recorded income tax expense of $3,610 and $10,139, which primarily consists of foreign tax expense.

Tax expense reflects taxes due to the taxing authorities and the tax effects of temporary differences between the basis of assets and liabilities recognized for financial reporting and tax purposes, and net operating loss and tax credit carryforwards. The significant components of our total deferred tax liability as of June 30, 2022 and December 31, 2021 relate to the tax effects of the basis difference between the intangible assets acquired in our acquisitions for financial reporting and for tax purposes along with basis differences arising from accelerated tax depreciation of fixed assets.

In 2008, we established a full valuation allowance against our U.S. deferred tax asset. Management believes the full valuation allowance is still appropriate at both June 30, 2022 and December 31, 2021 since the facts and circumstances necessitating the allowance have not changed.

12. Commitments and Contingencies

Litigation

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

In March 2021, we filed a complaint against Spectrum Solutions, LLC ("Spectrum") in the United States District Court for the Southern District of California alleging that certain saliva collection devices manufactured and sold by Spectrum infringe a patent held by DNAG. Spectrum has filed an answer to the initial complaint, asserting that its device does not infringe our patent and that our patent is invalid. In August 2021, we amended our complaint to add a second patent to this litigation. Spectrum responded to our amended complaint and asserted counterclaims for inequitable conduct and antitrust violations with respect to one of the patents in the litigation. DNAG filed a motion to dismiss Spectrum's counterclaims in October 2021, which was denied by the Court on March 30, 2022. The final pretrial conference is set for September 7, 2023.

13. Business Segment Information

Our business consists of two segments: our "Diagnostics" business, which primarily consists of the development, manufacture, and sale of rapid diagnostic tests used to determine if a person has a variety of infectious diseases including, HIV, HCV, and COVID-19. The Diagnostic business also manufactures and sells oral fluid substance abuse testing products. Our "Molecular Solutions" business is operated by our wholly-owned subsidiaries DNAG, Diversigen, and Novosanis. This segment of the business consists of the development, manufacture, and sale of kits that are used to collect, stabilize, transport and store a biological sample of genetic material for molecular testing. In addition, our Molecular Solutions business provides microbiome laboratory services.

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 1). We evaluate performance of our operating segments based on revenue and operating income. We do not allocate interest income, interest expense, other income, other expenses or income taxes to our operating segments. Reportable segments have no inter-segment revenues and inter-segment expenses have been eliminated.

The following table summarizes operating segment information for the three and six months ended June 30, 2022 and 2021, and asset information as of June 30, 2022 and December 31, 2021:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Net revenues:				
Diagnostics	$ 60,455	$ 19,311	$ 98,765	$ 33,857
Molecular Solutions	19,776	38,296	49,173	82,332
Total	$ 80,231	$ 57,607	$ 147,938	$ 116,189
Operating income (loss):				
Diagnostics	$ (11,776)	$ (11,850)	$ (31,563)	$ (23,967)
Molecular Solutions	(9,513)	13,648	(5,704)	36,187
Total	$ (21,289)	$ 1,798	$ (37,267)	$ 12,220
Depreciation and amortization:				
Diagnostics	$ 1,903	$ 939	$ 3,630	$ 1,829
Molecular Solutions	1,879	1,716	3,834	3,315
Total	$ 3,782	$ 2,655	$ 7,464	$ 5,144
Loss on impairment:				
Diagnostics	$ 8,517	$ —	$ 8,517	$ —
Molecular Solutions	2,025	—	2,025	—
Total	$ 10,542	$ —	$ 10,542	$ —
Capital expenditures:				
Diagnostics[(1)]	$ 4,302	$ 8,513	$ 23,434	$ 16,150
Molecular Solutions	919	3,355	2,006	6,779
Total	$ 5,221	$ 11,868	$ 25,440	$ 22,929

[(1)] Excludes $5,615 and $33,803 for purchases of property and equipment under government contracts for the three and six months ended June 30, 2022, respectively.

	June 30, 2022	December 31, 2021
Total assets:		
Diagnostics	$ 249,123	$ 209,674
Molecular Solutions	180,131	251,316
Total	$ 429,254	$ 460,990

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:

- *our ability to market and sell products, whether through our internal, direct sales force or third parties;*
- *our ability to fulfill our commitments under our contracts with the U.S. government for InteliSwab® COVID-19 Rapid Tests;*
- *the impact of significant customer concentration in the genomics business;*
- *our ability to successfully scale-up our manufacturing for InteliSwab®COVID-19 Rapid Tests;*
- *failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our products;*
- *our ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements;*
- *our ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products;*
- *our ability to comply with applicable regulatory requirements;*
- *our ability to effectively resolve warning letters, audit observations and other findings or comments from the U.S. Food and Drug Administration (or "FDA"), or other regulators;*
- *the impact of the COVID-19 pandemic on our business and labor force and supply chain;*
- *our ability to successfully develop new products, validate the expanded use of existing collector products, receive necessary regulatory approvals and authorizations, transport work-in-process goods and finished 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;*
- *our ability to meet increased demand for our products;*
- *our ability to diversify our customer base;*
- *the impact of replacing distributors on our business;*
- *inventory levels at distributors and other customers;*
- *our ability to achieve our financial and strategic objectives and continue to increase our revenues, including the ability to expand international sales;*
- *the impact of competitors, competing products and technology changes on our business;*
- *reduction or deferral of public funding available to customers;*
- *competition from new or better technology or lower cost products;*
- *our 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, or (the "CDC") or other agencies; ability to fund research and development and other products and operations;*
- *our ability to obtain and maintain new or existing product distribution channels;*
- *our reliance on sole supply sources for critical products and components;*

- *the availability of related products produced by third parties or products required for use of our products;*
- *the impact of contracting with the U.S. government on our business;*
- *the impact of negative economic conditions on our business; including as a result of inflation, hostilities or war;*
- *our ability to achieve and maintain sustained profitability;*
- *our ability to increase our gross margins;*
- *our ability to utilize net operating loss carry forwards or other deferred tax assets;*
- *the volatility of our stock price;*
- *uncertainty relating to patent protection and potential patent infringement claims;*
- *uncertainty and costs of litigation relating to patents and other intellectual property;*
- *the availability of licenses to patents or other technology;*
- *our ability to enter into international manufacturing agreements;*
- *obstacles to international marketing and manufacturing of products;*
- *our 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;*
- *our ability to attract and retain qualified personnel;*
- *our 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, civil unrest, hostilities and war; 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, 2021, 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

The overall goal of our Company is to empower the global community to improve health and wellness by providing access to accurate essential information. Our business consists of two segments: our "Diagnostics" segment and our "Molecular Solutions" segment.

Our Diagnostics business primarily consists of the development, manufacture, marketing and sale of simple, easy to use diagnostic products and specimen collection devices using our proprietary technologies, as well as other diagnostic products including immunoassays and other *in vitro* diagnostic tests that are used on other specimen types. The Diagnostics business includes tests for diseases including COVID-19, HIV and Hepatitis C that are performed on a rapid basis at the point of care, and tests for drugs of abuse that are processed in a laboratory. These products are sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations, and other public health organizations, distributors, government agencies, physicians' offices, and commercial and industrial entities. Our COVID-19 and HIV products are also sold in a consumer-friendly format in the over-the-counter ("OTC") market in the U.S. and, in the case of the HIV product, as a self-test to individuals in a number of other countries. Through our Diagnostics business we are also developing and commercializing products that measure adherence to HIV medications including pre-exposure prophylaxis ("PrEP"), the daily medication to prevent HIV, and anti-retroviral medications to suppress HIV. These products include laboratory-based tests that can measure levels of the medications in a patient's urine or blood, as well as point-of-care products currently in development. We began recording revenues on the sales of our InteliSwab® COVID-19 Rapid Tests during the third quarter of 2021.

Our Molecular Solutions business is operated by our wholly-owned subsidiaries, DNA Genotek, Inc. ("DNAG"), Diversigen, Inc. ('Diversigen"), and Novosanis NV ("Novosanis"). Our Molecular Solutions business sells its products and services directly to its customers, primarily through its internal sales force in the U.S. domestic market, and in many international markets, also through distributors. Our products primarily consist of collection kits and services used by clinical laboratories, direct-to-consumer laboratories, researchers, pharmaceutical companies, and animal health service and product providers. Most of our Molecular Solutions revenues are derived from product sales to commercial customers and sales into the academic and research markets. A significant portion of our total sales is from repeat customers in both markets. Molecular Solutions customers span the disease risk management, diagnostics, pharmaceutical, biotech, companion animal and environmental markets.

We have expanded the market focus of our Molecular Solutions business by selling existing collection products for use with COVID-19 tests. Demand for COVID-19 PCR testing has declined driven by the availability of antigen tests and the wider availability of vaccines, thereby negatively impacting the sales of the collection products. We have also developed new collection devices for the emerging microbiome market, which focuses on studying microbes and their effect on human health. Our primary product offering in the microbiome market, OMNIgene® • GUT, is focused on the human gut microbiome (microbes living in human stool). In 2021, the OMNIgene® • GUT collection device (OMD-200) was granted "FDA De Novo classification for the preservation and stabilization of the relative abundance of microbial nucleic acids in clinical samples." We leverage our existing sales force and global research connections to engage microbiome customers worldwide to establish ourselves among the leaders in ease-of-collection, stabilization, and transport of this challenging sample type.

Our Molecular Solutions segment includes the Colli-Pee® device, developed and sold by our Novosanis subsidiary, for the volumetric collection of first void urine. This product is in its early stages, and initial sales are occurring primarily through distributors and collaborations in the liquid biopsy and sexually transmitted disease markets. Our Molecular Solutions business also offers laboratory and analytical services for both genomics and microbiome customers to more fully meet their needs. These services are primarily provided to pharmaceutical, biotech companies, and research institutions.

Recent Developments

Impact of COVID-19

As COVID-19 continues to impact the economy of the United States and other countries around the world, we are committed to being a part of the response to this unprecedented challenge. We have made substantial investments to expand our operations in order to manufacture product used for COVID-19 testing in the United States.

Due to COVID-19, we have experienced volatility, including periods of material decline compared to prior year periods in testing volume of our base business (which excludes COVID-19 testing) and periods of significant demand for our COVID-19 testing product, with demand generally fluctuating in line with changes in prevalence of the virus and related variants. It is difficult for us to predict the duration or magnitude of the outbreak's effects on our business or results of operations.

Appointment of New CEO

Carrie Eglinton Manner was appointed President and Chief Executive Officer, effective June 4, 2022. Ms. Eglinton Manner also joined the OraSure Board of Directors (the "Board"). She succeeded Dr. Nancy Gagliano, who was appointed interim CEO in March 2022. Dr. Gagliano continues to serve on the OraSure Board.

Ms. Eglinton Manner, age 48, has years of leadership experience across multiple disciplines. Prior to joining the Company, Ms. Eglinton Manner served as Senior Vice President, Advanced & General Diagnostic and Clinical Solutions at Quest Diagnostics since January 2017. Prior to Quest, Ms. Eglinton Manner spent over 20 years in various leadership roles in healthcare businesses at GE Healthcare. From 2009 through 2016, she served as President & CEO of four distinct GE Healthcare global businesses in the areas of diagnostic imaging, lab services and medical devices. She has served as a director of Repligen Corporation since June 2020. Ms. Eglinton Manner holds a B.S. in mechanical engineering from the University of Notre Dame.

Exploration of Strategic Alternatives

Ms. Eglinton Manner's appointment as CEO came in tandem with a decision by the OraSure Board to conclude its previously announced review of strategic alternatives and for the Company to move forward under her leadership. Market conditions and the Board's belief in the Company's ability to further build upon recent operational successes with Ms. Eglinton Manner's leadership were factors in the decision.

Current Consolidated Financial Results

During the six months ended June 30, 2022, our consolidated net revenues increased 27% to $147.9 million, compared to $116.2 million for the six months ended June 30, 2021. Net product and services revenues during the six months ended June 30, 2022 increased 29% when compared to the same period of 2021, largely due to the inclusion of $65.3 million of InteliSwab® COVID-19 rapid test revenues. We began selling this product in August of 2021 resulting in no comparable revenues in the first half of 2021. Declines in sales of our molecular sample collection kits for COVID-19 testing, lower laboratory services revenues, and a decline in domestic sales of our HIV products partially offset this positive driver of revenue. Other revenues for the six months ended June 30, 2022 were $3.5 million compared to $3.9 million in the same period of 2021. This decrease was largely due to lower royalty income.

Our consolidated net loss for the six months ended June 30, 2022 was $38.8 million, or $0.54 per share on a fully diluted basis, compared to consolidated net income of $2.4 million, or $0.03 per share on a fully diluted basis, for the six months ended June 30, 2021. Results for the six months ended June 30, 2022 were impacted by lower gross margins rates caused by an unfavorable product mix of higher sales of lower margin products, increases in inventory reserves associated with excess inventory levels and manufacturing inefficiencies that occurred in the first quarter of 2022, lower absorption of labor costs and the absence of the Gates subsidy which expired in June 2021. Also contributing to our net loss is an increase in operating expense as a result of impairment charges taken in the second quarter of 2022 on idle manufacturing lines and goodwill, severance charges and accelerated stock compensation expense associated with our CEO transition and termination of our general counsel, and nonrecurring costs associated with our strategic alternatives process.

Cash used in operating activities during the six months ended June 30, 2022 was $45.5 million. Cash used in operating activities during the six months ended June 30, 2021 was $3.5 million. During the first half of 2022, our cash flow used in operating activities increased significantly as a result of our net loss and increased working capital requirements we scale our InteliSwab® manufacturing capacity to meet higher demand. As of June 30, 2022, we had $95.8 million in cash, cash equivalents and available-for-sale securities.

Results of Operations

Three months ended June 30, 2022 compared to June 30, 2021

CONSOLIDATED NET REVENUES

The table below shows a breakdown of total consolidated net revenues (dollars in thousands) generated by each of our business segments during the three months ended June 30, 2022 and 2021.

	For the Three Months Ended June 30,				
	Dollars			Percentage of Total Net Revenues	
	2022	2021	% Change	2022	2021
Diagnostics	$ 59,976	$ 18,252	229 %	75 %	32 %
Molecular Solutions	19,191	37,489	(49)	24	65
Net product and services revenues	79,167	55,741	42	99	97
Other	1,064	1,866	(43)	1	3
Net revenues	$ 80,231	$ 57,607	39 %	100 %	100 %

Consolidated net product and services revenues increased 42% to $79.2 million for the three months ended June 30, 2022 from $55.7 million for the three months ended June 30, 2021. The increase in revenues is largely due to the inclusion of $43.1 million of InteliSwab® COVID-19 rapid test revenues. We began selling this product in August of 2021 resulting in no comparable revenues in the second quarter of 2021. Declines in

revenues across all other product line partially offset this positive driver of revenue. Other revenues for the three months ended June 30, 2022 decreased 43% to $1.1 million from $1.9 million for the three months ended June 30, 2021 due to lower research and development funding associated with the development of our InteliSwab® COVID-19 rapid test and lower royalty income.

Consolidated net revenues derived from products sold to customers outside of the United States were $9.9 million and $10.0 million, or 12% and 17% of total net revenues, for the three months ended June 30, 2022 and 2021, 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

Diagnostics Segment

The table below shows a breakdown of total net revenues (dollars in thousands) generated by our Diagnostics segment during the three months ended June 30, 2022 and 2021.

	For the Three Months Ended June 30,				
	Dollars			Percentage of Total Net Revenues	
Market	2022	2021	% Change	2022	2021
Infectious disease testing:					
COVID-19	$ 43,114	$ 89	NM %	71 %	0 %
Other	14,232	15,534	(8)	23	80
Total infectious disease testing	57,346	15,623	267	95	81
Substance abuse testing	2,630	2,629	0	4	14
Net product revenues	59,976	18,252	229	99	95
Other	479	1,059	(55)	1	5
Net revenues	$ 60,455	$ 19,311	213 %	100 %	100 %

NM - not meaningful

Infectious Disease Testing Market

COVID-19 revenues were $43.1 million for the three months ended June 30, 2022, driven by sales of our InteliSwab® COVID-19 rapid test. We first began selling this product in August of 2021 and there are no comparable sales in the second quarter of 2021.

Sales to the other infectious disease testing markets decreased 8% to $14.2 million for the three months ended June 30, 2022 from $15.5 million for the three months ended June 30, 2021. This decrease resulted from lower worldwide OraQuick® HIV and international OraQuick® HCV product sales.

The table below shows a breakdown of our total net OraQuick® HIV and HCV product revenues (dollars in thousands) during the three months ended June 30, 2022 and 2021.

	For the Three Months Ended June 30,		
Market	2022	2021	% Change
Domestic HIV	$ 3,741	$ 4,135	(10) %
International HIV	6,616	6,809	(3)
Net HIV revenues	10,357	10,944	(5)
Domestic HCV	2,537	2,571	(1)
International HCV	1,154	1,729	(33)
Net HCV revenues	3,691	4,300	(14)
Net OraQuick® revenues	$ 14,048	$ 15,244	(8) %

Domestic OraQuick® HIV sales decreased 10% to $3.7 million for the three months ended June 30, 2022 from $4.1 million for the three months ended June 30, 2021, primarily as a result of a large second quarter 2021 order of our OraQuick® In-Home HIV test shipped to the CDC and used in an initiative to drive increased in-home HIV testing. A similar order did not occur in the second quarter of 2022.

International sales of our OraQuick® HIV tests decreased 3% to $6.6 million for the three months ended June 30, 2022 from $6.8 million for the three months ended June 30, 2021 due to the absence of the Gates Foundation subsidy which expired in June 2021 and is not included in revenues in the second quarter of 2022, initial stocking orders into Asia that did not recur in 2022, and the impact of the Russian and Ukraine war. These decline in revenues were partially offset by increased sales into Africa as the COVID-19 impact lessens.

Domestic OraQuick® HCV sales remained largely flat at $2.5 million for the three months ended June 30, 2022 compared to $2.6 million for the three months ended June 30, 2021.

International OraQuick® HCV sales decreased 33 % to $1.2 million for the three months ended June 30, 2022 compared to $1.7 million for the three months ended June 30, 2021 due to a stock order into Korea which did no repeat in 2022.

Substance Abuse Testing Market

Sales to the substance abuse testing assessment market remained flat at $2.6 million for both the three months ended June 30, 2022 and 2021.

Other Revenues

Other revenues for the three months ended June 30, 2022 decreased 55% to $479,000 from $1.1 million for the three months ended June 30, 2021, due to lower research and development funding associated with our InteliSwab® COVID-19 rapid test.

Molecular Solutions Segment

The table below shows a breakdown of our total net revenues (dollars in thousands) during the three months ended June 30, 2022 and 2021.

	For the Three Months Ended June 30,		
Market	2022	2021	% Change
Genomics	$ 15,486	$ 19,498	(21) %
Microbiome	1,832	2,447	(25)
COVID-19	264	11,981	(98)
Laboratory services	1,204	3,114	(61)
Other product and service revenues	405	449	(10)
Net molecular product and services revenues	$ 19,191	37,489	(49)
Other	585	807	(28)
Net molecular revenues	$ 19,776	$ 38,296	(48) %

Sales of our genomics products decreased 21% to $15.5 million for the three months ended June 30, 2022, compared to $19.5 million for the three months ended June 30, 2021, as result of customer ordering patterns.

Microbiome kit sales decreased 25% to $1.8 million for the three months ended June 30, 2022 compared to $2.4 million for the three months ended June 30, 2021, due to lower sales to certain Clinical Research Organizations ("CROs") as a result of delays in microbiome clinical studies.

Sales of our molecular sample collection kits for COVID-19 testing decreased 98% to $264,000 for the three months ended June 30, 2022 compared to $12.0 million during the comparable period in 2021 due to lower COVID-19 PCR testing sales to our core customers, driven by the availability of antigen tests, the wider availability of vaccines and high inventory levels held by some of those customers and the termination of public funding for PCR testing.

Laboratory services revenues declined 61% to $1.2 million for the three months ended June 30, 2022 compared to $3.1 million for the three months ended June 30, 2021 as a result of a large customer ceasing its operations and due to timing of clinical trials.

Other product and service revenues remained largely unchanged at $405,000 in the second quarter of 2022 compared to $449,000 in the second quarter of 2021.

Other revenues for the three months ended June 30, 2022 decreased 28% to $585,000 from $807,000 for the three months ended June 30, 2021, largely as a result of lower royalty income received under a litigation settlement agreement.

CONSOLIDATED OPERATING RESULTS

Consolidated gross profit margins were 34% for the three months ended June 30, 2022 compared to 53% for the three months ended June 30, 2021. The decrease in gross profit margins was primarily due to a less favorable product mix and increased scrap expense associated with reserves for excess inventory.

Consolidated operating loss for the three months ended June 30, 2022 was $21.3 million, a $23.1 million decrease from the $1.8 million operating income reported for the three months ended June 30, 2021. Results for the three months ended June 30, 2022 were negatively impacted by the

lower gross profit margin described above coupled with an increase in operating expenses as described below, including an aggregate impairment charge of $10.5 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 the U.S. and Canadian entities.

Diagnostics Segment

The gross profit margin for the Diagnostics segment was 36% for the three months ended June 30, 2022 compared to 34% for the three months ended June 30, 2021. This increase is due to improved product mix of higher margin product sales partially offset by the June 2021 expiration of subsidies under the support agreement with the Gates Foundation.

Research and development expenses increased 26% to $6.3 million for the three months ended June 30, 2022 compared to $5.0 million for the three months ended June 30, 2021 largely due to increased staffing costs associated with higher head count, increased clinical study activities related to obtaining CE mark for our InteliSwab® rapid test and higher subscription costs associated with our new quality system. Sales and marketing expenses increased 19% to $7.8 million for three months ended June 30, 2022 from $6.6 million for the three months ended June 30, 2021 due to increased staffing costs associated with higher head count and increased travel, trade show, and annual meetings expenses as travel and in person events have resumed as COVID-19 restrictions have been lifted. These increases in spend were partially offset by a decline in advertising and market research costs associated with our InteliSwab® test. General and administrative expenses increased 54% to $11.0 million for the three months ended June 30, 2022 from $7.1 million for the three months ended June 30, 2021 largely due to severance costs and accelerated stock compensation expense associated with our former general counsel's employment and termination agreements, stock compensation costs associated with restricted stock awards granted to certain board members with immediate vesting provisions, and higher legal, accounting, and information technologies contract fees.

Operating expenses for the Diagnostic segment also include an impairment charge of $4.9 million associated with an idle manufacturing line for which it has no projected cash flow and minimal resale or salvage value. Diagnostic operating expenses also included a goodwill impairment charge of $3.6 million. The decline in the Company's stock price was identified as a triggering event which required the Company to perform an quantitative goodwill impairment analysis. The results of this analysis indicated the Diagnostic segment's goodwill was impaired and was written down to $0.

All of the above contributed to the Diagnostics segment’s operating loss of $11.8 million for the three months ended June 30, 2022, which included the non-cash impairment charges of $8.5 million, non-cash charges of $1.9 million for depreciation and amortization and $2.8 million for stock-based compensation. The Diagnostics segment operating loss in the second quarter of 2021 included a $220,000 non-cash pre-tax benefit associated with the change in the fair value of acquisition-related contingent consideration. There was no similar benefit recorded in the second quarter of 2022.

Molecular Solutions Segment

The gross profit margin for the Molecular Solutions segment was 31% for the three months ended June 30, 2022 compared to 63% for the three months ended June 30, 2021. This decrease was due to an increase in reserves for excess inventory as result of a forecasted decline in demand of certain products used in COVID PCR testing and a less favorable product mix.

Research and development expenses remained relatively flat at $2.8 for the three months ended June 30, 2022 from $2.7 million for the three months ended June 30, 2021 . Sales and marketing expenses also remained flat at $3.9 million for the three months ended June 30, 2022 and 2021. General and administrative expenses increased 70% to $6.6 million for the three months ended June 30, 2022 from $3.9 million for the three months ended June 30, 2021 due to increased legal fees.

Operating expenses for the Molecular segment also include an impairment charge of $2.0 million for the three months ended June 30, 2022 associated with two idle manufacturing lines for which there are no projected cash flow and minimal resale or salvage value.

All of the above contributed to the Molecular Solutions segment’s operating loss of $9.5 million for the three months ended June 30, 2022, which included the non-cash impairment charge of $2.0 million, non-cash charges of $1.9 million for depreciation and amortization and $529,000 for stock-based compensation.

CONSOLIDATED INCOME TAXES

We continue to believe the full valuation allowance established against our total U.S. deferred tax asset is appropriate as the facts and circumstances necessitating the allowance have not changed. For the three months ended June 30, 2022, we recorded U.S. state tax expense of $183,000 compared to $54,000 of state income tax benefit for the three months ended June 30, 2021. For the three months ended June 30, 2022, we recorded a foreign tax benefit of $1.3 million compared to foreign tax expense of $3.7 million for the three months ended June 30, 2021. This overall decrease in foreign tax expense is largely a result of the decrease in income before taxes generated by our Canadian subsidiary.

Six months ended June 30, 2022 compared to June 30, 2021

CONSOLIDATED NET REVENUES

The table below shows a breakdown of total consolidated net revenues (dollars in thousands) generated by each of our business segments during the six months ended June 30, 2022 and 2021.

	For the Six Months Ended June 30,				
	Dollars			Percentage of Total Net Revenues	
	2022	2021	% Change	2022	2021
Diagnostics	$ 96,372	$ 31,585	205 %	65 %	27 %
Molecular Solutions	48,031	80,735	(41)	33	69
Net product and services revenues	144,403	112,320	29	98	96
Other	3,535	3,869	(9)	2	4
Net revenues	$ 147,938	$ 116,189	27 %	100 %	100 %

Consolidated net product and services revenues increased 29% to $144.4 million for the six months ended June 30, 2022 from $112.3 million for the six months ended June 30, 2021. The increase in revenues is largely due to the inclusion of $65.3 million of InteliSwab® COVID-19 rapid test revenues. We began selling this product in August of 2021 resulting in no comparable revenues in the first half of 2021. Declines in sales of our molecular sample collection kits for COVID-19 testing partially offset this positive driver of revenue. Other revenues for the six months ended June 30, 2022 decreased 9% to $3.5 million from $3.9 million for the six months ended June 30, 2021 largely due to lower royalty income.

Consolidated net revenues derived from products sold to customers outside of the United States were $19.6 million and $19.5 million, or 13% and 17% of total net revenues, for the six months ended June 30, 2022 and 2021, 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

Diagnostics Segment

The table below shows a breakdown of total net revenues (dollars in thousands) generated by our Diagnostics segment during the six months ended June 30, 2022 and 2021.

	For the Six Months Ended June 30,				
	Dollars			Percentage of Total Net Revenues	
Market	2022	2021	% Change	2021	2020
Infectious disease testing:					
COVID-19	$ 65,250	$ 262	NM %	66 %	0 %
Other	25,931	26,732	(3)	25	79
Total infectious disease testing	91,181	26,994	238	92	80
Substance abuse testing	5,191	4,591	13	5	14
Net product revenues	96,372	31,585	205	97	94
Other	2,393	2,272	5	3	6
Net revenues	$ 98,765	$ 33,857	192 %	100 %	100 %

NM - not meaningful

Infectious Disease Testing Market

COVID-19 revenues were $65.3 million for the six months ended June 30, 2022, driven by sales of our InteliSwab® COVID-19 rapid test. We first began selling this product in August of 2021 and there are no comparable sales in the first half of 2021.

Sales to the other infectious disease testing markets decreased 3% to $25.9 million for the six months ended June 30, 2022 from $26.7 million for the six months ended June 30, 2021. This decrease resulted from lower domestic OraQuick® HIV and international OraQuick® HCV product sales, partially offset by higher international OraQuick® HIV and domestic OraQuick® HCV sales.

The table below shows a breakdown of our total net OraQuick® HIV and HCV product revenues (dollars in thousands) during the six months ended June 30, 2022 and 2021.

	Six Months Ended June 30,		
Market	2022	2021	% Change
Domestic HIV	$ 7,506	$ 9,050	(17) %
International HIV	11,017	10,672	3
Net HIV revenues	18,523	19,722	(6)
Domestic HCV	4,574	3,754	22
International HCV	2,374	2,914	(19)
Net HCV revenues	6,948	6,668	4
Net OraQuick® revenues	$ 25,471	$ 26,390	(3) %

Domestic OraQuick® HIV sales decreased 17% to $7.5 million for the six months ended June 30, 2022 from $9.1 million for the six months ended June 30, 2021, primarily as a result of a large order fulfilled in the first half of 2021 for our OraQuick® In-Home HIV test shipped to the CDC and used in an initiative to drive increased in-home HIV testing. A similar order did not occur in the first half of 2022.

International sales of our OraQuick® HIV tests increased 3% to $11.0 million for the six months ended June 30, 2022 from $10.7 million for the six months ended June 30, 2021 due to increased sales into Africa as the COVID-19 impact lessens. This increase to revenues was partially offset by the absence of the Gates Foundation subsidy, which expired in June 2021 and is not included in revenues in the first quarter of 2022, as well as the impact of the Russia and Ukraine war.

Domestic OraQuick® HCV sales increased 22% to $4.6 million for the six months ended June 30, 2022 from $3.8 million for the six months ended June 30, 2021, driven by new funding granted by certain state governments, increased legislation regarding drug testing and rise in drug use requiring more testing.

International OraQuick® HCV sales decreased 19% to $2.4 million for the six months ended June 30, 2022 from $2.9 million for the six months ended June 30, 2021 due to large stock ordering shipped to Korea that did not repeat in 2022.

Sales to the substance abuse testing assessment market increased 13% to $5.2 million for the six months ended June 30, 2022 compared to $4.6 million for the six months ended June 30, 2021 due to market share gains.

Other Revenues

Other revenues for the six months ended June 30, 2022 increased minimally to $2.4 million from $2.3 million for the six months ended June 30, 2021, due to research and development funding for 510(k) clearance and CLIA waiver of our InteliSwab® COVID-19 rapid test partially offset by lower royalty income.

Molecular Solutions Segment

The table below shows a breakdown of our total net revenues (dollars in thousands) during the six months ended June 30, 2022 and 2021.

	Six Months Ended June 30,		
Market	2022	2021	% Change
Genomics	$ 30,578	$ 30,316	1 %
Microbiome	3,822	4,198	(9)
COVID-19	9,161	39,953	(77)
Laboratory services	2,938	5,611	(48)
Other product revenues	1,532	657	133
Net molecular product and services revenues	$ 48,031	$ 80,735	(41)
Other	1,142	1,597	(28)
Net molecular product and services revenues	$ 49,173	$ 82,332	(40) %

Sales of our genomics products remained largely flat and increased only 1% to $30.6 million for the six months ended June 30, 2022, compared to $30.3 million for the six months ended June 30, 2021.

Microbiome kit sales decreased 9% to $3.8 million for the six months ended June 30, 2022 compared to $4.2 million for the six months ended June 30, 2021, due to a decline in revenues to CROs driven by the timing of microbiome clinical studies.

Sales of our molecular sample collection kits for COVID-19 testing decreased 77% to $9.2 million for the six months ended June 30, 2022 compared to $40.0 million during the comparable period in 2021 due to lower COVID-19 PCR testing sales to our core customers, driven by the availability of antigen tests, the wider availability of vaccines, lower public funding for PCR testing, and high inventory levels held by some of those customers.

Laboratory services revenues declined 48% to $2.9 million for the six months ended June 30, 2022 compared to $5.6 million for the six months ended June 30, 2021 as a result of a large customer ceasing its operations and a slowdown in clinical trials.

Other product and service revenues increased 133% to $1.5 million for the six months ended June 30, 2022 compared to $657,000 for the six months ended June 30, 2021 largely due to increased sales by our Novosanis subsidiary.

Other revenues for the six months ended June 30, 2022 decreased 28% to $1.1 million from $1.6 million for the six months ended June 30, 2021, largely as a result of lower royalty income received under a litigation settlement agreement.

CONSOLIDATED OPERATING RESULTS

Consolidated gross profit margins were 35% for the six months ended June 30, 2022 compared to 59% for the six months ended June 30, 2021. The decrease in gross profit margins was caused by an unfavorable product mix of higher sales of lower margin product, increases in inventory reserves associated with excess inventory levels and manufacturing inefficiencies that occurred in the first quarter of 2022, lower absorption of labor costs and the absence of the Gates subsidy which expired in June 2021.

Consolidated operating loss for the six months ended June 30, 2022 was $37.3 million, a $49.5 million decrease from the $12.2 million operating income reported for the six months ended June 30, 2021. Results for the six months ended June 30, 2022 were negatively impacted by the lower gross profit margin described above coupled with an increase in operating expenses as described below, including an aggregate impairment charge of $10.5 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 the U.S. and Canadian entities.

Diagnostics Segment

The gross profit margin for the Diagnostics segment was 29% for the six months ended June 30, 2022 compared to 38% for the six months ended June 30, 2021. This decrease is due to inefficiencies in our InteliSwab® manufacturing process experienced in the beginning of the year causing high scrap rates, under-absorption of labor costs, and the June 2021 expiration of subsidies under the support agreement with the Gates Foundation, and a less favorable product mix.

Research and development expenses increased 2% to $11.8 million for the six months ended June 30, 2022 compared to $11.5 million for the six months ended June 30, 2021 largely due to higher staffing costs associated with increased head count offset by lower product development activities related to our InteliSwab® rapid test which did not repeat in the first half of 2022 as we received EUA authorization in June 2021. Sales and marketing expenses increased 25% to $15.9 million for six months ended June 30, 2022 from $12.8 million for the six months ended June 30, 2021 due to increased staffing costs associated with higher head count, increased travel and annual meetings expenses as travel and in person events have resumed as COVID-19 restrictions have been lifted, increased consultant costs, higher advertising and market research expenses and higher subscription costs associated with our new CRM system. This increase in spending was partially offset by a decline in our reserve for uncollectible accounts, lower recruiting fees and a decrease in commission expense. General and administrative expenses increased 82% to $24.7 million for the six months ended June 30, 2022 from $13.6 million for the six months ended June 30, 2021 largely due to increased consulting costs, higher stock compensation expense associated with accelerated vesting of shares under our former CEO's and general counsel's employment agreements, higher staffing costs associated with increased head count, increased legal costs, severance costs associated with our former general counsel, increased accounting fees, and higher recruitment expense largely associated with our CEO search.

Operating expenses for the Diagnostic segment also include an impairment charge of $4.9 million associated with an idle manufacturing line for which it has no projected cash flow and minimal resale or salvage value. Diagnostic operating expenses also included a goodwill impairment charge of $3.6 million. The decline in the Company's stock price was identified as a triggering event which required the Company to perform an quantitative goodwill impairment analysis. The results of this analysis indicated the Diagnostic segment's goodwill was impaired and was written down to $0.

All of the above contributed to the Diagnostics segment's operating loss of $31.6 million for the six months ended June 30, 2022, which included the non-cash impairment charge of $8.5 million, non-cash charges of $3.6 million for depreciation and amortization and $5.9 million for stock-based compensation. The Diagnostics segment operating loss also included a non-cash pre-tax benefit of $36,000 associated with the change in the fair value of acquisition-related contingent consideration. This is in comparison to an $1.0 million benefit recorded in the first half of 2021.

Molecular Solutions Segment

The gross profit margin for the Molecular Solutions segment was 47% for the six months ended June 30, 2022 compared to 68% for the six months ended June 30, 2021. This decrease was due to an increase in reserves for excess inventory as result of a forecasted decline in demand and a less favorable product mix.

Research and development expenses increased 11% to $5.7 million for the six months ended June 30, 2022 from $5.1 million for the six months ended June 30, 2021 due to higher staffing costs. Sales and marketing expenses increased 18% to $8.5 million for the six months ended June 30, 2022 from $7.2 million for the six months ended June 30, 2021 due to higher staffing costs related to increased head count, increased consulting expense associated with business strategy planning, and an increase in travel costs as COVID-19 restrictions are lifted. These increases in expenses were partially offset by lower amortization expense associated with an intangible asset that was fully amortized at the end of 2021. General and administrative expenses increased 58% to $12.1 million for the six months ended June 30, 2022 from $7.6 million for the six months ended June 30, 2021 due to increased legal fees and staffing costs.

Operating expenses for the Molecular segment also includes an impairment charge of $2.0 million for the six months ended June 30, 2022 associated with two idle manufacturing lines for which there are no projected cash flow and minimal resale or salvage value.

All of the above contributed to the Molecular Solutions segment's operating loss of $5.7 million for the six months ended June 30, 2022, which included the non-cash impairment charge of $2.0 million, $3.8 million for depreciation and amortization and $924,000 for stock-based compensation.

CONSOLIDATED INCOME TAXES

We continue to believe the full valuation allowance established against our total U.S. deferred tax asset is appropriate as the facts and circumstances necessitating the allowance have not changed. For the six months ended June 30, 2022, we recorded U.S. state tax expense of $400,000 compared to $115,000 of state income tax expense for the six months ended June 30, 2021. Additionally, in the first half of 2022, we recorded approximately $1.7 million of withholding taxes due to the Canada Revenue Agency associated with our repatriation of $65.0 million of cash from Canada to the United States. For the six months ended June 30, 2022, we recorded foreign tax expense of $665,000 compared to foreign tax expense of $10.0 million for the six months ended June 30, 2021. This overall decrease in foreign tax expense is largely a result of the decrease in income before taxes generated by our Canadian subsidiary.

Liquidity and Capital Resources

	June 30, 2022	December 31, 2021
	(In thousands)	
Cash and cash equivalents	$ 66,159	$ 116,762
Available for sale securities	29,625	53,288
Working capital	201,820	220,367

Our cash and cash equivalents and available-for-sale securities decreased to $95.8 million at June 30, 2022 from $170.1 million at December 31, 2021. Our working capital decreased to $201.8 million at June 30, 2022 from $220.4 million at December 31, 2021.

During the six months ended June 30, 2022, net cash used in operating activities was $45.5 million. Our net loss of $38.8 million included non-cash charges of $10.5 million associated with impairment charges taken against idle manufacturing lines and goodwill, depreciation and amortization expense of $7.5 million, stock-based compensation expense of $6.8 million, an inventory reserve of $2.0 million, and other non-cash expense of $1.2 million. Cash used to fund our working capital accounts included an increase in inventory of $20.4 million to meet

anticipated demand to support COVID-19 testing program, an increase in accounts receivable of $18.6 million largely associated with product shipped to the U.S. government, a $4.1 million increase in prepaid expenses and other assets associated with tax installments made to the Canadian Revenue Agency and a $2.9 million decrease in accrued expenses and other liabilities largely due to payment of our 2021 bonuses and severance payments to our former CEO. Offsetting these uses of cash was a $11.9 million increase in accounts payable due to the timing of invoices received and payments made.

Net cash used in investing activities was $2.3 million for the six months ended June 30, 2022, which reflects proceeds from the maturities and redemptions of investments of $23.0 million. This was offset by $25.4 million to acquire property and equipment largely to increase our manufacturing capacity.

Net cash used in financing activities was $2.5 million for the six months ended June 30, 2022, which is largely comprised of $2.0 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 operating and capital needs as well as those arising over the next twelve months. Our cash requirements, however, may vary materially from those now planned due to many factors, including, but not limited to, the timing of reimbursement under our $109 million DOD contract, 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, $74.7 million or 78% of our $95.8 million in cash, cash equivalents and available-for-sale securities belongs to our Canadian subsidiary. In the first quarter of 2022, we repatriated $65.0 million of cash from Canada into the United States and incurred approximately $1.7 million of Canadian withholding tax. Further repatriation of cash from Canada into the United States could have additional adverse tax consequences. It is our intention going forward to continue to permanently reinvest the historical undistributed earnings of our foreign subsidiaries.

A summary of our obligations to make future payments under contracts existing at December 31, 2021 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, 2021. As of June 30, 2022, 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, 2021 filed with the SEC. Except as presented below, no material changes have been made to such critical accounting policies during the six months ended June 30, 2022.

Goodwill

Goodwill is not amortized, but rather is tested annually for impairment or more frequently if we believe that indicators of impairment exist. Current generally accepted accounting principles permit us to make a qualitative evaluation about the likelihood of goodwill impairment and If it is determined that it is more likely than not that the fair value does not exceed the carrying amount, then a quantitative test is performed. The quantitative goodwill impairment test involves a comparison of the estimated fair value of the reporting unit to the respective carrying amount. An impairment charge is recognized in 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 process of evaluating the potential impairment of goodwill is highly subjective and requires significant judgment, including the identification of reporting units, qualitative evaluation of events and circumstances to determine if it is more likely than not that an impairment exists, and, if necessary, the estimation of the fair value of the applicable reporting unit.

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Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

As of June 30, 2022, we did not have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. Sales denominated in foreign currencies comprised 3.5% of our total revenues for the six months ended June 30, 2022. 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 $130.9 million in U.S. Dollars, which are included in the Company's consolidated balance sheet as of June 30, 2022. 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 $13.1 million in the six months ended June 30, 2022.

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 Interim Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) as of June 30, 2022. Based on that evaluation, the Company's management, including such officers, concluded that the Company's disclosure controls and procedures were effective as of June 30, 2022 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 Interim Chief Financial Officer, to allow timely decisions regarding required disclosure and was recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission.

(b) Changes in Internal Control Over Financial Reporting. There was no change in the Company's internal control over financial reporting that occurred during the three months ended June 30, 2022 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.

Spectrum Patent Litigation

In March 2021, we filed a complaint against Spectrum Solutions, LLC ("Spectrum") in the United States District Court for the Southern District of California alleging that certain saliva collection devices manufactured and sold by Spectrum infringe a patent held by DNAG. Spectrum has filed an answer to the initial complaint, asserting that its device does not infringe our patent and that our patent is invalid. In August 2021, we amended our complaint to add a second patent to this litigation. Spectrum responded to our amended complaint and asserted counterclaims for inequitable conduct and antitrust violations with respect to one of the patents in the litigation. DNAG filed a motion to dismiss Spectrum's counterclaims in October 2021, which was denied by the Court on March 30, 2022. On April 8, 2022, the Court assigned a new judge to preside over the matter, which vacated all dates for the trial. We await new dates to be set by the Court.

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, 2021, other than as set forth below.

Customer Concentration Creates Risk for Our Business.

One non-commercial customer accounted for 56% and 39% of net consolidated revenues for the three and six months ended June 30, 2022. We

expect that sales to the large non-commercial customer will continue to be a significant contributor to our net consolidated revenue. Certain parts of our business may continue to have a high customer concentration and depend disproportionately on a few large customers. To the extent that such a large customers fail to meet their purchase commitments, change their ordering patterns or business strategies, or otherwise reduce their purchases or stop purchasing our products, or if we experience difficulty in meeting the high demand by these larger customers for our products, our revenues and results of operations could be adversely affected.

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

Period	Total number of shares purchased		Average price paid per Share	Total number of shares purchased as part of publicly announced plans or programs	Maximum number (or approximate dollar value) of shares that may yet be repurchased under the plans or programs [1, 2]
April 1, 2022 - April 30, 2022	107,316	[3]	$ 7.08	—	11,984,720
May 1, 2022 - May 31, 2022	21,979	[3]	5.17	—	11,984,720
June 1, 2022 - June 30, 2022	12,311		3.83	—	11,984,720
	141,606			—	

(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 and performance shares, these shares were retired to satisfy minimum tax withholdings.

Item 3. DEFAULTS UPON SENIOR SECURITIES

None

Item 4. MINE SAFETY DISCLOSURES

Not applicable

Item 5. OTHER INFORMATION

None

Item 6. EXHIBITS

Exhibit Number	Exhibit
10.1**	Amended and Restated OraSure Technologies, Inc. 2000 Stock Award Plan is incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed May 18, 2022.
10.2**	Employment Agreement dated as of May 20, 2022, between OraSure Technologies, Inc. and Carrie Eglinton-Manner is incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed May 26, 2022.
31.1*	Certification of Carrie Eglinton-Manner required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.2*	Certification of Scott Gleason required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
32.1*+	Certification of Carrie Eglinton-Manner 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 Scott Gleason a required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the Instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
Exhibit 104	Cover Page from the Company’s Quarterly Report on Form 10-Q for the Quarter Ended June 30, 2021 has been formatted in Inline XBRL

*Filed herewith

** Management contract or compensatory plan or arrangement.

+This certification is deemed not filed for purposes of section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

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/ Scott Gleason

Date: August 9, 2022

Scott Gleason
Senior Vice President, Investor Relations and Corporate Communications
(Principal Financial Officer)

/s/Michele M. Miller

Date: August 9, 2022

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

Exhibit 31.1

Certification

I, Carrie Eglinton-Manner, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 9, 2022

/s/ Carrie Eglinton-Manner
Carrie Eglinton-Manner
President and Chief Executive Officer
(*Principal Executive Officer*)

Exhibit 31.2

Certification

I, Scott Gleason, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 9, 2022

/s/ *Scott Gleason*

Scott Gleason
Senior Vice President, Investor Relations and Corporate Communications
(*Principal Financial Officer*)

Exhibit 32.1

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

In connection with the Quarterly Report of OraSure Technologies, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Carrie Eglinton-Manner, 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/ Carrie Eglinton-Manner

Carrie Eglinton-Manner
President and Chief Executive Officer

August 9, 2022

Exhibit 32.2

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

In connection with the Quarterly Report of OraSure Technologies, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Scott Gleason, Interim 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/ Scott Gleason

Scott Gleason
Senior Vice President, Investor Relations & Corporate Communications

August 9, 2022