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 March 31, 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 May 5, 2022, the registrant had 72,455,507 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)

	March 31, 2022	December 31, 2021
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 70,721	$ 116,762
Short-term investments	41,503	36,279
Accounts receivable, net of allowance for doubtful accounts of $3,789 and $3,418	59,671	45,323
Inventories	61,536	53,138
Prepaid expenses	8,906	7,939
Other current assets	26,027	28,990
Total current assets	268,364	288,431
Noncurrent Assets:		
Property, plant and equipment, net	97,572	88,164
Operating right-of-use assets, net	12,169	9,056
Finance right-of-use assets, net	2,240	2,493
Intangible assets, net	13,692	14,343
Goodwill	40,389	40,279
Long-term investments	—	17,009
Other noncurrent assets	1,106	1,215
Total noncurrent assets	167,168	172,559
TOTAL ASSETS	**$ 435,532**	**$ 460,990**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 27,057	$ 28,024
Deferred revenue	2,906	2,936
Accrued expenses and other current liabilities	21,911	33,778
Finance lease liabilities	1,699	939
Operating lease liabilities	1,815	2,181
Acquisition-related contingent consideration obligation	199	206
Total current liabilities	55,587	68,064
Noncurrent Liabilities:		
Finance lease liabilities	1,207	1,952
Operating lease liabilities	10,727	7,202
Acquisition-related contingent consideration obligation	117	354
Other noncurrent liabilities	552	651
Deferred income taxes	2,456	2,234
Total noncurrent liabilities	15,059	12,393
TOTAL LIABILITIES	70,646	80,457
Commitments and contingencies (Note 11)		
STOCKHOLDERS' EQUITY		
Preferred stock, par value $.000001, 25,000 shares authorized, none issued	—	—
Common stock, par value $.000001, 120,000 shares authorized, 72,307 and 72,069 shares issued and outstanding	—	—
Additional paid-in capital	513,553	511,063
Accumulated other comprehensive loss	(8,247)	(10,077)
Accumulated deficit	(140,420)	(120,453)
Total stockholders' equity	364,886	380,533
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 435,532**	**$ 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 March 31,	
	2022	2021
NET REVENUES:		
Products and services	$ 65,236	$ 56,579
Other	2,471	2,003
	67,707	58,582
COST OF PRODUCTS AND SERVICES SOLD	43,435	20,256
Gross profit	24,272	38,326
OPERATING EXPENSES:		
Research and development	8,413	8,992
Sales and marketing	12,717	9,530
General and administrative	19,156	10,188
Change in the estimated fair value of acquisition-related contingent consideration	(36)	(806)
	40,250	27,904
Operating income (loss)	(15,978)	10,422
OTHER INCOME (LOSS)	(53)	(119)
Income (loss) before income taxes	(16,031)	10,303
INCOME TAX EXPENSE	3,936	6,529
NET INCOME (LOSS)	$ (19,967)	$ 3,774
INCOME (LOSS) PER SHARE:		
BASIC	$ (0.28)	$ 0.05
DILUTED	$ (0.28)	$ 0.05
SHARES USED IN COMPUTING INCOME (LOSS) PER SHARE:		
BASIC	72,194	71,878
DILUTED	72,194	72,766

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 March 31,	
	2022	2021
NET INCOME (LOSS)	$ (19,967)	$ 3,774
OTHER COMPREHENSIVE INCOME (LOSS)		
Currency translation adjustments	1,756	1,352
Unrealized gain on marketable securities	74	21
COMPREHENSIVE INCOME (LOSS)	$ (18,137)	$ 5,147

See accompanying notes to the consolidated financial statements.

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

	Three Months Ended March 31,	
	2022	**2021**
OPERATING ACTIVITIES:		
Net income (loss)	$ (19,967)	$ 3,774
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	3,524	1,464
Depreciation and amortization	3,682	2,489
Other non-cash amortization	80	138
Provision for doubtful accounts	347	598
Inventory reserve	1,092	129
Unrealized foreign currency (gain) loss	169	(100)
Interest expense on finance leases	32	14
Deferred income taxes	200	(94)
Loss on disposal of fixed assets	710	—
Change in the estimated fair value of acquisition-related contingent consideration	(36)	(806)
Payment of acquisition-related contingent consideration	—	(142)
Changes in assets and liabilities		
Accounts receivable	(15,295)	2,188
Inventories	(9,374)	(8,511)
Prepaid expenses and other assets	(736)	(766)
Accounts payable	4,398	(253)
Deferred revenue	(44)	(262)
Accrued expenses and other liabilities	(4,603)	(4,253)
Net cash used in operating activities	(35,821)	(4,393)
INVESTING ACTIVITIES:		
Proceeds from maturities and redemptions of investments	12,135	33,745
Purchases of property and equipment	(20,219)	(11,061)
Purchase of property and equipment under government contracts	(28,188)	—
Proceeds from funding under government contract	26,333	—
Other investing activities	—	(19)
Net cash (used in) provided by investing activities	(9,939)	22,665
FINANCING ACTIVITIES:		
Cash payments for lease liabilities	(153)	(282)
Proceeds from exercise of stock options	15	92
Payment of acquisition-related contingent consideration	(208)	(264)
Repurchase of common stock	(1,049)	(1,730)
Net cash used in financing activities	(1,395)	(2,184)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	1,114	786
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(46,041)	16,874
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	116,762	160,802
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 70,721	$ 177,676
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for income taxes	$ 3,570	$ 3,671
Non-cash investing and financing activities		
Accrued property and equipment purchases	642	4,267
Accrued property and equipment purchases under government contracts	1,905	—
Unrealized gain on marketable securities	74	21

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 months ended March 31, 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 with purchased maturities greater than ninety days. Available-for-sale securities are carried at fair value, based upon quoted market prices, with unrealized gains and losses, if any, reported in stockholders' equity as a component of accumulated other comprehensive loss.

We record an allowance for credit loss for our available-for-sale securities when a decline in investment market value is due to credit-related factors. When evaluating an investment for impairment, we review factors such as the severity of the impairment, changes in underlying credit ratings, forecasted recovery, the Company's intent to sell or the likelihood that it would be required to sell the investment before its anticipated recovery in market value and the probability that the scheduled cash payments will continue to be made. During the three months ended March 31, 2022, we recognized a provision for expected credit losses for our available-for-sale securities of $65.

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

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
March 31, 2022				
Guaranteed investment certificates	$ 33,578	$ —	$ —	$ 33,578
Corporate bonds	8,285	—	(360)	7,925
Total available-for-sale securities	$ 41,863	$ —	$ (360)	$ 41,503
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 March 31, 2022, maturities of our available-for-sale securities were as follows:				
Less than one year	$ 41,863	$ —	$ (360)	$ 41,503
Greater than one year	$ —	$ —	$ —	$ —

Fair Value of Financial Instruments. As of March 31, 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 March 31, 2022 and December 31, 2021. Our available-for-sale guaranteed investment certificates are measured as Level 1 instruments as of March 31, 2022 and December 31, 2021.

Included in cash and cash equivalents at March 31, 2022 and December 31, 2021, was $2,386 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 March 31, 2022 and December 31, 2021 was $1,660 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 March 31, 2022 and December 31, 2021 was $63,984 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 March 31, 2022 and December 31, 2021 was $31,142 and $30,412, respectively. The decrease in intangible assets from $14,343 as of December 31, 2021 to $13,692 as of March 31, 2022 was due to $568 in amortization expense and foreign currency translation losses of $83.

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 income in the period in which the change occurs. Net foreign exchange losses resulting from foreign currency transactions that are included in other income (loss) in our consolidated statements of income were $729 and $576 for the three months ended March 31, 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 March 31, 2022 consisted of $7,888 of currency translation adjustments and $359 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 update are elective and are effective upon issuance for all entities. Management is evaluating the impact of this ASU and does not expect this update to 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 of such income, which is reported as other income (loss) in our consolidated statement of operations for the three months ended March 31, 2022.

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

	March 31, 2022	December 31, 2021
Other current assets:		
Billed receivables	$ -	$ 9,913
Unbilled receivables	16,857	9,716
Total other current assets	16,857	19,629
Property, plant and equipment, net:		
Cost of assets	41,588	11,495
Reduction for funding earned, not yet received	(14,724)	(10,964)
Reduction for funding received	(26,864)	(531)
Total property, plant and equipment, net	—	—
Accrued expenses and other current liabilities	(788)	(8,103)

3. Inventories

	March 31, 2022	December 31, 2021
Raw materials	$ 40,211	$ 33,168
Work in process	2,507	2,252
Finished goods	18,818	17,718
	$ 61,536	$ 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 March 31,	
	2022	2021
Net income (loss)	$ (19,967)	$ 3,774
Weighted-average shares of common stock outstanding:		
Basic	72,194	71,878
Dilutive effect of stock options, restricted stock, and performance stock units	—	888
Diluted	72,194	72,766
Earnings (loss) per share:		
Basic	$ (0.28)	$ 0.05
Diluted	$ (0.28)	$ 0.05

For the three months ended March 31, 2022, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 463 shares were excluded from the computation of diluted loss per share. For the three months ended March 31, 2021, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 421 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 March 31,	
	2022	2021
COVID-19 [1]	$ 31,032	$ 27,972
Genomics [1]	15,093	10,818
HIV	8,166	8,778
HCV	3,257	2,367
Substance abuse	2,560	1,962
Microbiome [1]	1,990	1,751
Laboratory services	1,733	2,497
Other product and service revenues	1,405	434
Net product and services revenues	65,236	56,579
Royalty income	685	1,261
Other non-product revenues	1,786	742
Other revenues	2,471	2,003
Net revenues	$ 67,707	$ 58,582

[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 March 31, 2021 by $583, $(246) and $(337), 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 March 31,	
	2022	2021
United States	$ 57,987	$ 49,100
Europe	4,286	4,552
Other regions	5,434	4,930
	$ 67,707	$ 58,582

Customer and Vendor Concentrations. At March 31, 2022, one non-commercial customer accounted for 21% 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 18% of net consolidated revenues for the three months ended March 31, 2022. Another customer accounted for 17% of net consolidated revenues for the three months ended March 31, 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 March 31, 2022 and December 31, 2021 includes customer prepayments of $1,900 and $1,843, respectively. Deferred revenue as of March 31, 2022 and December 31, 2021 also includes $1,006 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. Accrued Expenses and other current liabilities

	March 31, 2022	December 31, 2021
Payroll and related benefits	$ 11,279	$ 15,570
Commitment to purchase under government contract	—	8,103
Deferred income for government contract	788	—
Professional fees	3,537	3,335
Sales tax payable	1,725	2,227
Other	4,582	4,543
	$ 21,911	$ 33,778

7. 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 March 31, 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 March 31,	
	2022	2021
Operating lease cost	$ 699	$ 420
Variable and short-term lease cost	75	—
Finance lease cost:		
Amortization of right-of use assets	385	127
Interest on lease liabilities	32	14
Total finance lease cost	417	141
Total lease cost	$ 1,191	$ 561

Supplemental cash flow information related to leases is as follows:

	Three Months Ended March 31,	
	2022	2021
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 1,186	$ 408
Operating cash flows from financing leases	32	14
Financing cash flows from financing leases	153	282
Non-cash activity:		
Right-of-use assets obtained in exchange for operating lease obligations	3,666	629
Right-of-use assets obtained in exchange for finance lease obligations	117	—

Supplemental balance sheet information related to leases is as follows:

	March 31, 2022	December 31, 2021
Operating Leases		
Right-of-use assets	$ 12,169	$ 9,056
Lease liabilities:		
Current lease liabilities	1,815	2,181
Non-current lease liabilities	10,727	7,202
Total operating lease liabilities	$ 12,542	$ 9,383
Finance Leases		
Right-of-use assets	$ 2,240	$ 2,493
Lease liabilities:		
Current lease liabilities	1,699	939
Non-current lease liabilities	1,207	1,952
Total finance lease liabilities	$ 2,906	$ 2,891
Weighted Average Remaining Lease Term		
Weighted-average remaining lease term—operating leases	6.86 years	5.26 years
Weighted-average remaining lease term—finance leases	2.04 years	2.21 years
Weighted Average Discount Rate		
Weighted-average discount rate—operating leases	4.09%	3.90%
Weighted-average discount rate—finance leases	3.54%	3.57%

As of March 31, 2022, minimum lease payments by period are expected to be as follows:

	Finance	Operating
2022 (excluding the three months ended March 31, 2022)	951	1,936
2023	1,285	1,729
2024	742	2,337
2025	20	1,968
2026	12	1,750
Thereafter	—	4,871
Total minimum lease payments	3,010	14,591
Less: imputed interest	(104)	(2,049)
Present value of lease liabilities	$ 2,906	$ 12,542

8. Stockholders' Equity

Reconciliation of the changes in stockholders' equity for the three months ended March 31, 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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
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

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 three months ended March 31, 2022 and 2021 was $348 and $250, respectively.

The following table summarizes the stock option activity for the three months ended March 31, 2022:

	Options
Outstanding on January 1, 2022	1,410
Granted	589
Exercised	(2)
Expired	(6)
Forfeited	(95)
Outstanding on March 31, 2022	1,896

Compensation expense of $2,706 and $1,036 related to restricted shares was recognized during the three months ended March 31, 2022 and 2021, respectively.

The following table summarizes time-vested restricted stock award and restricted stock unit activity for the three months ended March 31, 2022:

	Units
Issued and unvested, January 1, 2022	701
Granted	1,332
Vested	(243)
Forfeited	(120)
Issued and unvested, March 31, 2022	1,670

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 $470 and $178 related to PSUs was recognized during the three months ended March 31, 2022 and 2021, respectively.

The following table summarizes the PSU activity for the three months ended March 31, 2022:

	Units
Issued and unvested, January 1, 2022	622
Granted [1]	206
Performance adjustment [2]	36
Vested	(109)
Forfeited	(152)
Issued and unvested, March 31, 2022	603

[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 three months ended March 31, 2022 and 2021.

9. 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 totaling 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 $1,380 of expense in relation to Dr. Tang's stock compensation during the three months ended March 31, 2022.

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, starting on April 1, 2022, Dr. Gagliano began receiving a monthly base salary of $56 per month. Additionally, she was granted a one-time award of fully vested shares of the Company's common stock with a

grant date fair value of $100 and a one-time restricted stock unit award with a grant date fair value of $670, which vest in twelve equal monthly installments (with the first installment vesting on April 30, 2022 and subsequent installments vesting on the last day of the following eleven calendar months), subject to Dr. Gagliano's continued employment as Interim Chief Executive Officer through the applicable vesting dates.

10. Income Taxes

During the three months ended March 31, 2022 and 2021, we recorded income tax expense of $3,936 and $6,529, 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 balance of $2,234 for the first quarter of 2022 primarily consisted of foreign tax expense. Income taxes for the first quarter of 2021 also primarily consisted 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 March 31, 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 March 31, 2022 and December 31, 2021 since the facts and circumstances necessitating the allowance have not changed.

11. 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. 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.

12. 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 months ended March 31, 2022 and 2020, and asset information as of March 31, 2022 and December 31, 2021:

	Three Months Ended March 31,	
	2022	2021
Net revenues:		
Diagnostics	$ 38,310	$ 14,546
Molecular Solutions	29,397	44,036
Total	$ 67,707	$ 58,582
Operating income (loss):		
Diagnostics	$ (19,787)	$ (12,118)
Molecular Solutions	3,809	22,540
Total	$ (15,978)	$ 10,422
Depreciation and amortization:		
Diagnostics	$ 1,727	$ 890
Molecular Solutions	1,955	1,599
Total	$ 3,682	$ 2,489
Capital expenditures:		
Diagnostics[(1)]	$ 19,132	$ 7,637
Molecular Solutions	1,087	3,424
Total	$ 20,219	$ 11,061

(1) Excludes $28,188 for purchases of property and equipment under government contracts for the three months ended March 31, 2022.

	March 31, 2022	December 31, 2021
Total assets:		
Diagnostics	$ 245,961	$ 209,674
Molecular Solutions	189,571	251,316
Total	$ 435,532	$ 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:

- *risk that our exploration of strategic alternatives may not result in any definitive transaction or enhance stockholder value and may create a distraction or uncertainty that may adversely affect operating results, business or investor perceptions.*
- *the diversion of management's attention from our ongoing business and regular business responsibilities and due to our exploration of strategic alternatives;*
- *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;*
- *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;*
- *the impact of COVID-19 on our 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 "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;*
- *reliance on sole supply sources for critical products and components;*
- *availability of related products produced by third parties or products required for use of our products;*
- *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 hostilities or war;*
- *our ability to maintain sustained profitability;*
- *our ability to increase our gross margins;*
- *the ability to utilize net operating loss carry forwards or other deferred tax assets;*
- *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;*
- *availability of licenses to patents or other technology;*
- *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 or 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. 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 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.

Exploration of Strategic Alternatives

The COVID-19 pandemic has provided us an opportunity to fundamentally transform into a higher growth, more innovative and efficient organization with broader customer reach, both within and outside the United States. We believe we are well positioned to address current public health challenges and capitalize on diagnostic trends in the market and enhance its operational and competitive profile. Against this backdrop, our Board of Directors is exploring and evaluating a broad range of strategic alternatives with the goal of maximizing value for stockholders.

There can be no assurance that the exploration of strategic alternatives will result in any agreements or transactions, or that, if completed, any agreements or transactions will be successful or on attractive terms.

CEO Recruitment
We have hired an external search firm and are in the process of looking for a permanent full time Chief Executive Officer. Nancy J. Gagliano has been appointed as interim President and CEO by our Board of Directors but is not a candidate for the full-time position.

Current Consolidated Financial Results

During the three months ended March 31, 2022, our consolidated net revenues increased 16% to $67.7 million, compared to $58.6 million for the three months ended March 31, 2021. Net product and services revenues during the three months ended March 31, 2022 increased 15% when compared to the same period of 2021, largely due to the inclusion of $22.1 million of InteliSwab® COVID-19 rapid test revenues. We began selling this product in August of 2021 resulting in no comparable revenues in the first quarter of 2021. Also contributing to the increase in revenues was higher genomics sales and increased international sales of our HIV product. Declines in sales of our molecular sample collection kits for COVID-19 testing and in domestic sales of our HIV products partially offset these positive drivers of revenue. Other revenues for the three months ended March 31, 2022 were $2.5 million compared to $2.0 million in the same period of 2021. This increase was largely 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.

Our consolidated net loss for the three months ended March 31, 2022 was $20.0 million, or $(0.28) per share on a fully diluted basis, compared to consolidated net income of $3.8 million, or $0.05 per share on a fully diluted basis, for the three months ended March 31, 2021. Results for the three months ended March 31, 2022 were impacted by lower gross margins rates caused by manufacturing inefficiencies and nonrecurring costs associated with our strategic alternatives process and our CEO transition.

Cash used in operating activities during the three months ended March 31, 2022 was $35.8 million. Cash used in operating activities during the three months ended March 31, 2021 was $4.4 million. During the first quarter of 2022, our cash flow used in operating activities increased significantly as a result of our net loss, increased receivables due from the U.S government for end of quarter shipments, and increased investment in building InteliSwab® inventory levels to support expected demand. As of March 31, 2022, we had $112.2 million in cash, cash equivalents and available-for-sale securities.

Results of Operations

Three months ended March 31, 2022 compared to March 31, 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 March 31, 2022 and 2021.

	For the Three Months Ended March 31,				
	Dollars			Percentage of Total Net Revenues	
	2022	2021	% Change	2022	2021
Diagnostics	$ 36,396	$ 13,333	173 %	54 %	23 %
Molecular Solutions	28,840	43,246	(33)	43	74
Net product and services revenues	65,236	56,579	15	97	97
Other	2,471	2,003	23	3	3
Net revenues	$ 67,707	$ 58,582	16 %	100 %	100 %

Consolidated net product and services revenues increased 15% to $65.2 million for the three months ended March 31, 2022 from $56.6 million for the three months ended March 31, 2021. The increase in revenues is largely due to the inclusion of $22.1 million of InteliSwab® COVID-19 rapid test revenues. We began selling this product in August of 2021 resulting in no comparable revenues in the first quarter of 2021. Also contributing to the increase in revenues was higher genomics sales and increased international sales of our HIV product. Declines in sales of our molecular sample collection kits for COVID-19 testing and in domestic sales of our HIV products partially offset these positive drivers of revenue. Other revenues for the three months ended March 31, 2022 increased 23% to $2.5 million from $2.0 million for the three months ended March 31, 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.

Consolidated net revenues derived from products sold to customers outside of the United States were $9.7 million and $9.5 million, or 14% and 16% of total net revenues, for the three months ended March 31, 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 March 31, 2022 and 2021.

	For the Three Months Ended March 31,				
	Dollars			Percentage of Total Net Revenues	
Market	2022	2021	% Change	2022	2021
Infectious disease testing:					
COVID-19	$ 22,136	$ -	NM %	58 %	0 %
Other	11,700	11,371	3	30	78
Total infectious disease testing	33,836	11,371	198	88	78
Substance abuse testing	2,560	1,962	30	7	13
Net product revenues	36,396	13,333	173	95	91
Other	1,914	1,213	58	5	9
Net revenues	$ 38,310	$ 14,546	163 %	100 %	100 %

NM - not meaningful

Infectious Disease Testing Market

COVID-19 revenues were $22.1 million for the three months ended March 31, 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 quarter of 2021.

Sales to the other infectious disease testing markets increased 3% to $11.7 million for the three months ended March 31, 2022 from $11.4 million for the three months ended March 31, 2021. This increase resulted from higher international OraQuick® HIV and world-wide OraQuick® HCV product sales, partially offset by lower domestic OraQuick® HIV 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 March 31, 2022 and 2021.

	For the Three Months Ended March 31,		
Market	2022	2021	% Change
Domestic HIV	$ 3,765	$ 5,293	(29) %
International HIV	4,401	3,486	26
Net HIV revenues	8,166	8,779	(7)
Domestic HCV	2,036	1,182	72
International HCV	1,221	1,184	3
Net HCV revenues	3,257	2,366	38
Net OraQuick® revenues	$ 11,423	$ 11,145	2 %

Domestic OraQuick® HIV sales decreased 29% to $3.8 million for the three months ended March 31, 2022 from $5.3 million for the three months ended March 31, 2021, primarily as a result of a large first quarter 2021 order of our OraQuick® In-Home HIV test shipped to the Center for Disease Control and Prevention ("CDC") and used in an initiative to drive increased in-home HIV testing. A similar order did not occur in the first quarter of 2022.

International sales of our OraQuick® HIV tests increased 26% to $4.4 million for the three months ended March 31, 2022 from $3.5 million for the three months ended March 31, 2021 due to customer ordering patterns and increased sales into Africa as the COVID-19 impact lessens. These increases to revenues were 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.

Domestic OraQuick® HCV sales increased 72% to $2.0 million for the three months ended March 31, 2022 from $1.2 million for the three months ended March 31, 2021, driven by the timing of certain orders which occurred in the first quarter of 2022, compared to the second quarter of 2021.

International OraQuick® HCV sales remained largely flat at $1.2 million for both the three months ended March 31, 2022 and 2021.

Substance Abuse Testing Market

Sales to the substance abuse testing assessment market increased 30% to $2.6 million for the three months ended March 31, 2022 compared to $2.0 million for the three months ended March 31, 2021 due to market share gains.

Other Revenues

Other revenues for the three months ended March 31, 2022 increased to $1.9 million from $1.2 million for the three months ended March 31, 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 three months ended March 31, 2022 and 2021.

	For the Three Months Ended March 31,		
Market	**2022**	**2021**	**% Change**
Genomics	$ 15,093	$ 10,818	40 %
Microbiome	1,990	1,751	14
COVID-19	8,896	27,972	(68)
Laboratory services	1,733	2,497	(31)
Other product and service revenues	1,128	208	442
Net molecular product and services revenues	$ 28,840	43,246	(33)
Other	557	790	(29)
Net molecular revenues	$ 29,397	$ 44,036	(33) %

Sales of our genomics products increased 40% to $15.1 million for the three months ended March 31, 2022, compared to $10.8 million for the three months ended March 31, 2021, as result of increased sales to several commercial customers due to customer ordering patterns, organic growth, and a return to pre-COVID-19 ordering levels.

Microbiome kit sales increased 14% to $2.0 million for the three months ended March 31, 2022 compared to $1.8 million for the three months ended March 31, 2021, as the company has expanded the number of customers and clinical research studies it is supporting.

Sales of our molecular sample collection kits for COVID-19 testing decreased 68% to $8.9 million for the three months ended March 31, 2022 compared to $28.0 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.

Laboratory services revenues declined 31% to $1.7 million for the three months ended March 31, 2022 compared to $2.5 million for the three months ended March 31, 2021 as the business continues to be impacted by delays in customer clinical trials due to COVID-19.

Other product and service revenues increased 442% to $1.1 million for the three months ended March 31, 2022 compared to $208,000 for the three months ended March 31, 2021 largely due to increased sales by our Novosanis subsidiary.

Other revenues for the three months ended March 31, 2022 decreased 29% to $557,000 from $790,000 for the three months ended March 31, 2021, largely as a result of lower royalty income received under a litigation settlement agreement.

CONSOLIDATED OPERATING RESULTS

Consolidated gross profit margins were 36% for the three months ended March 31, 2022 compared to 65% for the three months ended March 31, 2021. The decrease in gross profit margins was primarily due to a less favorable product mix, increased scrap expense, lower absorption of labor, and no subsidies for the international sale of our HIV Self-Test under the charitable support agreement with the Gates Foundation which expired in June 2021.

Consolidated operating loss for the three months ended March 31, 2022 was $16.0 million, a $26.4 million decrease from the $10.4 million operating income reported for the three months ended March 31, 2021. Results for the three months ended March 31, 2022 were negatively impacted by the lower gross profit margin described above coupled with an increase in operating expenses as described below.

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 19% for the three months ended March 31, 2022 compared to 43% for the three months ended March 31, 2021. This decrease is due to inefficiencies in our InteliSwab® manufacturing process including high scrap rates at the beginning of 2022 and under-absorption of labor costs as well a less favorable product mix and the June 2021 expiration of subsidies under the support agreement with the Gates Foundation. The inefficiencies in our InteliSwab® manufacturing process were largely corrected by the end of the first quarter of 2022.

Research and development expenses decreased 16% to $5.5 million for the three months ended March 31, 2022 compared to $6.6 million for the three months ended March 31, 2021 largely due to clinical study activities in the first quarter of 2021 related to our InteliSwab® rapid test which did not repeat in the first quarter of 2022 as we received EUA authorization in June 2021. Sales and marketing expenses increased 30% to $8.1 million for three months ended March 31, 2022 from $6.2 million for the three months ended March 31, 2021 due to an increase in spend associated with our InteliSwab® test, increased staffing costs associated with higher head count, and increased travel expenses as travel has resumed as COVID-19 restrictions have been lifted. These increases in spend were partially offset by a decline in reserves for uncollectible accounts. General and administrative expenses increased 112% to $13.7 million for the three months ended March 31, 2022 from $6.4 million for the three months ended March 31, 2021 largely due to increased consulting costs, higher stock compensation expense associated with accelerated vesting of shares under our former CEO's employment agreement, increased legal costs, higher staffing costs associated with increased head count, and higher recruitment expense largely associated with our CEO search.

All of the above contributed to the Diagnostics segment's operating loss of $19.8 million for the three months ended March 31, 2022, which included non-cash charges of $1.7 million for depreciation and amortization and $3.1 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 $806,000 benefit recorded in the first quarter of 2021.

Molecular Solutions Segment

The gross profit margins for the Molecular Solutions segment was 58% for the three months ended March 31, 2022 compared to 73% for the three months ended March 31, 2021. This decrease was due to a less favorable product mix.

Research and development expenses increased 20% to $2.9 million for the three months ended March 31, 2022 from $2.4 million for the three months ended March 31, 2021 due to higher staffing costs. Sales and marketing expenses increased 39% to $4.6 million for the three months ended March 31, 2022 from $3.3 million for the three months ended March 31, 2021 due to higher staffing costs related to increased head count, increased consulting expense associated with business strategy planning, and an increase in our reserve for uncollectible accounts. 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 47% to $5.5 million for the three months ended March 31, 2022 from $3.7 million for the three months ended March 31, 2021 due to increased legal fees and staffing costs.

All of the above contributed to the Molecular Solutions segment's operating income of $3.8 million for the three months ended March 31, 2022, which included $2.0 million for depreciation and amortization and $396,000 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 March 31, 2022, we recorded U.S. state tax expense of $216,000 compared to $169,000 of state income tax expense for the three months ended March 31, 2021. Additionally, in the first quarter 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 three months ended March 31, 2022, we recorded foreign tax expense of $2.0 million compared to foreign tax expense of $6.4 million for the three months ended March 31, 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

	March 31, 2022	December 31, 2021
	(In thousands)	
Cash and cash equivalents	$ 70,721	$ 116,762
Available for sale securities	41,503	53,288
Working capital	212,777	220,367

Our cash and cash equivalents and available-for-sale securities decreased to $112.2 million at March 31, 2022 from $170.1 million at December 31, 2021. Our working capital decreased to $212.8 million at March 31, 2022 from $220.4 million at December 31, 2021.

During the three months ended March 31, 2022, net cash used in operating activities was $35.8 million. Our net loss of $20.0 million included non-cash charges for depreciation and amortization expense of $3.7 million, stock-based compensation expense of $3.5 million, an inventory reserve of $1.1 million, and other non-cash expense of $1.5 million. Cash used to fund our working capital accounts included an increase in accounts receivable of $15.3 million largely associated with end of the quarter shipments of product to the U.S. government, an increase in inventory of $9.4 million to meet anticipated demand to support COVD-19 testing programs, and a $4.6 million decrease in accrued expenses and other liabilities largely due to payment of our 2021 bonuses. Offsetting these uses of cash was a $4.4 million increase in accounts payable due to the timing of invoices received and payments made.

Net cash used in investing activities was $9.9 million for the three months ended March 31, 2022, which reflects proceeds from the maturities and redemptions of investments of $12.1 million. This was offset by $20.2 million to acquire property and equipment largely to increase our manufacturing capacity. Cash used in investing activities also reflects net cash used of $1.8 million to build additional manufacturing capacity as required by our $109 million agreement with the U.S. Department of Defense (the “DOD”), which is expected to be reimbursed in the second quarter of 2022.

Net cash used in financing activities was $1.4 million for the three months ended March 31, 2022, which is largely comprised of $1.0 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 and foreseeable operating and capital needs. Our cash requirements, however, may vary materially from those now planned due to many factors, including, but not limited to, the 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, $72.7 million or 65% of our $112.2 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 March 31, 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. During the first three months of 2022, there were no material changes to our critical accounting policies.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

As of March 31, 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 5.1% of our total revenues for the three months ended March 31, 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 $139.4 million in U.S. Dollars, which are included in the Company's consolidated balance sheet as of March 31, 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 $13.9 million in the three months ended March 31, 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 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 March 31, 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 March 31, 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 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 March 31, 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.

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]
January 1, 2022 - January 31, 2022	—	[3]	$ —	—	11,984,720
February 1, 2022 - February 28, 2022	116,149	[3]	8.86	—	11,984,720
March 1, 2022 - March 31, 2022	636		6.92	—	11,984,720
	116,785			—	

(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**	Transition Agreement dated as of January 2, 2022, between OraSure Technologies, Inc. and Stephen S. Tang, Ph.D. is incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed January 6, 2022.
10.2**	Employment Agreement dated as of March 21, 2022 between OraSure Technologies, Inc. and Nancy J. Gagliano, M.D., M..B.A. is incorporated by reference to Item 10.1 to the Company's Current Report on Form 8-K Filed on March 23, 2022.
10.3	Industrial Lease between Core5 at Laughman Farms Phase 1, LLC as Landlord and OraSure Technologies, Inc. as Tenant, dated January 3, 2022, is incorporated by reference to Exhibit 10.30 to the Company's Annual Report on form 10-K filed March 1, 2022.
31.1*	Certification of Nancy J. Gagliano, M.D., M.B.A. 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 Nancy J. Gagliano, M.D., M.B.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.
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: May 10, 2022

Scott Gleason
Interim Chief Financial Officer
(Principal Financial Officer)

/s/Michele M. Miller

Date: May 10, 2022

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

Exhibit 31.1

Certification

I, Nancy J. Gagliano, M.D., 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: May 10, 2022

/s/ Nancy J. Gagliano, M.D., MBA
Nancy J. Gagliano, M.D., MBA
Interim 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: May 10, 2022

/s/ *Scott Gleason*
Scott Gleason
Interim Chief Financial Officer
(*Principal Financial Officer*)

Exhibit 32.1

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

In connection with the Quarterly Report of OraSure Technologies, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Nancy J. Gagliano, M.D., Interim 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/ Nancy J. Gagliano, M.D., MBA

Nancy J. Gagliano, M.D., MBA
Interim Chief Executive Officer

May 10, 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 March 31, 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
Interim Chief Financial Officer

May 10, 2022