

**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, 2023.

OR

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

For the transition period from _____ to _____.

Commission File Number 001-16537

ORASURE TECHNOLOGIES, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction of
Incorporation or Organization)

36-4370966

(IRS Employer Identification No.)

220 East First Street, Bethlehem, Pennsylvania

(Address of Principal Executive Offices)

18015

(Zip code)

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

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

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

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

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

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

Large accelerated filer Accelerated filer

Non-accelerated filer Smaller reporting company

Emerging growth company

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

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

As of May 3, 2023, the registrant had 73,262,370 shares of common stock, \$0.000001 par value per share, outstanding.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains certain “forward-looking statements” within the meaning of the Federal securities laws. These may include statements about our expected revenues, earnings/losses per share, net income (loss), expenses, cash flow or other financial performance, or developments, clinical trial or development activities, expected regulatory filings and approvals, planned business transactions, views of future industry, competitive or market conditions, and other factors that could affect our future operations, results of operations or financial position. These statements often include words, such as “believes,” “expects,” “anticipates,” “intends,” “plans,” “estimates,” “may,” “will,” “should,” “could,” or similar expressions.

Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include, but are not limited to:

- Our ability to market and sell products, whether through our internal, direct sales force or third parties;
 - Our ability to fulfill our commitments under our contracts with the U.S. government for InteliSwab® COVID-19 Rapid Tests;
 - Failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our products;
 - Significant customer concentrations that exist or may develop in the future;
 - 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; 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 other regulators;
 - The impact of the COVID-19 pandemic on our business, supply chain and workforce;
 - The impact of the U.S. government ending the COVID-19 related Public Health Emergency;
 - 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;
 - 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 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;
 - 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 and civil unrest; and
- General political, business and economic conditions, including inflationary pressures and banking instability.

These and other factors that could affect our results are discussed more fully under the section titled “Risk Factors,” set forth in Part II, Item 1A of this Quarterly Report on Form 10-Q, if any, in Part I, Item 1A of our Annual Report on Form 10-K filed with the Securities and Exchange Commission (the “SEC”) on March 3, 2023, and in other SEC filings. 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, unless we are required to do so by law. If we do update one or more forward-looking statements, no inference should be drawn that we will make updates with respect to other forward-looking statements or that we will make any further updates to those forward-looking statements at any future time.

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.

PART I. FINANCIAL INFORMATION

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Item 1. FINANCIAL STATEMENTS

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

	March 31, 2023	December 31, 2022
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 90,194	\$ 83,980
Short-term investments	22,178	26,867
Accounts receivable, net of allowance of \$2,297 and \$2,365	107,445	70,797
Inventories	77,189	95,704
Prepaid expenses	6,161	6,273
Other current assets	40,428	41,569
Total current assets	343,595	325,190
Noncurrent Assets:		
Property, plant and equipment, net of accumulated depreciation of \$72,400 and \$69,881	57,343	59,413
Operating right-of-use assets, net	9,922	10,399
Finance right-of-use assets, net	1,136	1,293
Intangible assets, net of accumulated amortization of \$31,732 and \$31,077	11,184	11,694
Goodwill	35,204	35,104
Other noncurrent assets	1,031	1,087
Total noncurrent assets	115,820	118,990
TOTAL ASSETS	\$ 459,415	\$ 444,180
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 27,396	\$ 38,020
Deferred revenue	1,989	2,273
Accrued expenses and other current liabilities	22,673	25,762
Finance lease liability	1,229	1,179
Operating lease liability	1,761	1,764
Acquisition-related contingent consideration obligation	75	65
Total current liabilities	55,123	69,063
Noncurrent Liabilities:		
Finance lease liability	472	503
Operating lease liability	8,623	9,101
Acquisition-related contingent consideration obligation	—	99
Other noncurrent liabilities	609	581
Deferred income taxes	409	408
Total noncurrent liabilities	10,113	10,692
TOTAL LIABILITIES	65,236	79,755
Commitments and contingencies (Note 12)		
STOCKHOLDERS' EQUITY		
Preferred stock, par value \$.000001, 25,000 shares authorized, none issued	—	—
Common stock, par value \$.000001, 120,000 shares authorized, 73,254 and 72,734 shares issued and outstanding	—	—
Additional paid-in capital	521,964	520,446
Accumulated other comprehensive loss	(17,418)	(18,435)
Accumulated deficit	(110,367)	(137,586)
Total stockholders' equity	394,179	364,425
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 459,415	\$ 444,180

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,	
	2023	2022
NET REVENUES:		
Products and services	\$ 152,914	\$ 65,236
Other	2,049	2,471
	<u>154,963</u>	<u>67,707</u>
COST OF PRODUCTS AND SERVICES SOLD		
Gross profit	65,815	24,299
OPERATING EXPENSES:		
Research and development	10,560	8,634
Sales and marketing	12,142	12,717
General and administrative	17,711	19,156
Loss on impairments	1,105	—
Change in the estimated fair value of acquisition-related contingent consideration	(24)	(36)
	<u>41,494</u>	<u>40,471</u>
Operating income (loss)	24,321	(16,172)
OTHER INCOME		
Income (loss) before income taxes	26,994	(16,004)
INCOME TAX (BENEFIT) EXPENSE	(225)	3,936
NET INCOME (LOSS)	\$ 27,219	\$ (19,940)
INCOME (LOSS) PER SHARE:		
BASIC	\$ 0.37	\$ (0.28)
DILUTED	\$ 0.37	\$ (0.28)
WEIGHTED-AVERAGE SHARES OUTSTANDING:		
BASIC	73,112	72,194
DILUTED	73,966	72,194

See accompanying notes to the consolidated financial statements.

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

	<u>Three Months Ended March 31,</u>	
	<u>2023</u>	<u>2022</u>
NET INCOME (LOSS)	\$ 27,219	\$ (19,940)
OTHER COMPREHENSIVE INCOME		
Currency translation adjustments	797	1,756
Unrealized gain on marketable securities	220	74
COMPREHENSIVE INCOME (LOSS)	<u>\$ 28,236</u>	<u>\$ (18,110)</u>

See accompanying notes to the consolidated financial statements.

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

	For the Three Months Ended March 31,	
	2023	2022
OPERATING ACTIVITIES:		
Net income (loss)	\$ 27,219	\$ (19,940)
Adjustments to reconcile net income (loss) to net cash (used in) provided by operating activities:		
Stock-based compensation	2,655	3,524
Depreciation and amortization	3,696	3,682
Loss on impairments	1,105	—
Other non-cash amortization	—	80
Provision for credit losses	(67)	347
Unrealized foreign currency loss	44	169
Interest expense on finance leases	15	32
Deferred income taxes	—	200
Loss on sale of fixed assets	—	710
Change in the estimated fair value of acquisition-related contingent consideration	(24)	(36)
Payment of acquisition-related contingent consideration	(19)	—
Changes in assets and liabilities		
Accounts receivable	(36,613)	(15,295)
Inventories	18,540	(8,198)
Prepaid expenses and other assets	5,299	(736)
Accounts payable	(12,097)	4,287
Deferred revenue	(279)	(44)
Accrued expenses and other liabilities	(3,472)	(4,603)
Net cash provided by (used in) operating activities	<u>6,002</u>	<u>(35,821)</u>
INVESTING ACTIVITIES:		
Purchases of investments	(22,330)	—
Proceeds from maturities and redemptions of investments	27,304	12,135
Purchases of property and equipment	(1,191)	(20,219)
Purchase of property and equipment under government contracts	(2,767)	(28,188)
Proceeds from funding under government contract	—	26,333
Net cash provided by (used in) investing activities	<u>1,016</u>	<u>(9,939)</u>
FINANCING ACTIVITIES:		
Cash payments for lease liabilities	(148)	(153)
Proceeds from exercise of stock options	66	15
Payment of acquisition-related contingent consideration	(46)	(208)
Repurchase of common stock	(1,203)	(1,049)
Net cash used in financing activities	<u>(1,331)</u>	<u>(1,395)</u>
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	527	1,114
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	6,214	(46,041)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	83,980	116,762
CASH AND CASH EQUIVALENTS, END OF PERIOD	<u>\$ 90,194</u>	<u>\$ 70,721</u>
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for income taxes	\$ (10)	\$ 3,570
Non-cash investing activities		
Accrued property and equipment purchases	\$ 733	\$ 642
Accrued property and equipment purchases under government contracts	\$ —	\$ 1,905

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
Notes to the Consolidated Financial Statements
(Unaudited)
(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 the Company’s 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 the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2022. Results of operations for the three months ended March 31, 2023 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 its Annual Report on Form 10-K for the fiscal year ended December 31, 2022 that have had a material impact on the consolidated financial statements and related notes except as discussed herein. See Note 11 for the discussion regarding the change in business segments.

Investments. The Company considers all investments in debt securities to be available-for-sale securities. These securities consist of guaranteed investment certificates and corporate bonds purchased with maturities greater than ninety days. Available-for-sale securities are carried at fair value, based upon quoted market prices, with unrealized gains and losses, if any, reported in stockholders’ equity as a component of accumulated other comprehensive loss.

The Company records an allowance for credit loss for its available-for-sale securities when a decline in investment market value is due to credit-related factors. When evaluating an investment for impairment, the Company reviews 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.

The following is a summary of the Company’s available-for-sale securities:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
March 31, 2023				
Guaranteed investment certificates	\$ 22,178	\$ —	\$ —	\$ 22,178
Corporate bonds	—	—	—	—
Total	<u>\$ 22,178</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 22,178</u>
December 31, 2022				
Guaranteed investment certificates	\$ 22,109	\$ —	\$ —	\$ 22,109
Corporate bonds	4,978	—	(220)	4,758
Total	<u>\$ 27,087</u>	<u>\$ —</u>	<u>\$ (220)</u>	<u>\$ 26,867</u>
At March 31, 2023, maturities of the Company’s available-for-sale securities were as follows:				
Less than one year	<u>\$ 22,178</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 22,178</u>
Greater than one year	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

Fair Value of Financial Instruments. As of March 31, 2023 and December 31, 2022, 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 the Company's available-for-sale corporate bonds are measured as Level 2 instruments as of December 31, 2022. The Company's available-for-sale guaranteed investment certificates are measured as Level 1 instruments as of March 31, 2023 and December 31, 2022.

Included in cash and cash equivalents at March 31, 2023 and December 31, 2022, was \$6,846 and \$1,730 invested in money market funds. These money market funds have investments in government securities and are measured as Level 1 instruments.

The Company offers a nonqualified deferred compensation plan for certain eligible employees and members of its 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, 2023 and December 31, 2022 was \$678 and \$747, 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.

Foreign Currency Translation. Net foreign exchange gains and (losses) resulting from foreign currency transactions that are included in other income in the Company's consolidated statements of operations were \$(50) and \$729 for the three months ended March 31, 2023 and 2022, respectively.

Accumulated Other Comprehensive Loss. Changes in Accumulated other comprehensive loss by component is listed below.

	<u>Foreign Currency</u>	<u>Marketable Securities</u>	<u>Total</u>
Balance at December 31, 2022	\$ (18,215)	\$ (220)	\$ (18,435)
Other comprehensive gain	797	220	1,017
Balance at March 31, 2023	<u>\$ (17,418)</u>	<u>\$ 0</u>	<u>\$ (17,418)</u>

Immaterial Correction of Errors. Inventories, accounts payable and cost of products and services were reduced by \$528, \$1,329 and \$801, respectively, as of and for the year ended December 31, 2022 to correct for the accounting of a vendor rebate earned in 2022. The tax impact of the vendor rebate was negligible. This correction was deemed to be immaterial to the consolidated financial statements as of and for the year ended December 31, 2022. For the three months ended March 31, 2022, cost of products and services sold was reduced by \$27. The respective operating activities on the consolidated statement of cash flows for the three months ended March 31, 2022 has also been adjusted. Furthermore, stockholder's equity at March 31, 2022 has been adjusted to reflect the reduction in cost of products and services sold.

Reclassification. Certain prior period amounts have been reclassified to conform to current year presentations. For the three months ended March 31, 2022, \$221 of research and development expenses were reclassified to other income in relation to the U.S. Department of Defense (the "DOD") engineering consulting costs further described in Note 2. This reclassification was made to conform to the presentation in our Annual Report on Form 10-K for the year ended December 31, 2022.

2. Government Capital Contracts

In September 2021, the Company entered into an agreement for \$109,000 in funding from the DOD, in coordination with the Department of Health and Human Services, to build additional manufacturing capacity in the United States for its 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 December 2023 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 validation testing, which is scheduled to occur in late 2023. The Company began making payments to vendors for the capital project during the fourth quarter of 2021. The Company

began receiving funds from the DOD in January 2022 and has received \$60,862, as of March 31, 2023. The remaining \$48,138 is expected to be collected during 2023.

Activity for these capital contracts is accounted for pursuant to International Accounting Standards ("IAS") 20, *Accounting for Government Grants and Disclosure of Government Assistance*. Funding received 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.

The DOD also reimburses the Company for certain engineering consulting costs. These expenses are reflected in research and development as incurred with the corresponding reimbursement presented in other income. For the three months ended March 31, 2023 and 2022, \$1,051 and \$221, respectively, were recorded in research and development and other income. Amounts earned in excess of the Company's expected costs for the project for project management are recognized straight-line in other income over the term of the government contract. The Company recognized \$561 of such income, which is reported as other income in the Company's consolidated statement of operations for both the three months ended March 31, 2023 and 2022.

The balances corresponding to government contracts included in the Company's consolidated balance sheet are as follows:

	March 31, 2023	December 31, 2022
Other current assets:		
Billed receivables	\$ 17,792	\$ —
Unbilled receivables	13,604	27,013
Total other current assets	31,396	27,013
Accrued expenses and other current liabilities	\$ (679)	\$ (318)

The activity corresponding to the government contracts included in the Company's consolidated statements of cash flows is as follows:

	March 31, 2023	December 31, 2022
Cost of assets, cumulative	\$ 86,126	\$ 83,359
Reduction for funding earned to date, not yet received	(25,264)	(22,497)
Reduction for funding received to date	(60,862)	(60,862)
Total property, plant and equipment, net	\$ —	\$ —

3. Inventories

	March 31, 2023	December 31, 2022
Raw materials	\$ 35,607	\$ 42,445
Work in process	2,182	2,335
Finished goods	39,400	50,924
	\$ 77,189	\$ 95,704

4. Property, Plant and Equipment, net

	March 31, 2023	December 31, 2022
Land	\$ 1,118	\$ 1,118
Buildings and improvements	35,626	35,582
Machinery and equipment	61,827	60,725
Computer equipment and software	16,917	16,681
Furniture and fixtures	4,068	4,064
Construction in progress	10,187	11,124
	129,743	129,294
Accumulated depreciation	(72,400)	(69,881)
	\$ 57,343	\$ 59,413

During the three months ended March 31, 2023, the Company determined several manufacturing lines will not be utilized due to changes in forecasted demand for the products the equipment is intended to produce. As a result of this decision, the Company determined that the carrying values of the equipment is not recoverable and recorded an aggregate pre-tax asset impairment charge of \$1,105 during the three months ended March 31, 2023. This charge is reported within loss on impairments in the consolidated statement of operations.

The Company estimated the fair value of the impaired long-lived assets using a market approach, which required the Company to estimate the value that would be received for the equipment in the principal or most advantageous market for that equipment in an orderly transaction between market participants. Due to the extremely specialized nature of the manufacturing equipment and various market data points, the estimated fair value was zero.

5. Accrued Expenses and other current liabilities

	<u>March 31,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
Payroll and related benefits	\$ 7,989	\$ 14,103
Professional fees	7,981	4,685
Sales tax payable	1,512	1,519
Other	5,191	5,455
	<u>\$ 22,673</u>	<u>\$ 25,762</u>

6. Termination Benefits

On February 14, 2023, the Company announced a reduction in its non-production workforce. This was accounted for pursuant to Accounting Standards Codification ("ASC") 420, *Exit or Disposal Cost Obligations*.

The expense included in the Company's consolidated statements of operations are as follows:

	<u>Three Months Ended March 31, 2023</u>
Cost of products and services sold	\$ 35
Research and development	566
Sales and marketing	1,448
General and administrative	586
Total	<u>\$ 2,635</u>

As of March 31, 2023, the Company had \$1,894 accrued and had paid \$741 related to the reduction in workforce.

7. Revenues

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

	<u>Three Months Ended March 31,</u>	
	<u>2023</u>	<u>2022</u>
COVID-19 ⁽¹⁾	\$ 118,409	\$ 31,032
HIV	13,904	8,166
Molecular Products ⁽²⁾	12,942	17,933
HCV	3,186	3,257
Risk assessment testing	2,628	2,560
Molecular Services	1,379	1,733
Other product and service revenues	466	555
Net product and services revenues	152,914	65,236
Other non-product revenues ⁽³⁾	2,049	2,471
Net revenues	<u>\$ 154,963</u>	<u>\$ 67,707</u>

(1) Includes COVID-19 Diagnostics and COVID-19 Molecular Products.

(2) Includes Genomics and Microbiome and Novosanis Products.

(3) Other non-product and services revenues include funded research and development contracts, royalty income, and grant revenues.

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,	
	2023	2022
United States	\$ 145,019	\$ 57,987
Europe	1,852	4,286
Other regions	8,092	5,434
	<u>\$ 154,963</u>	<u>\$ 67,707</u>

Customer and Vendor Concentrations. At March 31, 2023, one non-commercial customer accounted for 77% of the Company's consolidated accounts receivable. The same non-commercial customer accounted for more than 57% of the Company's consolidated accounts receivable as of December 31, 2022. The same non-commercial customer also accounted for 78% and 18% of net consolidated revenues for the three months ended March 31, 2023 and 2022, respectively.

The Company currently purchases certain products and critical components of its products from sole-supply vendors. If these vendors are unable or unwilling to supply the required components and products, the Company could be subject to increased costs and substantial delays in the delivery of its products to its customers. Third-party suppliers also manufacture certain products. The Company's inability to have a timely supply of any of these components and products could have a material adverse effect on its business, as well as its financial condition and results of operations.

Deferred Revenue. The Company records deferred revenue when funds are received prior to the recognition of the associated revenue. Deferred revenue as of March 31, 2023 and December 31, 2022 included customer prepayments of \$1,358 and \$1,180, respectively. Deferred revenue as of March 31, 2023 and December 31, 2022 also included \$631 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.

8. Income Taxes

During the three months ended March 31, 2023 and 2022, the Company recorded income tax expense (benefit) of \$(225) and \$3,936, respectively. Income taxes for 2023 is comprised of a U.S. state tax benefit. Income taxes for the first quarter of 2022 are primarily comprised of Canadian withholding tax on the repatriation of \$65,000 of unremitted earnings from Canada to the United States with the remainder of tax primarily consisted of foreign tax expense. The decline in foreign tax expense in 2023 compared to 2022 is a result of the decrease in projected income before taxes expected to be generated by the Company's Canadian subsidiary.

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 the Company's total deferred tax liability as of March 31, 2023 and December 31, 2022 relate to the tax effects of the basis difference between the intangible assets acquired in its acquisitions for financial reporting and for tax purposes along with basis differences arising from accelerated tax depreciation of fixed assets.

A valuation allowance is recorded to the extent it is more likely than not that the some portion or all of the deferred tax assets will not be realized. A full valuation allowance was recorded on the Company's U.S. deferred tax assets as of March 31, 2023 and December 31, 2022.

9. Income (Loss) Per Share

Basic income (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.

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, 2023, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 2,237 shares were excluded from the computation of dilute earnings per share as their inclusion would have been anti-dilutive.

10. Stockholders' Equity

Reconciliation of the changes in stockholder's equity for the three months ended March 31, 2023 and 2022.

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balance at December 31, 2022	72,734	\$ —	\$ 520,446	\$ (18,435)	\$ (137,586)	\$ 364,425
Common stock issued upon exercise of options	12	—	66	—	—	66
Vesting of restricted stock and performance stock units	737	—	—	—	—	—
Purchase and retirement of common shares	(229)	—	(1,203)	—	—	(1,203)
Stock-based compensation	—	—	2,655	—	—	2,655
Net income	—	—	—	—	27,219	27,219
Currency translation adjustments	—	—	—	797	—	797
Unrealized gain on marketable securities	—	—	—	220	—	220
Balance at March 31, 2023	<u>73,254</u>	<u>\$ —</u>	<u>\$ 521,964</u>	<u>\$ (17,418)</u>	<u>\$ (110,367)</u>	<u>\$ 394,179</u>
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	—	—	—	—	(19,940)	(19,940)
Currency translation adjustments	—	—	—	1,756	—	1,756
Unrealized gain on marketable securities	—	—	—	74	—	74
Balance at March 31, 2022	<u>72,307</u>	<u>\$ —</u>	<u>\$ 513,553</u>	<u>\$ (8,247)</u>	<u>\$ (140,393)</u>	<u>\$ 364,913</u>

11. Business Segments

The Company is organized on the basis of products and services under a new organizational structure. All products and services reside under the same reporting hierarchy. Historically there was separate management leading the Company's Diagnostics and Molecular Solutions businesses. In February 2023 the Company announced a corporate restructuring to combine the commercial and innovation teams across the Diagnostics and Molecular Solutions segments into one operating segment with sales, marketing, product development and research teams covering all product lines and reporting to a Chief Product Officer. Resources are allocated and performance is assessed on a consolidated basis by our Chief Executive Officer, whom we have determined to be our Chief Operating Decision Maker ("CODM"). The CODM reviews the business based on individual product success. Therefore, our historical reportable segments, Diagnostics and Molecular Solutions are now considered one reportable segment and there will no longer be a distinction between Diagnostics and Molecular Solutions, only the Company holistically.

12. Commitments and Contingencies

Litigation

From time to time, the Company is 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 the Company's future financial position or results of operations.

In March 2021, the Company 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 the Company's patent and that the Company's patent is invalid. In August 2021, the Company amended its complaint to add a second patent to this litigation. Spectrum responded to the Company's amended complaint and asserted counterclaims for inequitable conduct and antitrust violations with respect to one of the patents in the litigation and subsequently filed a request for review of the second patent at the Patent and Trademark Office ("PTO"), which was granted by the PTO. On May 2, 2023, the District Court issued two orders. First, the District Court granted Spectrum's motion for summary judgment of noninfringement, holding that Spectrum's saliva collection devices are not "kits for collecting and preserving a biological sample," among other rulings. The Company intends to appeal the Court's grant of summary judgment. Second, the Court denied Spectrum's motion to supplement its allegations of alleged antitrust violations. A separate motion by Spectrum to amend its counterclaims remains pending. An inter partes review is currently pending before the PTO regarding the second asserted patent. The final pretrial conference in the District Court is set for October 26, 2023.

13. Subsequent Events

In May 2023, the Company announced a reduction in its workforce and estimates the expense will be in the range of \$500 to \$600. This will be accounted for pursuant to ASC 420, *Exit or Disposal Cost Obligations*.

Item 2. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with (i) our unaudited condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and (ii) our audited consolidated financial statements and related notes and management’s discussion and analysis of financial condition and results of operations included in our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the Securities and Exchange Commission on March 3, 2023. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and impact and potential impacts on our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including, without limitation, those factors set forth in the “Risk Factors” section of our Annual Report on Form 10-K for the year ended December 31, 2022 and the “Risk Factors” section of subsequent Quarterly Reports on Form 10-Q, our actual results or timing of certain events could differ materially from the results or timing described in, or implied by, these forward-looking statements.

Business Overview

The overall goal of the Company is to empower the global community to improve health and wellness by providing access to accurate essential information through effortless tests, collection kits and services. In 2022, our business previously consisted of two segments: our “Diagnostics” segment, and our “Molecular Solutions” segment. In February 2023, we announced a corporate restructuring to combine the commercial and innovation teams across the two segments into one business unit with sales, marketing, product development and research teams covering multiple product lines. This change is intended to accelerate innovation, enhance customer experience and result in operational synergies.

The Company's business consists of the development, manufacture, marketing and sale of simple, easy to use diagnostic products and specimen collection devices using the Company's proprietary technologies, as well as other diagnostic products including immunoassays and other *in vitro* diagnostic tests that are used on other specimen types. The Company's diagnostic products 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. The Company's 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.

The Company's business also includes molecular collection kits and services used by clinical laboratories, direct-to-consumer laboratories, researchers, pharmaceutical companies, and animal health service and product providers. These revenues are derived from product sales to commercial customers and sales into the academic and research markets. Customers span the disease risk management, diagnostics, pharmaceutical, biotech, companion animal and environmental markets. The Company has also developed collection devices for the emerging microbiome market, which focuses on studying microbiomes and their effect on human and animal health. The Company also has a urine collection device which allows 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. Additionally, the Company 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.

Results of Operations

Three months ended March 31, 2023 compared to March 31, 2022

CONSOLIDATED NET REVENUES

The table below shows an outline of total consolidated net revenues (dollars in thousands) for the three months ended March 31, 2023 and 2022:

	Three Months Ended March 31,					
	Dollars			Percentage of Total Net Revenues		
	2023	2022	% Change	2023	2022	
COVID-19 Diagnostics	\$ 118,254	\$ 22,136	434 %	76 %	33 %	
Diagnostics ⁽¹⁾	17,090	11,423	50	11	17	
Molecular Products	12,942	17,933	(28)	8	26	
Other products and services ⁽²⁾	3,094	3,115	(1)	2	5	
Molecular Services	1,379	1,733	(20)	1	3	
COVID-19 Molecular Products	155	8,896	(98)	1	12	
Net product and services revenues	152,914	65,236	134	99	96	
Non-product and services revenues	2,049	2,471	(17)	1	4	
Net revenues	\$ 154,963	\$ 67,707	129 %	100 %	100 %	

(1) Includes HIV and HCV product revenues.

(2) Includes Risk assessment testing and other product and services revenues.

Product and Services Revenues

Consolidated net product and services revenues increased 134% to \$152.9 million for the three months ended March 31, 2023 from \$65.2 million for the three months ended March 31, 2022. The Company expects total net product and services revenues to taper off throughout 2023 as demand for its COVID-19 Diagnostic product has declined.

COVID-19 Diagnostics revenues increased by 434% to \$118.3 million for the three months ended March 31, 2023 compared to \$22.1 million in the three months ended March 31, 2022 due to increased sales of the Company's IntelliSwab[®] tests through its government procurement contracts.

Sales of the Company's Diagnostics products increased 50% to \$17.0 million for the three months ended March 31, 2023 from \$11.4 million for the three months ended March 31, 2022. This increase in revenues was primarily driven by higher sales of the Company's OraQuick[®] In-Home HIV tests in support of the CDC's "Together Take Me Home" HIV self-test program which commenced during the first quarter of 2023 and higher sales of the Company's OraQuick[®] HIV Self-Test in the international markets due to customer ordering patterns.

Molecular Products revenues decreased 28% to \$12.9 million for the three months ended March 31, 2023 from \$17.9 million for the three months ended March 31, 2022. Sales of the Company's Molecular Products are being impacted by macro-economic factors in the markets in which its customers operate. One of the Company's largest customer scaled down purchasing after they reorganized their business in the second half of 2022 and certain other customers placed large orders in Q1 2022 which did not repeat in the first quarter of 2023. Furthermore revenues are impacted by customer ordering patterns whereby customers purchased at the end of 2022 and did not require further inventory in the first quarter of 2023.

Other products and services revenues were largely flat at \$3.1 million for the three months ended March 31, 2023 and 2022.

Molecular Services revenues, which are largely derived from the Company's laboratory services, decreased 20% to \$1.4 million for the three months ended March 31, 2023 from \$1.7 million for the three months ended March 31, 2022. The decline in services revenues was the direct result of loss of two large customers in 2022. One customer ceased operations in 2022 and the other deprioritized microbiome studies.

Sales of the Company's COVID-19 Molecular Products collection kits decreased significantly by 98% to \$0.2 million for the three months ended March 31, 2023 from \$8.9 million for the three months ended March 31, 2022 due to decline in demand for COVID PCR testing given the availability of rapid antigen tests.

Non-product and Services Revenues

Non-product and services revenues decreased 17% to \$2.0 million for the three months ended March 31, 2023 from \$2.5 million for the three months ended March 31, 2022 as a result the timing of activities under the Company's funded research and development agreements for the development of a second generation Ebola test and to obtain 510(k) clearance and CLIA waiver for our IntelliSwab® test coupled with lower royalty income.

CONSOLIDATED OPERATING RESULTS

Consolidated gross profit margin increased to 42.5% for the three months ended March 31, 2023 and 2022 from 36% for the three months ended March 31, 2022. This improvement in margins was driven by IntelliSwab® sales which generated higher margins due to reduced costs associated with the correction of manufacturing inefficiencies which occurred during the first quarter of 2022, a packaging change implemented during the first quarter of 2023, and lower freight charges. These improved margins were partially offset by lower COVID-19 Molecular Products revenue which historically generated higher margins. Lower scrap expense in the first quarter of 2023 compared to the first quarter of 2022 also contributed to the improved margins.

Consolidated operating income for the three months ended March 31, 2023 was \$24.3 million, a \$40.5 million increase from the \$16.2 million operating loss reported for the three months ended March 31, 2022. Results for the three months ended March 31, 2023 were positively impacted by the increase in revenues and gross margins described above and were partially offset by impairment charges of \$1.1 million taken for idle manufacturing lines.

Operating expenses in the first quarter of 2023, excluding the impairment charge, remained largely flat compared to the first quarter of 2022. Research and development expenses increased 22% to \$10.6 million for the three months ended March 31, 2023 from \$8.6 million for the three months ended March 31, 2022 largely due to an increase in clinical study activities related to obtaining 510(k) clearance and CLIA waiver for our IntelliSwab® rapid test, severance costs associated with our reduction in workforce that occurred during the quarter and higher costs incurred under our DOD expansion contract. Increased spend in research and development was offset by lower sales and marketing and general and administrative costs.

Sales and marketing expenses decreased 5% to \$12.1 million for the three months ended March 31, 2023 from \$12.7 million for the three months ended March 31, 2022 due to a decrease in our reserve for expected credit losses and lower consulting fees offset by severance cost related to our reduction in workforce. General and administrative expenses decreased 8% to \$17.7 million for the three months ended March 31, 2023 from \$19.2 million for the three months ended March 31, 2022 largely due to lower consulting fees, stock compensation expense and recruitment fees. In the first quarter of 2022, the company incurred high stock compensation expense associated with the accelerated vesting of shares under our former CEO's employment agreement and higher recruitment expense associated with the new CEO search. These decreases in expense were partially offset by increased legal fees and severance costs associated with the reduction in workforce.

All of the above contributed to the Company's operating income of \$24.3 million for the three months ended March 31, 2023, which included the non-cash impairment charge of \$1.1 million related to equipment that will no longer be used in production, non-cash charges of \$3.7 million for depreciation and amortization and \$2.7 million for stock-based compensation. The Company's operating loss of \$16.2 million for the three months ended March 31, 2022 included non-cash charges of \$3.7 million for depreciation and amortization and \$3.5 million for stock-based compensation.

Other income for the three months ended March 31, 2023 was \$2.7 million compared to \$0.2 million for the months ended March 31, 2022. This increase is largely due to the reimbursement of costs incurred under our DOD expansion contract which are presented in research and development expenses as discussed above.

CONSOLIDATED INCOME TAXES

The Company continues to believe the full valuation allowance established against its 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, 2023, the Company recorded a U.S. state tax benefit of \$0.2 million compared to \$3.9 million of tax expense for the three months ended March 31, 2022. The 2022 tax expense is comprised of U.S. state tax expense of \$0.2 million, \$1.7 million of withholding taxes associated with our repatriation of \$65.0 million of cash from Canada to the United States, and Canadian income tax expense of \$2.0 million. No foreign taxes were recorded for the three months ended March 31, 2023 due to it being more likely than not that the Canadian subsidiary will not produce sufficient income to receive a tax benefit for the year to date loss.

Liquidity and Capital Resources

	March 31, 2023	December 31, 2022
	(In thousands)	
Cash and cash equivalents	\$ 90,194	\$ 83,980
Available-for-sale securities	22,178	26,867
Working capital	288,472	256,127

The Company's cash and cash equivalents and available-for-sale securities increased to \$112.4 million at March 31, 2023 from \$110.8 million at December 31, 2022. \$72.8 million or 65% of the \$112.4 million in cash, cash equivalents and available-for-sale securities is held by DNAG, the Company's Canadian subsidiary. In 2022, the Company repatriated \$65.0 million of cash into the United States and incurred \$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 still the Company's intention going forward to continue to permanently reinvest the historical undistributed earnings of our foreign subsidiaries.

The Company's working capital increased to \$288.5 million at March 31, 2023 from \$256.1 million at December 31, 2022. Working capital increased primarily due to increased accounts receivable of \$36.6 million. Working capital is primarily a function of sales, purchase volumes, inventory requirements, and vendor payment terms.

Analysis of Our Cash Flows

Operating Activities

During the three months ended March 31, 2023, net cash provided by operating activities was \$6.0 million. Cash flows from operations can be significantly impacted by factors such as timing of receipt from customers, inventory purchases, and payments to vendors. The Company's net income of \$27.2 million included non-cash charges of depreciation and amortization expense of \$3.7 million, stock-based compensation expense of \$2.7 million, and impairment charges taken for idle equipment of \$1.1 million. Cash used to fund the working capital accounts included an increase in accounts receivable of \$36.6 million largely associated with product shipped to the U.S. government at the end of the first quarter 2023, a decrease in accounts payable of \$12.1 million due to reduced inventory purchasing and the timing of payments made and invoices received, and a decrease in accrued expenses of \$3.5 million largely associated with the payment of the Company's 2022 year-end bonuses. Offsetting these uses of cash was a decrease in inventory of \$18.5 million as demand for the Company's IntelliSwab[®] COVID-19 rapid test is declining, and a \$5.3 million decrease in prepaid and other assets as the Company received payment of its Employee Retention Credit filed for in 2021.

Investing Activities

Net cash used in investing activities was \$1.0 million for the three months ended March 31, 2023, which reflects proceeds from the maturities of investments of \$27.3 million offset by \$22.3 million used to purchase investments, \$2.8 million to build additional manufacturing capacity as required by the \$109 million agreement with the DOD and, \$1.2 million to acquire property and equipment to support the normal operations of the business.

Financing Activities

Net cash used in financing activities was \$1.3 million for the three months ended March 31, 2023, which is largely comprised of \$1.2 million used for the repurchase of common stock to satisfy withholding taxes related to the vesting of restricted shares awarded to the Company's employees.

Resources

The Company expects existing cash and cash equivalents and available-for-sale securities will be sufficient to fund its operating expenses and capital expenditure requirements over the next twelve months. The Company's cash requirements, however, may vary materially from those now planned due to many factors, including, but not limited to, the timing of reimbursement under its \$109 million DOD contract, the scope and timing of future strategic acquisitions, the progress of its 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.

A summary of the Company's obligations to make future payments under contracts existing at December 31, 2022 is included in Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations, of its Annual Report on Form 10-K for the year ended December 31, 2022. As of March 31, 2023, there were no significant changes to this information.

Critical Accounting Policies and Estimates

A more detailed review of the Company's critical accounting policies is contained in its Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC. No material changes have been made to such critical accounting policies during the three months ended March 31, 2023.

CAUTIONARY NOTICE ABOUT FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 2 of Part I of this report, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Exchange Act. Some of these statements can be identified by the use of terminology such as "believes," "expects," "anticipates," "may," "will," "should," "seeks," "approximately," "intends," "projects," "plans," "estimates," or the negative of these words and other comparable terminology. The discussion of financial trends, strategy, plans, assumptions, or intentions may also include forward-looking statements. Readers should not place undue reliance on forward-looking statements, which speak only as of the date such statements were first made. Except to the extent required by law, we undertake no obligation to update or revise our forward-looking statements. Forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from those projected, anticipated, or implied. Although it is not possible to predict or identify all such risks and uncertainties, they include, but are not limited to, factors described in the Risk Factors discussion in Item 1A of Part I of our most recently filed Annual Report.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There has been no material change in the Company's assessment of its sensitivity to market risk since its presentation set forth in Item 7A, "Quantitative and Qualitative Disclosures About Market Risk," in its Annual Report on Form 10-K for the year ended December 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, 2023. 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, 2023 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, 2023 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, the Company is 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 the Company's future financial position or results of operations.

Spectrum Patent Litigation

In March 2021, the Company 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 the Company's patent and that the Company's patent is invalid. In August 2021, the Company amended its complaint to add a second patent to this litigation. Spectrum responded to the Company's amended complaint and asserted counterclaims for inequitable conduct and antitrust violations with respect to one of the patents in the litigation and subsequently filed a request for review of the second patent at the Patent and Trademark Office ("PTO"), which was granted by the PTO. On May 2, 2023, the District Court issued two orders. First, the District Court granted Spectrum's motion for summary judgment of noninfringement, holding that Spectrum's saliva collection devices are not "kits for collecting and preserving a biological sample," among other rulings. The Company intends to appeal the Court's grant of summary judgment. Second, the Court denied Spectrum's motion to supplement its allegations of alleged antitrust violations. A separate motion by Spectrum to amend its counterclaims remains pending. An inter partes review is currently pending before the PTO regarding the second asserted patent. The final pretrial conference in the District Court is set for October 26, 2023.

Item 1A. RISK FACTORS

There have been no material changes to the risk factors disclosed in Item 1A, entitled "Risk Factors," in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, other than as set forth below.

Conditions in the banking system and financial markets, including the failure of banks and financial institutions, could have an adverse effect on our operations and financial results.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10 and March 12, 2023, the Federal Deposit Insurance Corporation took control and was appointed receiver of Silicon Valley Bank, and Signature Bank and Silvergate Capital Corp, respectively, after each bank was unable to continue their operations. Since then, additional financial institutions have experienced similar failures and have been placed into receivership. It is possible that other banks will face similar difficulty in the future.

Although we do not maintain any deposit accounts, credit agreements or letters of credit with any financial institution currently in receivership, we are unable to predict the extent or nature of the impacts of these evolving circumstances at this time. If, for example, other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash, cash equivalents and investments may be threatened. While it is not possible at this time to predict the extent of the impact that the failure of these financial institutions or the high market volatility and instability of the banking sector could have on economic activity and our business in particular, the failure of other banks and financial institutions and the measures taken by governments, businesses and other organizations in response to these events could adversely impact our business, financial condition and results of operations.

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, 2023-January 31, 2023	158,726 ⁽³⁾	\$ 5.64	—	11,984,720
February 1, 2023-February 28, 2023	70,685 ⁽³⁾	5.14	—	11,984,720
March 1, 2023-March 31, 2023	— ⁽³⁾	—	—	11,984,720
	<u>229,411</u>		<u>—</u>	

- (1) On August 5, 2008, the Company's Board of Directors approved a share repurchase program pursuant to which the Company is 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. The Company has 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
3.1*	<u>Second Amended and Restated Bylaws of OraSure Technologies, Inc., as of May 9, 2023.</u>
31.1*	<u>Certification of Carrie Eglinton-Manner required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.</u>
31.2*	<u>Certification of Kenneth J. McGrath required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.</u>
32.1**+	<u>Certification of Carrie Eglinton-Manner required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
32.2**+	<u>Certification of Kenneth J. McGrath 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.</u>
101.INS	Inline XBRL Instance Document – the Instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
Exhibit 104	Cover Page from the Company’s Quarterly Report on Form 10-Q for the Quarter Ended September 30, 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.

Date: May 10, 2023

/s/ Kenneth J. McGrath

Kenneth J. McGrath
Chief Financial Officer
(Principal Financial Officer)

Date: May 10, 2023

/s/Michele M. Anthony

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

**SECOND AMENDED AND RESTATED BYLAWS
OF
ORASURE TECHNOLOGIES, INC.**

Effective as of May 9, 2023

**ARTICLE I
Name and Location**

SECTION 1. Name.

The name of the Corporation shall be the name set forth in the Certificate of Incorporation.

SECTION 2. Principal Office.

The principal office of the Corporation is located at 220 East First Street, Bethlehem, Pennsylvania 18015-1360.

SECTION 3. Additional Offices.

Other offices for the transaction of business of the Corporation may be located at such place or places as the Board of Directors may from time to time determine.

**ARTICLE II
Capital Stock**

SECTION 1. Shares of Stock.

The shares of the capital stock of the Corporation shall be represented by a certificate, unless and until the Board of Directors of the Corporation adopts a resolution permitting shares to be uncertificated. Notwithstanding the adoption of any such resolution providing for uncertificated shares, every holder of capital stock of the Corporation theretofore represented by certificates shall be entitled to continue to hold such certificates until surrender to the Corporation, and, upon written request to the transfer agent or registrar of the Corporation, every holder of uncertificated shares shall be entitled to receive and hold a certificate for shares of capital stock of the Corporation signed by, or in the name of, the Corporation, by (a) the Chairman of the Board of Directors, the Chief Executive Officer, the President or any Vice President of the Corporation, and (b) the Treasurer or an Assistant Treasurer or the Secretary or an Assistant Secretary of the Corporation, certifying the number of shares owned by such stockholder in the Corporation and sealed with the corporate seal.

SECTION 2. Stock Transfers.

Stock of the Corporation shall be transferable in the manner prescribed by applicable law and in these Bylaws. Transfers of stock shall be made on the books of the Corporation, and (a) in the case of certificated shares of stock, only by the person named in the certificate or by such person's attorney lawfully constituted in writing and upon the surrender of the certificate therefor, properly endorsed for transfer and payment of all necessary transfer taxes; or (b) in the case of uncertificated shares of stock, upon receipt of proper transfer instructions from the registered holder of the shares or by such person's attorney lawfully constituted in writing, and upon payment of all necessary transfer taxes and compliance with appropriate procedures for transferring shares in uncertificated form; provided, however, that such surrender and endorsement, payment of taxes or compliance shall not be required in any case in which the officers of the Corporation shall determine to waive such requirement. With respect to certificated shares of stock, every certificate exchanged, returned or surrendered to the Corporation shall be marked "Cancelled," with the date of cancellation, by the Secretary or Assistant Secretary of the Corporation or the transfer agent thereof. No transfer of stock shall be valid as against the Corporation for any purpose until it shall have been entered in the stock records of the Corporation by an entry showing from and to whom transferred.

SECTION 3. Lost or Destroyed Stock Certificates.

A new certificate of stock may be issued in the place of any certificate theretofore issued, alleged to have been lost or destroyed, and the Corporation may, in its discretion, require the owner of the lost or destroyed certificate, or its legal representative, to give a bond sufficient to indemnify the Corporation against any claim that may be made against it on account of the alleged loss of any certificate; provided, however, that if such shares have ceased to be certificated, a new certificate shall be issued only upon written request by the owner to the transfer agent or registrar of the Corporation.

SECTION 4. Preemptive Rights Denied.

No holder of shares of any class of the Corporation, or holder of any securities or obligations convertible into shares of any class of the Corporation, shall have any preemptive right whatsoever to subscribe for, purchase or otherwise acquire shares of the Corporation of any class, whether now or hereafter authorized; provided, however, that nothing in this Section 4 shall prohibit the Corporation from granting, contractually or otherwise, to any such holder, the right to purchase additional securities of the Corporation.

ARTICLE III Stockholders' Meetings

SECTION 1. Annual Meeting.

The annual meeting of the stockholders of the Corporation shall be held, either within or without the State of Delaware, on such date and at such time as may from time to time be determined by the Board of Directors. At such meeting the stockholders shall elect directors in the manner provided in the Certificate of Incorporation of the Corporation. The stockholders may transact such other business at such annual meetings as may properly come before the meeting.

SECTION 2. Special Meeting.

A special meeting of the holders of any one or more classes of the capital stock of the Corporation entitled to vote as a class or classes with respect to any matter, as required by law or as provided by the Certificate of Incorporation, may be called at any time and place, either within or without the state of Delaware, only by the Chairman of the Board, the Chief Executive Officer, the President or the Board of Directors.

SECTION 3. Notice.

Notice of the time and place of all annual meetings and of the time, place and purpose of all special meetings shall be mailed by the Secretary to each stockholder at his or her last known post office address as it appears on the records of the Corporation at least ten (10) days before the date set for such meeting.

SECTION 4. Nomination of Directors.

Nomination of persons for election to the Board of Directors of the Corporation at a meeting of the stockholders may be made by or at the direction of the Board of Directors or may be made at a meeting of stockholders by any stockholder of the Corporation who is a stockholder of record at the time of giving of notice provided for in this Section 4 and at the time of the meeting is entitled to vote for the election of Directors at the meeting and complies with the notice procedures set forth in this Section 4 of ARTICLE III. Such nomination, other than those made by or at the direction of the Board of Directors, shall be made pursuant to timely notice in writing to the Secretary of the Corporation. To be timely, a stockholder's notice shall be delivered to or mailed and received at the principal executive offices of the Corporation not less than ninety (90) days nor more than one hundred twenty (120) days prior to the meeting; provided, however, that in the event that less than one hundred (100) days' notice or prior public disclosure of the date of the meeting is given or made to stockholders, notice by the stockholder to be timely must be so received no later than the close of business on the tenth (10th) day following the day on which such notice of the date of the meeting was mailed or such public disclosure was made, whichever first occurs. In no event

shall any adjournment or postponement of an annual meeting or the announcement thereof commence a new time period for the giving of a stockholder's notice as described above. Such stockholder's notice to the Secretary shall set forth: (a) as to each person whom the stockholder proposes to nominate for election or re-election as a Director, (i) the name, age, business address and residence address of the person, (ii) the principal occupation or employment of the person, (iii) the class and number of shares of capital stock of the Corporation which are beneficially owned or owned of record by the person, and (iv) any other information relating to the person that is required to be disclosed in solicitations for proxies for election of Directors pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended (the "Exchange Act") (including such person's written consent to being named in the proxy statement as a nominee and to serving as a Director, if elected); and (b) as to the stockholder giving the notice and the beneficial owner, if any, on whose behalf the nomination is made: (i) the name and address of the stockholder, as they appear in the Corporation's books and records, and of such beneficial owner; (ii) the class and number of shares of capital stock of the Corporation which are held of record or beneficially owned by such stockholder and such beneficial owner and any other direct or indirect pecuniary or economic interest in any capital stock of the Corporation of such stockholder and such beneficial owner, including without limitation, any derivative instrument, swap, option, warrant, short interest, hedge, profit sharing arrangement or borrowed or loaned shares; (iii) a description of any arrangements or understandings between such stockholder and each proposed nominee and any other person (including their names) pursuant to which the nomination(s) are to be made by such stockholder and such beneficial owner or with respect to actions to be proposed or taken by such nominee if elected as a Director; (iv) a representation that such stockholder intends to appear in person or by proxy at the meeting to nominate the persons named in its notice; (v) a statement whether either such stockholder and/or the other Proposing Person(s) (as defined below), if any, intends to (a) deliver a proxy statement and form of proxy to holders of, in the case of a proposal, at least the percentage of the voting power of all of the shares of capital stock of the Corporation required under applicable law to carry the proposal or, in the case of a nomination or nominations, at least 67 percent of the voting power of all of the shares of capital stock of the Corporation entitled to vote on the election of directors or (b) otherwise solicit proxies in support of director nominees other than the Corporation's director nominees in accordance with Rule 14a-19 promulgated under the Exchange Act. Notwithstanding the foregoing, if a Proposing Person or Nominating Person no longer plans to solicit proxies in accordance with its representation pursuant to this Section 4 of ARTICLE III, such Proposing Person or Nominating Person shall inform the Corporation of this change by delivering a written notice to the Secretary at the principal executive offices of the Corporation no later than two (2) business days after making the determination not to proceed with a solicitation of proxies. The term "Nominating Person" shall mean (a) the stockholder providing the notice of nomination proposed to be made at the meeting, (b) the beneficial owner or beneficial owners, if different, on whose behalf the notice of the nomination proposed to be made at the meeting is made, and (c) any other participant in such solicitation. The term "Proposing Person" shall mean (a) the stockholder providing the notice of business proposed to be brought before an annual meeting, (b) the beneficial owner or beneficial owners, if different, on whose behalf the notice of the business proposed to be brought before the annual meeting is made, and (c) any other participant in such solicitation and (vi) any other information relating to such stockholder and such beneficial owner that would be required to be disclosed in a proxy statement or other filings required to be made in connection with solicitations of proxies for election of Directors, or may otherwise be required, in each case pursuant to Section 14 of the Exchange Act and the rules and regulations promulgated thereunder. The Corporation may require any proposed nominee to furnish such other information as may reasonably be required by the Corporation to determine the eligibility of such proposed nominee to serve as a Director of the Corporation. No person shall be eligible for election as a Director of the Corporation at a meeting of the stockholders unless such person has been nominated in accordance with the procedures set forth herein. If the facts warrant, the Chairman of the meeting shall determine and declare to the meeting that a nomination does not satisfy the requirements set forth in the preceding sentence and the defective nomination shall be disregarded, notwithstanding that proxies in respect of such nomination may have been received by the Corporation. If the facts warrant, the Chairman of the meeting shall determine and declare to the meeting that a nomination fails to comply with any applicable requirements of the Exchange Act, including, but not limited to, Rule 14a-19 promulgated thereunder, such stockholder's proposed nomination shall be deemed to have not been made in compliance with these Bylaws and shall be disregarded. The requirements of this Section 4 of ARTICLE III shall apply to any nomination of a person for election as a Director, whether such nominee is to be included in the Corporation's proxy statement pursuant to Rule 14a-8 (or any successor provision) of the Exchange Act or presented to stockholders by means of an independently financed proxy solicitation. Further notwithstanding the foregoing provisions of these Bylaws, unless otherwise required by law, if any Nominating Person (A) provides notice pursuant to Rule 14a-19(b) promulgated under the Exchange Act, (B) subsequently fails to comply with the requirements of Rule 14a-19(a)(2) or Rule 14a-19(a)(3) promulgated under the Exchange Act, including the

provision to the Corporation of notices required thereunder with timely notice, and (C) no other Nominating Person has provided notice pursuant to, and in compliance with, Rule 14a-19 under the Exchange Act that it intends to solicit proxies in support of the election of such proposed nominee in accordance with Rule 14a-19(b) under the Exchange Act, then such proposed nominee shall be disqualified from nomination, the Corporation shall disregard the nomination of such proposed nominee, and no vote on the election of such proposed nominee shall occur. Upon request by the Corporation, if any Nominating Person provides notice pursuant to Rule 14a-19(b) promulgated under the Exchange Act, such Nominating Person shall deliver to the Corporation, no later than five (5) business days prior to the applicable meeting date, reasonable evidence that it has met the requirements of Rule 14a-19(a)(3) promulgated under the Exchange Act. Nothing in this Section 4 shall be deemed to affect any right of a stockholder to request inclusion of a proposal in, nor the right of the Corporation to omit a proposal from, the Corporation's proxy statement pursuant to Rule 14a-8 (or any successor provision) under the Exchange Act. Nothing in this Section 4 shall be construed to affect the requirements for proxy statements of the Corporation under Regulation 14A of the Exchange Act.

SECTION 5. Presentation of Business at Stockholders' Meetings.

At any meeting of the stockholders, only such business shall be conducted as shall have been properly brought before the meeting. To be properly brought before a meeting, business must be: (a) specified in the notice of meeting (or any supplement thereto) given by or at the direction of the Board of Directors, (b) otherwise properly brought before the meeting by or at the direction of the Board of Directors, or (c) otherwise properly brought before the meeting by a stockholder who is a stockholder of record at the time of giving the notice provided for in this Section 5 and at the time of the meeting is entitled to vote at such meeting and complies with the notice procedures set forth in this Section 5 of ARTICLE III. For business to be properly brought before a meeting by such a stockholder, the stockholder must have given timely notice thereof in writing to the Secretary of the Corporation. To be timely, a stockholder's notice shall be delivered to or mailed and received at the principal executive offices of the Corporation not less than ninety (90) days nor more than one hundred twenty (120) days prior to the meeting; provided, however, that in the event that less than one hundred (100) days' notice or prior public disclosure of the date of the meeting is given or made to stockholders, notice by the stockholder to be timely must be so received no later than the close of business on the tenth (10th) day following the day on which such notice of the date of the meeting was mailed or such public disclosure was made, whichever first occurs. In no event shall any adjournment or postponement of an annual meeting or the announcement thereof commence a new time period for the giving of a stockholder's notice as described above. Such stockholder's notice to the Secretary shall set forth: (a) as to each matter the stockholder proposes to bring before the meeting, a brief description of the business desired to be brought before the meeting and the reasons for conducting such business at the meeting, and (b) as to the stockholder giving the notice and the beneficial owner, if any, on whose behalf notice of the proposed business is made: (i) the name and address of the stockholder, as they appear in the Corporation's books and records, and of such beneficial owner; (ii) any material interest of such stockholder and such beneficial holder in such business; (iii) the class and number of shares of capital stock of the Corporation which are held of record or beneficially owned by the stockholder and such beneficial owner and any other direct or indirect pecuniary or economic interest in any capital stock of the Corporation of such stockholder and such beneficial owner, including without limitation, any derivative instrument, swap, option, warrant, short interest, hedge, profit sharing arrangement or borrowed or loaned shares; (iv) a representation that such stockholder intends to appear in person or by proxy at the meeting to propose the business described in its notice; and (v) any other information relating to such business matter that would be required to be disclosed in a proxy statement or other filings required to be made in connection with solicitations of proxies pursuant to Section 14 of the Exchange Act and the rules and regulations promulgated thereunder. Notwithstanding the foregoing provisions of this Section 5 of ARTICLE III, a stockholder shall also comply with all applicable requirements of state law and of the Exchange Act and the rules and regulations thereunder with respect to the matters set forth in this Section 5. Notwithstanding anything in these Bylaws to the contrary, no business shall be conducted at a meeting of the stockholders unless proposed in accordance with the procedures set forth herein. The Chairman of the meeting shall, if the facts warrant, determine and declare to the meeting that business was not properly brought before the meeting in accordance with the foregoing procedure and such business shall not be transacted, notwithstanding that proxies in respect of such business may have been received by the Corporation. The requirements of this Section 5 of ARTICLE III shall apply to any business to be brought before a meeting by a stockholder (other than the nomination of a person for election as a Director, which is governed by Section 4 of ARTICLE III) whether such business is to be included in the Corporation's proxy statement pursuant to Rule 14a-8 (or any successor provision) of the Exchange Act or presented to stockholders by means of an independently

financed proxy solicitation. Nothing in this Section 5 shall be deemed to affect any right of a stockholder to request inclusion of a proposal in, nor the right of the Corporation to omit a proposal from, the Corporation's proxy statement pursuant to Rule 14a-8 (or any successor provision) under the Exchange Act. Nothing in these Bylaws shall require the Corporation to include in any notice, proxy statement or other mailing to stockholders any information regarding proposals made by stockholders except as otherwise required by law. To the extent this Section 5 shall be deemed by the Board of Directors or the Securities and Exchange Commission, or finally adjudged by a court of competent jurisdiction, to be inconsistent with the right of stockholders to request inclusion of a proposal in the Corporation's proxy statement pursuant to Rule 14a-8 promulgated under the Exchange Act, such rule shall prevail.

SECTION 6. Presiding Officials.

The Chairman of the Board of Directors, or in his or her absence or inability to act, the Chief Executive Officer, or in his or her absence or inability to act, the President, or in his or her absence or inability to act, any Vice President, shall preside at all stockholders' meetings.

SECTION 7. Voting.

Except as otherwise provided in the Certificate of Incorporation of the Corporation, at each meeting of the stockholders, each stockholder shall be entitled to cast one vote for each share of voting stock standing of record on the books of the Corporation, in his or her name, and may cast such vote either in person or by proxy. All proxies shall be in writing and filed with the Secretary of the meeting. Any stockholder directly or indirectly soliciting proxies from other stockholders must use a proxy card color other than white, which shall be reserved for the exclusive use by the Board of Directors.

SECTION 8. Quorum; Adjournment.

At any meeting held for the purpose of electing directors, the presence in person or by proxy of the holders of at least a majority of the then outstanding voting shares of the Corporation shall be required and be sufficient to constitute a quorum for the election of directors. At a meeting held for any purpose other than the election of directors, shares representing a majority of the votes entitled to be cast on such matter, present in person or represented by proxy, shall constitute a quorum. In the absence of the required quorum at any meeting of stockholders, a majority of such holders present in person or by proxy shall have the power to adjourn the meeting, from time to time, without notice (except as required by law) other than an announcement at the meeting, until a quorum shall be present.

SECTION 9. Annual Statement of Business.

At each of the annual stockholders' meetings, one of the executive officers of the Corporation shall submit a statement of the business done during the preceding year, together with a report of the general financial condition of the Corporation.

ARTICLE IV Directors

SECTION 1. Powers of the Board.

The business and property of the Corporation shall be managed by a Board of Directors consisting of such number of Directors as is determined from time to time in accordance with the provisions of the Certificate of Incorporation of the Corporation. The Board of Directors may elect one of their number to act as Chairman of the Board.

SECTION 2. Qualification and Election of Directors.

Each Director upon his or her election shall qualify by filing his or her written acceptance with the Secretary or an Assistant Secretary and by fulfilling any prerequisite to qualification that may be set forth in the Certificate of Incorporation of the Corporation.

At each annual meeting of stockholders, the class of Directors whose term is expiring shall be elected. In an uncontested election of Directors, provided a quorum is present, a nominee for Director shall be elected to the Board of Directors if the votes validly cast "for" such nominee's election exceed the votes validly cast "against" such nominee's election in such election (with "abstentions" and "broker nonvotes" not counted as a vote cast either for or against such nominee's election). In a contested election of Directors, provided a quorum is present, each Director will be elected by the affirmative vote of a plurality of the shares present in person or represented by proxy at any such meeting and entitled to vote on the election of Directors. An election of Directors will be considered "contested" if, as of the record date for the applicable meeting of stockholders, there are more nominees for election than positions on the Board of Directors to be filled by election at such meeting. All other elections of Directors will be considered "uncontested."

In any uncontested election of Directors, any Director nominee who does not receive the vote of the majority of shares present in person or represented by proxy at the meeting, shall, within ten (10) days following the certification of the election results, tender his or her resignation, and the Board of Directors shall decide, through a process managed by the Board committee responsible for Director nominations, whether to accept or reject the resignation, or whether other action should be taken.

SECTION 3. Annual Meetings.

The annual meeting of the Board of Directors shall be held immediately after the adjournment of each annual meeting of the stockholders and in the event a quorum is not present, said meeting shall be held within ten (10) days after adjournment upon proper notice by the Chairman of the Board of Directors, the Chief Executive Officer, the President or a Vice President.

SECTION 4. Special Meetings.

Special meetings of the Board of Directors may be called at any time or place by the Chairman of the Board, the Chief Executive Officer, or by the President, and in the absence or inability of all of them to act, by any Vice President, and may also be called by any two members of the Board of Directors. By unanimous consent of the Directors, special meetings of the Board of Directors may be held without notice, at any time and place.

SECTION 5. Notice; Telephonic Attendance; Unanimous Consent.

Notice of all regular and special meetings of the Board of Directors or the Executive Committee or any committee established pursuant to this ARTICLE IV (an "Other Committee") shall be sent to each Director or member of such committee, as the case may be, by the Secretary or any Assistant Secretary, by a means reasonably calculated to be received at least seven (7) days prior to the time fixed for such meeting, or notice of special meetings of the Board of Directors or the Executive Committee or any Other Committee may be given by telephone, telegraph, telefax or telex to each Director or member of such committee, as the case may be, at least twenty-four (24) hours prior to the time fixed for such meeting, or on such shorter notice as the person or persons calling the meeting may reasonably deem necessary or appropriate in the circumstances. To the extent provided in the notice of the meeting or as otherwise determined by the Chairman of the Board or the Board of Directors, Directors may participate in any regular or special meeting by means of conference telephone, videoconference or similar communications equipment which allows all persons participating in such meeting to hear each other, and participation in such meeting by means of such a device shall constitute presence in person at such meeting. Attendance of a director at any meeting shall constitute a waiver of notice of such meeting except where a director attends a meeting for the express purpose of objecting to the transaction of any business because the meeting is not lawfully called or convened.

If all the directors shall severally or collectively consent in writing to any action to be taken by the directors, such consents shall have the same force and effect as a unanimous vote of the directors at a meeting duly held. The Secretary shall file such consents with the minutes of the meetings of the Board of Directors.

SECTION 6. Quorum; Adjournment.

Except as otherwise provided in the Certificate of Incorporation of the Corporation, a quorum for the transaction of business at any meeting of the directors shall consist of a majority of the members of the Board of Directors, but the directors present, although less than a quorum, shall have the power to adjourn the meeting from time to time or to some future date.

SECTION 7. Election of Officers.

The directors shall elect the officers of the Corporation and fix their salaries and other compensation. Such election shall be made at the Directors' meeting following each annual stockholders' meeting.

SECTION 8. Advisers to the Board of Directors.

The Board of Directors from time to time, as they may deem proper, shall have authority to appoint a general manager, counsel or attorneys and other employees for such length of time and upon such terms and conditions and at such salaries and other compensation as they may deem necessary and/or advisable.

SECTION 9. Compensation; Reimbursement of Expenses.

The members of the Board of Directors shall receive compensation for their services in such amount as may be reasonable and proper and consistent with the time and service rendered. The members of the Board of Directors shall receive the reasonable expenses necessarily incurred in the attendance of meetings and in the transaction of business for the Corporation.

SECTION 10. Indemnification; Insurance.

(a) Indemnification.

(1) Actions Other than Those by or in the Right of the Corporation. To the extent permitted by Delaware law from time to time in effect and subject to the provisions of paragraph (c) of this Section 10, the Corporation shall indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the Corporation) by reason of the fact that such person is or was a director, officer, employee or agent of the Corporation, or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the Corporation (or such other corporation or organization), and, with respect to any criminal action or proceeding, had no reasonable cause to believe such person's conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction, or upon a plea of nolo contendere or its equivalent shall not, of itself, create a presumption that the person did not act in good faith and in a manner which such person reasonably believed to be in or not opposed to the best interests of the Corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that such person's conduct was unlawful.

(2) Action by or in the Right of the Corporation. To the extent permitted by Delaware law from time to time in effect and subject to the provisions of paragraph (c) of this Section 10, the Corporation shall indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the Corporation to procure a judgment in its favor by reason of the fact that such person is or was a director, officer, employee or agent of the Corporation or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise,

against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the Corporation (or such other corporation or organization) and except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the Corporation (or such other corporation or organization) unless and only to the extent that the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which such court shall deem proper.

(3) Successful Defense of Action. Notwithstanding, and without limitation of, any other provision of this Section 10, to the extent that a director, officer, employee or agent of the Corporation has been successful on the merits or otherwise in defense of any action, suit or proceeding referred to in sub-paragraph (1) or (2) of this paragraph (a), or in defense of any claim, issue or matter therein, such director, officer, employee or agent shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection therewith.

(4) Determination Required. Any indemnification under sub-paragraph (1) or (2) of this paragraph (a) (unless ordered by a court) shall be made by the Corporation only as authorized in the specific case upon a determination that indemnification of the director, officer, employee or agent is proper in the circumstances because such director, officer, employee or agent has met the applicable standard of conduct set forth in said sub-paragraph. Such determination shall be made: (i) by the Board of Directors by a majority vote of a quorum consisting of directors who were not parties to the particular action, suit or proceeding, or (ii) if such a quorum is not obtainable, or, even if obtainable, a quorum of disinterested directors so directs, by independent legal counsel in a written opinion, or (iii) by the stockholders.

(b) Insurance. The Corporation may, when authorized by the Board of Directors, purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the Corporation, or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against such person and incurred by such person in any such capacity, or arising out of such person's status as such, whether or not the Corporation would have the power to indemnify him against such liability under the provisions of this Section 10. The risks insured under any insurance policies purchased and maintained on behalf of any person as aforesaid or on behalf of the Corporation shall not be limited in any way by the terms of this Section 10 and to the extent compatible with the provisions of such policies, the risks insured shall extend to the fullest extent permitted by law, common or statutory.

(c) Advancement of Expenses; Nonexclusivity; Duration. Expenses (including attorneys' fees) incurred by an officer or director in defending any civil, criminal, administrative or investigative action, suit or proceeding shall be paid by the Corporation in advance of the final disposition of such action, suit or proceeding upon receipt of an undertaking by or on behalf of such officer or director to repay such amount if it shall ultimately be determined that such person is not entitled to be indemnified by the Corporation as authorized in this Section 10. Such expenses (including attorneys' fees) incurred by other employees and agents may be so paid by the Corporation upon such terms and conditions, if any, as the Board of Directors deems appropriate. The indemnifications, advancement of expenses and rights provided by, or granted pursuant to, this Section 10 shall not be deemed exclusive of any other indemnifications, advancement of expenses, rights or limitations of liability to which any person seeking indemnification or advancement of expenses may be entitled under any Bylaw, agreement, vote of stockholders or disinterested directors, or otherwise, either as to action in such person's official capacity or as to action in another capacity while holding office, and they shall continue although such person has ceased to be a director, officer, employee or agent and shall inure to the benefit of such person's heirs, executors and administrators. The authorization to purchase and maintain insurance set forth in paragraph (b) shall likewise not be deemed exclusive.

SECTION 11. Committees.

(a) The Board of Directors may, by resolution or resolutions adopted by a majority of the whole Board of Directors, designate one or more committees, each of which shall consist of two or more directors of the Corporation. Each such committee, to the extent provided in such resolution or resolutions or in a Charter adopted by the Board of Directors, shall have and may exercise all of the authority of the Board of Directors in the management of the

Corporation and may authorize the seal of the Corporation to be affixed to all papers which may require it; provided, however, that the designation of each such committee and the delegation thereto of authority shall not operate to relieve the Board, or any member thereof, of any responsibility imposed upon it or such member by law.

(b) The Board of Directors, by resolution adopted by a majority of the whole Board of Directors, may designate one or more additional directors as alternate members of any committee to replace any absent or disqualified member at any meeting of that committee, and at any time may change the membership of any committee or amend or rescind the resolution designating the committee or any Charter adopted for such committee. In the absence or disqualification of a member or alternate member of a committee, the member or members thereof present at any meeting and not disqualified from voting, whether or not the member or members constitute a quorum, may unanimously appoint another director to act at the meeting in the place of any such absent or disqualified member, provided that the director so appointed meets any qualifications stated in these Bylaws, the Charter (if any) approved by the Board of Directors for the committee or the resolutions designating the committee or any amendment thereto.

(c) Notwithstanding any other provision of these Bylaws, no committee of the Board of Directors shall have the power or authority of the Board of Directors with respect to (i) amending the Certificate of Incorporation, (ii) approving or recommending to stockholders any type or form of "business combination" (as defined in Section 203 of the General Corporation Law of Delaware as in effect on January 1, 1996), (iii) approving or recommending to stockholders an agreement of merger or consolidation or the sale, lease or exchange of all or substantially all of the Corporation's property or assets, (iv) approving or recommending to the stockholders a dissolution of the Corporation or a revocation of a dissolution, (v) amending these Bylaws, (vi) declaring a dividend or making any other distribution to the stockholders, or (vii) authorizing the issuance of stock otherwise than pursuant to the grant or exercise of a stock option under employee stock options of the Corporation.

(d) Each such committee shall keep regular minutes of its proceedings, which minutes shall be recorded in the minute book of the Corporation. The Secretary or an Assistant Secretary of the Corporation may act as Secretary for each such committee if the committee so requests.

(e) Unless otherwise provided in these Bylaws, or in the resolutions designating any committee or the Charter (if any) approved by the Board of Directors for the committee, any committee may fix its rules or procedures, fix the time and place of its meetings and specify what notice of meetings, if any, shall be given.

ARTICLE V

Officers

SECTION 1. Designations.

The officers of this Corporation shall be a Chairman of the Board of Directors, a Chief Executive Officer, a President, as many Vice Presidents as the Board of Directors may from time to time deem advisable and one or more of which may be designated Executive Vice President or Senior Vice President, a Secretary, a Treasurer, and such Assistant Secretaries and Assistant Treasurers as the Board of Directors may from time to time deem advisable, and such other officers as the Board of Directors may from time to time deem advisable and designate. The Chairman of the Board of Directors shall be a member of and be elected by the Board of Directors. All other officers shall be elected by the Board of Directors. All officers shall hold office until their respective successors are elected and shall have qualified. Any two offices may be held by one person except the office of President and Vice President.

SECTION 2. Chairman of the Board.

The Chairman of the Board of Directors shall preside at all meetings of the Directors and stockholders at which he or she is present and shall have such other duties, power and authority as may be prescribed by the Board of Directors from time to time or elsewhere in these Bylaws.

SECTION 3. Chief Executive Officer.

The Chief Executive Officer shall have such general executive powers and duties as are usually vested in the office of the chief executive officer and shall perform such other duties as are authorized by the Board of Directors. Unless the Board of Directors otherwise provides, the Chief Executive Officer, or any person designated in writing by the Chief Executive Officer, shall have full power and authority on behalf of the Corporation to: (i) attend and to vote or take action at any meeting of the holders of securities of corporations in which the Corporation may hold securities, and at such meetings shall possess and may exercise any and all rights and powers incident to being a holder of such securities, and (ii) execute and deliver waivers of notice and proxies for and in the name of this Corporation with respect to securities of any such corporation held by this Corporation.

SECTION 4. President.

The President shall have such general executive powers and duties of supervision and management as are usually vested in such office and shall perform such other duties as are authorized by the Board of Directors or the Chief Executive Officer. The Chairman of the Board, the Chief Executive Officer, or the President shall sign contracts, certificates and other instruments of the Corporation as authorized by the Board of Directors.

SECTION 5. Vice Presidents.

A Vice President shall have the right and power to perform all duties and exercise all authority of the President, in case of the absence of the President or upon vacancy in the office of President or delegation by the Board of Directors, until the Board of Directors otherwise provides, and shall have all power and authority usually enjoyed by a person holding the office of Vice President.

SECTION 6. Secretary and Assistant Secretaries.

The Secretary shall issue notices of all directors' and stockholders' meetings, and shall attend and keep the minutes of the same; shall have charge of all corporate books, records and papers; shall be custodian of the corporate seal; shall attest with his or her signature, which may be a facsimile signature if authorized by the Board of Directors, and impress with the corporate seal, all stock certificates and written contracts of the Corporation; and shall perform all other duties as are incident to his or her office. Any Assistant Secretary, in the absence or inability of the Secretary, shall perform all duties of the Secretary and such other duties as may be required.

SECTION 7. Treasurer and Assistant Treasurers.

The Treasurer shall have custody of all money and securities of the Corporation and shall give bond in such sum and with such sureties as the directors may specify, conditioned upon the faithful performance of the duties of his or her office. He or she shall keep regular books of account and shall submit them, together with all of his or her records and other papers, to the directors for their examination and approval annually; and quarterly or as and when directed by the Board of Directors, he or she shall submit to each director a statement of the condition of the business and accounts of the Corporation; and shall perform all such other duties as are incident to his or her office. An Assistant Treasurer, in the absence or inability of the Treasurer, shall perform all the duties of the Treasurer and such other duties as may be required.

SECTION 8. Bonding.

Any officer or employee of the Corporation shall give such bond for the faithful performance of his or her duties in such sum, as and when the Board of Directors may direct.

ARTICLE VI Dividends

SECTION 1. Dividends shall be paid out of the net income or earned surplus of the Corporation, determined after making proper provision for required sinking fund deposits for debt obligations and proper provisions for working

capital and such reserves as may be required by good and generally accepted accounting practice, when declared from time to time by resolution of the Board of Directors. No such dividends shall be declared or paid which will impair the capital of the Corporation.

ARTICLE VII
Amendments

SECTION 1. Except as otherwise provided in the Certificate of Incorporation of the Corporation, these Bylaws may be amended, altered or repealed by the affirmative vote of a majority of the Board of Directors, subject to the power of stockholders to amend, alter or repeal the Bylaws, or as otherwise may from time to time be authorized by the laws of the State of Delaware.

ARTICLE VIII
Corporate Seal

SECTION 1. The corporate seal of this Corporation shall have inscribed thereon the name of the Corporation and its state of incorporation.

* * *

Certification

I, Carrie Eglinton Manner, certify that:

1. I have reviewed this report on Form 10-Q of OraSure Technologies, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d – 15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, 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, 2023

/s/ Carrie Eglinton Manner

Carrie Eglinton Manner

President and Chief Executive Officer

(*Principal Executive Officer*)

Certification

I, Kenneth J. McGrath, 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 those entities, 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, 2023

/s/ Kenneth J. McGrath

Kenneth J. McGrath

Chief Financial Officer

(*Principal Financial Officer*)

**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, 2023 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Carrie Eglinton Manner, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Carrie Eglinton Manner

Carrie Eglinton Manner
President and Chief Executive Officer

May 10, 2023

**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, 2023 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Kenneth J. McGrath, 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/ Kenneth J. McGrath

Kenneth J. McGrath
Chief Financial Officer

May 10, 2023
