

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

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended June 30, 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	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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

Indicate by checkmark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No   
As of August 1, 2023, the registrant had 73,414,695 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 contract with the U.S. government for InteliSwab<sup>®</sup> 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;
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- 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.

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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.

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**Item 1. FINANCIAL STATEMENTS**

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

	June 30, 2023	December 31, 2022
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 185,936	\$ 83,980
Short-term investments	—	26,867
Accounts receivable, net of allowance of \$1,908 and \$2,365	52,750	70,797
Inventories	73,284	95,704
Prepaid expenses	5,248	6,273
Other current assets	24,349	41,569
Total current assets	341,567	325,190
Noncurrent Assets:		
Property, plant and equipment, net of accumulated depreciation of \$84,423 and \$69,881	49,282	59,413
Operating right-of-use assets, net	13,443	10,399
Finance right-of-use assets, net	803	1,293
Intangible assets, net of accumulated amortization of \$32,737 and \$31,077	10,665	11,694
Goodwill	35,606	35,104
Deferred tax asset	1,230	—
Other noncurrent assets	998	1,087
Total noncurrent assets	112,027	118,990
<b>TOTAL ASSETS</b>	<b>\$ 453,594</b>	<b>\$ 444,180</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 17,753	\$ 38,020
Deferred revenue	1,841	2,273
Accrued expenses and other current liabilities	23,811	25,762
Finance lease liability	1,080	1,179
Operating lease liability	1,895	1,764
Acquisition-related contingent consideration obligation	40	65
Total current liabilities	46,420	69,063
Noncurrent Liabilities:		
Finance lease liability	436	503
Operating lease liability	12,013	9,101
Acquisition-related contingent consideration obligation	—	99
Other noncurrent liabilities	586	581
Deferred income taxes	—	408
Total noncurrent liabilities	13,035	10,692
<b>TOTAL LIABILITIES</b>	<b>59,455</b>	<b>79,755</b>
Commitments and contingencies (Note 12)		
<b>STOCKHOLDERS' EQUITY</b>		
Preferred stock, par value \$0.000001, 25,000 shares authorized, none issued	—	—
Common stock, par value \$0.000001, 120,000 shares authorized, 73,413 and 72,734 shares issued and outstanding	—	—
Additional paid-in capital	523,861	520,446
Accumulated other comprehensive loss	(14,559)	(18,435)
Accumulated deficit	(115,163)	(137,586)
Total stockholders' equity	394,139	364,425
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 453,594</b>	<b>\$ 444,180</b>

See accompanying notes to the consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
<b>NET REVENUES:</b>				
Products and services	\$ 84,738	\$ 79,167	\$ 237,652	\$ 144,403
Other	703	1,064	2,752	3,535
	<u>85,441</u>	<u>80,231</u>	<u>240,404</u>	<u>147,938</u>
<b>COST OF PRODUCTS AND SERVICES SOLD</b>	<u>59,070</u>	<u>52,434</u>	<u>148,218</u>	<u>95,842</u>
Gross profit	26,371	27,797	92,186	52,096
<b>OPERATING EXPENSES:</b>				
Research and development	7,661	9,463	18,221	18,097
Sales and marketing	8,535	11,684	20,677	24,401
General and administrative	16,424	17,579	34,135	36,735
Loss on impairments	215	10,542	1,320	10,542
Change in the estimated fair value of acquisition-related contingent consideration	(35)	—	(59)	(36)
	<u>32,800</u>	<u>49,268</u>	<u>74,294</u>	<u>89,739</u>
Operating income (loss)	(6,429)	(21,471)	17,892	(37,643)
<b>OTHER INCOME</b>	<u>1,467</u>	<u>1,713</u>	<u>4,140</u>	<u>1,881</u>
Income (loss) before income taxes	(4,962)	(19,758)	22,032	(35,762)
<b>INCOME TAX (BENEFIT) EXPENSE</b>	<u>(166)</u>	<u>(1,169)</u>	<u>(391)</u>	<u>2,767</u>
<b>NET INCOME (LOSS)</b>	<u>\$ (4,796)</u>	<u>\$ (18,589)</u>	<u>\$ 22,423</u>	<u>\$ (38,529)</u>
<b>INCOME (LOSS) PER SHARE:</b>				
BASIC	<u>\$ (0.07)</u>	<u>\$ (0.26)</u>	<u>\$ 0.31</u>	<u>\$ (0.53)</u>
DILUTED	<u>\$ (0.07)</u>	<u>\$ (0.26)</u>	<u>\$ 0.30</u>	<u>\$ (0.53)</u>
<b>WEIGHTED-AVERAGE SHARES OUTSTANDING:</b>				
BASIC	<u>73,324</u>	<u>72,496</u>	<u>73,219</u>	<u>72,361</u>
DILUTED	<u>73,324</u>	<u>72,496</u>	<u>74,115</u>	<u>72,361</u>

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 June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
NET INCOME (LOSS)	\$ (4,796)	\$ (18,589)	\$ 22,423	\$ (38,529)
OTHER COMPREHENSIVE INCOME				
Currency translation adjustments	2,859	(4,349)	3,656	(2,593)
Unrealized gain on marketable securities	—	82	220	156
COMPREHENSIVE INCOME (LOSS)	<u>\$ (1,937)</u>	<u>\$ (22,856)</u>	<u>\$ 26,299</u>	<u>\$ (40,966)</u>

See accompanying notes to the consolidated financial statements.

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

	<b>Six Months Ended June 30,</b>	
	<b>2023</b>	<b>2022</b>
<b>OPERATING ACTIVITIES:</b>		
Net income (loss)	\$ 22,423	\$ (38,529)
Adjustments to reconcile net income (loss) to net cash (used in) provided by operating activities:		
Stock-based compensation	5,012	6,804
Depreciation and amortization	14,011	7,464
Loss on impairments	1,320	10,542
Other non-cash amortization	1	313
Provision for credit losses	(478)	(152)
Unrealized foreign currency gain (loss)	106	(62)
Interest expense on finance leases	28	55
Deferred income taxes	(1,815)	361
Loss on sale of fixed assets	—	718
Change in the estimated fair value of acquisition-related contingent consideration	(59)	(36)
Payment of acquisition-related contingent consideration	(19)	—
Changes in assets and liabilities:		
Accounts receivable	18,652	(18,646)
Inventories	22,556	(18,179)
Prepaid expenses and other assets	5,495	(4,416)
Accounts payable	(22,187)	11,485
Deferred revenue	(450)	(252)
Accrued expenses and other liabilities	(1,326)	(2,959)
Net cash provided by (used in) operating activities	<u>63,270</u>	<u>(45,489)</u>
<b>INVESTING ACTIVITIES:</b>		
Proceeds from maturities and redemptions of investments	27,305	23,017
Purchases of property and equipment	(2,893)	(25,440)
Purchase of property and equipment under government contracts	(4,034)	(33,803)
Proceeds from funding under government contract	17,793	33,962
Net cash provided by (used in) investing activities	<u>38,171</u>	<u>(2,264)</u>
<b>FINANCING ACTIVITIES:</b>		
Cash payments for lease liabilities	(320)	(392)
Proceeds from exercise of stock options	66	15
Payment of acquisition-related contingent consideration	(46)	(208)
Repurchase of common stock	(1,663)	(1,954)
Net cash used in financing activities	<u>(1,963)</u>	<u>(2,539)</u>
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	2,478	(311)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	101,956	(50,603)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	83,980	116,762
CASH AND CASH EQUIVALENTS, END OF PERIOD	<u>\$ 185,936</u>	<u>\$ 66,159</u>
<b>SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:</b>		
Cash paid for income taxes	\$ 623	\$ 9,107
Non-cash investing and financing activities		
Accrued property and equipment purchases	\$ 314	\$ 1,900
Accrued property and equipment purchases under government contracts	\$ —	\$ 2,023
Unrealized gain on marketable securities	\$ —	\$ 156

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 and six months ended June 30, 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.

**Cash Equivalents & 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
<b>December 31, 2022</b>				
Guaranteed investment certificates	\$ 22,109	\$ —	\$ —	\$ 22,109
Corporate bonds	4,978	—	(220)	4,758
<b>Total</b>	<b>\$ 27,087</b>	<b>\$ —</b>	<b>\$ (220)</b>	<b>\$ 26,867</b>

**Fair Value of Financial Instruments.** As of June 30, 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 and the Company's available-for-sale guaranteed investment certificates are measured as Level 1 instruments as of December 31, 2022.

Included in cash and cash equivalents at June 30, 2023 and December 31, 2022, was \$6,928 and \$1,730 invested in money market funds. These money market funds have investments in government securities and are measured as Level 1 instruments. Included in cash and cash equivalents at June 30, 2023 was \$22,642 of guaranteed investment certificates which are also 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 June 30, 2023 and December 31, 2022 was \$644 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 \$(492) and \$783 for the three months ended June 30, 2023 and 2022, respectively. Net foreign exchange gains and (losses) resulting from foreign currency transactions for the six months ended June 30, 2023 and 2022 were \$(542) and \$54, 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>
<b>Balance at December 31, 2022</b>	\$ (18,215)	\$ (220)	\$ (18,435)
Other comprehensive gain	3,656	220	3,876
<b>Balance at June 30, 2023</b>	<u>\$ (14,559)</u>	<u>\$ —</u>	<u>\$ (14,559)</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 and six months ended June 30, 2022, cost of products and services sold was reduced by \$213 and \$240, respectively. The respective operating activities on the consolidated statement of cash flows for the six months ended June 30, 2022 has also been adjusted. Furthermore, stockholder's equity at June 30, 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 and six months ended June 30, 2022, \$395 and \$616 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.

Change in Accounting Estimate. During the three months ended June 30, 2023, the Company shortened the useful lives of machinery and equipment utilized for InteliSwab® production in Thailand. This reduction in useful lives resulted in \$6,900 of accelerated depreciation during the three months ended June 30, 2023, recorded in cost of products and services sold.

## 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 \$78,124, as of June 30, 2023. The remaining \$30,876 is expected to be collected during the remainder of 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.

Amounts earned for the Company's guaranteed profit which covers project management costs are recognized straight-line in other income over the term of the government contract. Any amount received in excess of the guaranteed profit discussed above will be recorded in other income at time of payment. 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 June 30, 2023 and 2022. The Company recognize \$1,123 of such income, for both the six months ended June 30, 2023 and 2022.

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 June 30, 2023 and 2022, \$537 and \$395, respectively, were recorded in research and development and other income. For the six months ended June 30, 2023 and 2022, \$1,588 and \$616, respectively, were recorded in research and development and other income.

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

	June 30, 2023	December 31, 2022
Other current assets:		
Billed receivables	\$ —	\$ —
Unbilled receivables	15,429	27,013
Total other current assets	15,429	27,013
Accrued expenses and other current liabilities	\$ (118)	\$ (318)

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

	June 30, 2023	December 31, 2022
Cost of assets, cumulative	\$ 87,057	\$ 83,359
Reduction for funding earned to date, not yet received	(8,402)	(22,497)
Reduction for funding received to date	(78,655)	(60,862)
Total property, plant and equipment, net	\$ —	\$ —

**3. Inventories**

	<u>June 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
Raw materials	\$ 29,647	\$ 42,445
Work in process	1,885	2,335
Finished goods	41,752	50,924
	<u>\$ 73,284</u>	<u>\$ 95,704</u>

**4. Property, Plant and Equipment, net**

	<u>June 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
Land	\$ 1,118	\$ 1,118
Buildings and improvements	35,765	35,582
Machinery and equipment	65,204	60,725
Computer equipment and software	17,065	16,681
Furniture and fixtures	4,100	4,064
Construction in progress	10,453	11,124
	<u>133,705</u>	<u>129,294</u>
Accumulated depreciation	(84,423)	(69,881)
	<u>\$ 49,282</u>	<u>\$ 59,413</u>

During the six months ended June 30, 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. Additionally, the Company elected not to proceed with certain leasehold improvements to its research and development laboratories. As a result of these decisions, the Company determined that the carrying values of the equipment and leasehold improvements made to date are not recoverable and recorded an aggregate pre-tax asset impairment charge of \$1,320 during the six months ended June 30, 2023. Due to the extremely specialized nature of the equipment and various market data points, the estimated fair value was zero. These charges are reported within loss on impairments in the consolidated statement of operations.

**5. Accrued Expenses and other current liabilities**

	<u>June 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
Payroll and related benefits	\$ 11,028	\$ 14,103
Professional fees	7,038	4,685
Sales tax payable	1,321	1,519
Other	4,424	5,455
	<u>\$ 23,811</u>	<u>\$ 25,762</u>

**6. Termination Benefits**

During the first and second quarters of 2023, the Company executed a reduction in 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:

	Three Months Ended June 30, 2023		Six months ended June 30, 2023	
Cost of products and services sold	\$	334	\$	369
Research and development		—		566
Sales and marketing		95		1,543
General and administrative		201		787
<b>Total</b>	<b>\$</b>	<b>629</b>	<b>\$</b>	<b>3,264</b>

As of June 30, 2023 the Company had \$1,591 accrued and had paid \$1,674 related to the reduction in workforce.

## 7. Revenues

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
COVID-19 <sup>(1)</sup>	\$ 47,507	\$ 43,378	\$ 165,916	\$ 74,411
HIV	15,964	10,357	29,868	18,523
Molecular Products <sup>(2)</sup>	13,050	17,581	25,992	35,514
HCV	3,870	3,691	7,056	6,948
Risk assessment testing	2,358	2,630	4,986	5,191
Molecular Services	1,354	1,204	2,733	2,938
Other product and service revenues	635	326	1,101	878
Net product and services revenues	84,738	79,167	237,652	144,403
Other non-product revenues <sup>(3)</sup>	703	1,064	2,752	3,535
Net revenues	\$ 85,441	\$ 80,231	\$ 240,404	\$ 147,938

<sup>(1)</sup> Includes COVID-19 Diagnostics and COVID-19 Molecular Products.

<sup>(2)</sup> Includes Genomics and Microbiome and Novosanis Products.

<sup>(3)</sup> 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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
United States	\$ 73,871	\$ 70,320	\$ 218,890	\$ 128,307
Europe	2,453	2,436	4,305	6,722
Other regions	9,117	7,475	17,209	12,909
	\$ 85,441	\$ 80,231	\$ 240,404	\$ 147,938

Customer and Vendor Concentrations. At June 30, 2023, one non-commercial customer accounted for 47% 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 56% of net consolidated revenues for both the three months ended June 30, 2023 and 2022, respectively. The same non-commercial customer also accounted for 70% and 39% of net consolidated revenues for the six months ended June 30, 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 June 30, 2023 and December 31, 2022 included customer prepayments of \$1,285 and \$1,533, respectively. Deferred revenue as of June 30, 2023 and December 31, 2022 also included \$556 and \$740, 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

The components of income tax expense (benefits) are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
State income tax expense (benefit)	\$ 1,481	\$ 183	\$ 1,257	\$ 400
Foreign income tax expense (benefit)	(1,648)	(1,352)	(1,648)	665
Foreign withholding tax	—	—	—	1,702
	<u>\$ (166)</u>	<u>\$ (1,169)</u>	<u>\$ (391)</u>	<u>\$ 2,767</u>

Income taxes for the first six months of 2022 includes \$1,702 of Canadian withholding tax on the repatriation of \$65,000 of unremitted earnings from Canada to the United States. The increase in state tax expense in 2023 compared to 2022 is a result of the increase in projected income before taxes to be generated by the Company's U.S. operations. Conversely, the increase in foreign tax benefit 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 asset as of June 30, 2023 relate to foreign net operating losses. The significant components of the Company's total deferred tax liability at 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 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 June 30, 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 June 30, 2023 outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 966 shares were excluded from the computation of diluted loss per share. For the six months ended June 30, 2023, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 2,030 shares were excluded from the computation of diluted earnings per share as their inclusion



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

## 10. Stockholders' Equity

Reconciliation of the changes in stockholder's equity for the three and six months ended June 30, 2023 and 2022.

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
<b>Balance at December 31, 2022</b>	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
<b>Balance at March 31, 2023</b>	73,254	\$ —	\$ 521,964	\$ (17,418)	\$ (110,367)	\$ 394,179
Vesting of restricted stock and performance stock units	241	—	—	—	—	—
Purchase and retirement of common shares	(82)	—	(460)	—	—	(460)
Stock-based compensation	—	—	2,357	—	—	2,357
Net loss	—	—	—	—	(4,796)	(4,796)
Currency translation adjustments	—	—	—	2,859	—	2,859
<b>Balance at June 30, 2023</b>	73,413	\$ —	\$ 523,861	\$ (14,559)	\$ (115,163)	\$ 394,139

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
<b>Balance at December 31, 2021</b>	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
<b>Balance at March 31, 2022</b>	72,307	\$ —	\$ 513,553	\$ (8,247)	\$ (140,393)	\$ 364,913
Common stock issued upon exercise of options	407	—	—	—	—	—
Vesting of restricted stock and performance stock units	(142)	—	(905)	—	—	(905)
Stock-based compensation	—	—	3,280	—	—	3,280
Net loss	—	—	—	—	(18,589)	(18,589)
Currency translation adjustments	—	—	—	(4,349)	—	(4,349)
Unrealized gain on marketable securities	—	—	—	82	—	82
<b>Balance at June 30, 2022</b>	72,572	\$ —	\$ 515,928	\$ (12,514)	\$ (158,982)	\$ 344,432

## 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 June 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. The District Court issued multiple pretrial orders, resolving the infringement, antitrust, and inequitable

conduct claims without trial. 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 has appealed the grant of summary judgment to the Court of Appeal on June 8, 2023. Second, the District Court denied Spectrum’s motion to amend its allegations of alleged antitrust violations, finding that if such an amendment were allowed, Spectrum’s claims would not survive a motion for summary judgment. Spectrum thereafter withdrew its antitrust and inequitable conduct counterclaims. Spectrum did not appeal the District Court’s denial of its motion to amend. Both parties have filed motions seeking sanctions in the District Court. An *inter partes* review is currently pending before the PTO regarding the second asserted patent.

## **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**

OraSure Technologies transforms health through powerful insight by providing access to accurate, essential information. In 2022, our business 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 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 June 30, 2023 compared to June 30, 2022.

### CONSOLIDATED NET REVENUES

The table below shows an outline of total consolidated net revenues (dollars in thousands) for the three months ended June 30, 2023 and June 30, 2022:

	Three Months Ended June 30,				
	Dollars			Percentage of Total Net Revenues	
	2023	2022	% Change	2023	2022
COVID-19 Diagnostics	\$ 47,477	\$ 43,114	10 %	56 %	54 %
Diagnostics <sup>(1)</sup>	19,834	14,048	41	23	18
Molecular Products	13,050	17,581	(26)	15	22
Other products and services <sup>(2)</sup>	2,993	2,956	1	4	4
Molecular Services	1,354	1,204	12	2	2
COVID-19 Molecular Products	30	264	(89)	—	—
Net product and services revenues	84,738	79,167	7	99	99
Non-product and services revenues	703	1,064	(34)	1	1
Net revenues	\$ 85,441	\$ 80,231	6 %	100 %	100 %

<sup>(1)</sup> Includes HIV and HCV product revenues.

<sup>(2)</sup> Includes Risk assessment testing and other product and services revenues.

### Product and Services Revenues

Consolidated net revenues increased 6% to \$85.4 million for the three months ended June 30, 2023 from \$80.2 million for the three months ended June 30, 2022.

COVID-19 Diagnostics revenues increased by 10% to \$47.5 million for the three months ended June 30, 2023 compared to \$43.1 million in three months ended June 30, 2022 due to increased sales of the Company's IntelliSwab<sup>®</sup> tests through its government procurement contracts.

Sales of the Company's Diagnostics products increased 41% to \$19.8 million for the three months ended June 30, 2023 from \$14.0 million for the three months ended June 30, 2022. This increase in revenues was primarily driven by higher sales of the Company's OraQuick<sup>®</sup> 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<sup>®</sup> HIV Self-Test in international markets due to customer ordering patterns.

Molecular Products revenues decreased 26% to \$13.1 million for the three months ended June 30, 2023 from \$17.6 million for the three months ended June 30, 2022. Sales of the Company's Molecular Products are being impacted by macro-economic factors in the markets in which its customers operate and as a result one of the Company's largest customers scaled down purchasing after they reorganized their business in the second half of 2022.

Other products and services revenues remained flat at \$3.0 million for the three months ended June 30, 2023 and 2022.

Molecular Services revenues, which are largely derived from the Company's laboratory services, increased 12% to \$1.4 million for the three months ended June 30, 2023 from \$1.2 million for the three months ended June 30, 2022. The increase in services revenues was largely due to the timing of work performed for certain clinical studies.

Sales of the Company's COVID-19 Molecular Products collection kits decreased by 89% to \$0.3 million for the three months ended June 30, 2023 from \$3.0 million for the three months ended June 30, 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 34% to \$0.7 million for the three months ended June 30, 2023 from \$1.1 million for the three months ended June 30, 2022 as a result of lower royalty income.

### **CONSOLIDATED OPERATING RESULTS**

Consolidated gross profit margin decreased to 31% for the three months ended June 30, 2023 from 35% for the three months ended June 30, 2022. This decline in margins was driven by \$7.0 million of accelerated depreciation recorded in the quarter associated with the wind-down of InteliSwab® manual assembly in Thailand as we on-shore and automate manufacturing of this product at our Pennsylvania facilities. This negative impact to margins was partially offset by a cost savings associated with the InteliSwab® packaging redesign, reduction in scrap expense and lower freight costs.

Consolidated operating loss for the three months ended June 30, 2023 was \$6.4 million, a \$15.0 million improvement from the \$21.5 million operating loss reported for the three months ended June 30, 2022. Results for the three months ended June 30, 2023 were positively impacted by reduced operating expense and lower impairment losses. Results for the three months ended June 30, 2022 included \$10.5 million of impairment losses compared to \$0.2 million for the three months ended June 30, 2023.

Operating expenses in the second quarter of 2023, excluding the impairment charge, decreased \$6.1 million compared to the second quarter of 2022 reflecting the impact of our cost saving measures and headcount reductions. Research and development expenses decreased 19% to \$7.7 million for the three months ended June 30, 2023 from \$9.5 million for the three months ended June 30, 2022 largely due to a decrease in headcount and lower manufacturing support costs.

Sales and marketing expenses decreased 27% to \$8.5 million for the three months ended June 30, 2023 from \$11.7 million for the three months ended June 30, 2022 due to a decrease in headcount, lower advertising, marketing and sales meeting spend, and a decrease in our reserve for expected credit losses.

General and administrative expenses decreased 7% to \$16.4 million for the three months ended June 30, 2023 from \$17.6 million for the three months ended June 30, 2022 largely due to lower severance and accelerated stock compensation expense associated with our former general counsel's employment and termination agreements, a decrease in headcount, lower consulting fees associated with project management of our \$109 million manufacturing expansion contract, lower board of director fees associated with less board members and a decrease in accounting and recruitment fees. These decreases in expense were partially offset by increased legal fees.

All of the above contributed to the Company's operating loss of \$6.4 million for the three months ended June 30, 2023, which included a non-cash impairment charge of \$0.2 million, non-cash charges of \$10.3 million for depreciation and amortization, and \$2.4 million for stock-based compensation. The Company's operating loss of \$21.5 million for the three months ended June 30, 2022 included a non-cash impairment charge of \$10.5 million, non-cash charges of \$3.8 million for depreciation and amortization, and \$3.3 million for stock-based compensation.

### **OTHER INCOME**

Other income for the three months ended June 30, 2023 was \$1.5 million compared to \$1.7 million for the three months ended June 30, 2022. This decrease is largely due to higher foreign currency losses offset by higher interest income.

### **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 June 30, 2023, the Company recorded U.S. state tax expense of \$1.5 million compared to \$0.2 million for the three months ended June 30, 2022 and a foreign tax benefit of \$1.6 million for the three months ended June 30, 2023 compared to \$1.4 million expense for the three months ended June 30, 2022. U.S. tax expense is higher due to increased projected earnings while decreased foreign earnings resulted in the foreign tax benefit.

## Results of Operations

Six months ended June 30, 2023 compared to June 30, 2022.

### CONSOLIDATED NET REVENUES

The table below shows an outline of total consolidated net revenues (dollars in thousands) for the six months ended June 30, 2023 and June 30, 2022:

	Six Months Ended June 30,				
	Dollars			Percentage of Total Net Revenues	
	2023	2022	% Change	2023	2022
COVID-19 Diagnostics	\$ 165,731	\$ 65,250	154 %	69 %	44 %
Diagnostics <sup>(1)</sup>	36,924	25,471	45	16	17
Molecular Products	25,992	35,514	(27)	11	24
Other products and services <sup>(2)</sup>	6,087	6,069	—	3	4
Molecular Services	2,733	2,938	(7)	1	2
COVID-19 Molecular Products	185	9,161	(98)	—	6
Net product and services revenues	237,652	144,403	65	99	98
Non-product and services revenues	2,752	3,535	(22)	1	2
Net revenues	\$ 240,404	\$ 147,938	63 %	100 %	100 %

<sup>(1)</sup> Includes HIV and HCV product revenues.

<sup>(2)</sup> Includes Risk assessment testing and other product and services revenues.

### Product and Services Revenues

Consolidated net product and services revenues increased 63% to \$240.4 million for the six months ended June 30, 2023 from \$147.9 million for the six months ended June 30, 2022. The Company expects total net product and services revenues for the second half of 2023 to be lower than the first half of 2023 as demand for its COVID-19 Diagnostic product has declined from the levels experienced in the first quarter of 2023 and the second half of 2022.

COVID-19 Diagnostics revenues increased by 154% to \$165.7 million for the six months ended June 30, 2023 compared to \$65.3 million for the six months ended June 30, 2022 due to increased sales of the Company's IntelliSwab<sup>®</sup> tests through its government procurement contracts.

Sales of the Company's Diagnostics products increased 45% to \$36.9 million for the six months ended June 30, 2023 from \$25.5 million for the six months ended June 30, 2022. This increase in revenues was primarily driven by higher sales of the Company's OraQuick<sup>®</sup> 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<sup>®</sup> HIV Self-Test in international markets due to customer ordering patterns.

Molecular Products revenues decreased 27% to \$26.0 million for the six months ended June 30, 2023 from \$35.5 million for the six months ended June 30, 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 customers scaled down purchasing after they reorganized their business in the second half of 2022 and certain other customers placed large orders in the first half of 2022 that have not been repeated in the six months ending June 30, 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 half of 2023.

Other products and services revenues were largely flat at \$6.1 million for the six months ended June 30, 2023 and 2022.

Molecular Services revenues, which are largely derived from the Company's laboratory services, decreased 7% to \$2.7 million for the six months ended June 30, 2023 from \$2.9 million for the six months ended June 30, 2022. The decline in services revenues was the direct result of loss of two customers in 2022. One customer ceased operations in 2022 and the

other deprioritized microbiome studies. These decreases were offset by higher revenues generated by certain customer contracts due to the timing of work performed for certain clinical studies.

Sales of the Company's COVID-19 Molecular Products collection kits decreased significantly by 98% to \$0.2 million for the six months ended June 30, 2023 from \$9.2 million for the six months ended June 30, 2022 due to decline in demand for COVID PCR testing given the availability of rapid antigen tests.

Non-product and services revenues decreased 22% to \$2.8 million for the six months ended June 30, 2023 from \$3.5 million for the six months ended June 30, 2022 as a result of lower royalty income.

### **CONSOLIDATED OPERATING RESULTS**

Consolidated gross profit margin increased to 38% for the six months ended June 30, 2023 from 35% for the six months ended June 30, 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. Lower scrap expense in the first half of 2023 compared to the first half of 2022 also contributed to the margins improvement. These improved margins were partially offset by \$7.0 million of accelerated depreciation recorded in the second quarter of 2023 associated with the wind-down of IntelliSwab® manual assembly in Thailand as we on-shore and automate the manufacturing of this product at our Pennsylvania facilities and lower COVID-19 Molecular Products revenue which historically generated higher margins.

Consolidated operating income for the six months ended June 30, 2023 was \$17.9 million, a \$55.5 million increase from the \$37.6 million operating loss reported for the six months ended June 30, 2022. Results for the six months ended June 30, 2023 were positively impacted by the increase in revenues and gross margins described above and were positively impacted by reduced operating expense and lower impairment losses. Results for the six months ended June 30, 2022 included \$10.5 million of impairment losses compared to \$1.3 million for the six months ended June 30, 2023.

Operating expenses in the six months ended June 30, 2023, excluding the impairment charge, decreased \$6.2 million compared to the first half of 2022. Research and development expenses increased to \$18.2 million for the six months ended June 30, 2023 from \$18.1 million for the six months ended June 30, 2022.

Sales and marketing expenses decreased 15% to \$20.7 million for the six months ended June 30, 2023 from \$24.4 million for the six months ended June 30, 2022 due to a decrease in our reserve for expected credit losses and lower advertising, marketing, sales meeting, and consulting spend.

General and administrative expenses decreased 7% to \$34.1 million for the six months ended June 30, 2023 from \$36.7 million for the six months ended June 30, 2022 largely due to lower severance and stock compensation expense and recruitment fees. In the first half of 2022, the Company incurred high severance and stock compensation expense associated with the accelerated vesting of shares under our former CEO's and general counsel's employment agreements and higher recruitment expense associated with the new CEO search. Also contributing to the decrease in expense was lower consulting fees, lower board of director fees, due to fewer board members, and lower sales tax penalties. These decreases in expense were partially offset by increased legal fees.

All of the above contributed to the Company's operating income of \$17.9 million for the six months ended June 30, 2023, which included a non-cash impairment charge of \$1.3 million largely related to equipment that will no longer be used in production, non-cash charges of \$14.0 million for depreciation and amortization, and \$5.0 million for stock-based compensation. The Company's operating loss of \$37.6 million for the six months ended June 30, 2022 included a non-cash impairment charge of \$10.5 million, non-cash charges of \$7.5 million for depreciation and amortization, and \$6.8 million for stock-based compensation.

### **OTHER INCOME**

Other income for the six months ended June 30, 2023 was \$4.1 million compared to \$1.9 million for the six months ended June 30, 2022. This increase is largely due to higher interest income and higher reimbursement of costs incurred under our DOD expansion contract which are presented in research and development expenses.



## 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 six months ended June 30, 2023, the Company recorded U.S. state tax expense of \$1.3 million compared to \$0.4 million for the six months ended June 30, 2022 and a foreign tax benefit of \$1.6 million for the six months ended June 30, 2023 compared to foreign tax expense of \$0.7 million for the six months ended June 30, 2022. The 2022 foreign tax expense is also comprised of \$1.7 million of withholding taxes associated with our repatriation of \$65.0 million of cash from Canada to the United States. The 2023 U.S. state tax expense is higher due to higher expected US earnings while foreign income tax expense is lower due to lower expected foreign earnings.

### Liquidity and Capital Resources

	June 30, 2023	December 31, 2022
	(In thousands)	
Cash and cash equivalents	\$ 185,936	\$ 83,980
Available-for-sale securities	—	26,867
Working capital	295,147	256,127

The Company's cash and cash equivalents and available-for-sale securities increased to \$185.9 million at June 30, 2023 from \$110.8 million at December 31, 2022. \$72.1 million or 39% of the \$185.9 million in cash and cash equivalents 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 \$295.1 million at June 30, 2023 from \$256.1 million at December 31, 2022. Working capital increased primarily due to the increase in cash and cash equivalents and lower accounts payable balances. 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 six months ended June 30, 2023, net cash provided by operating activities was \$63.3 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 \$22.4 included non-cash charges of depreciation and amortization expense of \$14.0 million, stock-based compensation expense of \$5.0 million, impairment charges taken for idle equipment of \$1.3 million and a non-cash deferred tax benefit of \$1.8 million. Cash provided by the working capital accounts included a decrease in inventory of \$22.6 million as we fulfilled demand for our IntelliSwab® product in the first half of the year, a decrease in accounts receivable of \$18.7 million largely associated with collections of monies due from the U.S. government for IntelliSwab® shipments, a \$5.5 million decrease in prepaid and other assets as the Company received payment of its Employee Retention Credit filed for in 2021. Offsetting these increases in cash is a decrease in accounts payable of \$22.2 million and a decrease in accrued expenses of \$1.3 million.

#### *Investing Activities*

Net cash provided by investing activities was \$38.2 million for the six months ended June 30, 2023, which reflects proceeds from the maturities of investments of \$27.3 million, \$17.8 million in reimbursement received under our \$109 million contract with the U.S. government offset by \$4.0 million to build additional manufacturing capacity as required by the contract, and \$2.9 million to acquire property and equipment to support the normal operations of the business.

### *Financing Activities*

Net cash used in financing activities was \$2.0 million for the six months ended June 30, 2023, which is largely comprised of \$1.7 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 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 June 30, 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 six months ended June 30, 2023.

### **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 June 30, 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 June 30, 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 June 30, 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 June 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. The District Court issued multiple pretrial orders, resolving the infringement, antitrust, and inequitable conduct claims without trial. 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 has appealed the grant of summary judgment to the Court of Appeal on June 8, 2023. Second, the District Court denied Spectrum's motion to amend its allegations of alleged antitrust violations, finding that if such an amendment were allowed, Spectrum's claims would not survive a motion for summary judgment. Spectrum thereafter withdrew its antitrust and inequitable conduct counterclaims. Spectrum did not appeal the District Court's denial of its motion to amend. Both parties have filed motions seeking sanctions in the District Court. An *inter partes* review is currently pending before the PTO regarding the second asserted patent.

### 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.

#### ***An Impairment of Goodwill Could Reduce our Earnings.***

Throughout the year, we consider whether any events or changes in the business environment have occurred which indicate that goodwill may be impaired. For example, a significant decline in the closing share price of our common stock and market capitalization may suggest that the fair value of our reporting unit has fallen below its carrying amount, indicating that an interim goodwill impairment test is required. We monitor changes in our stock price during interim periods between annual goodwill impairment tests and consider overall stock market conditions, the underlying reasons for the decline in our stock price, the significance of the decline, and the duration of time that our securities have been trading at a lower value.

While our stock price has experienced volatility, we have experienced a decline in its market capitalization as a result of a decline in our stock price. As of July 31, 2023 our market value was \$346.5 million which is below our carrying value. If our stock price remains at such levels or deteriorates, our goodwill may be determined to be impaired and we would record a non-cash impairment charge, which could have a material adverse effect on our consolidated balance sheet, results of operations or our stock price

**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 <sup>(1, 2)</sup>
April 1, 2023 - April 30, 2023	7,945 <sup>(3)</sup>	\$ 2.77	—	11,984,720
May 1, 2023 - May 31, 2023	86,825 <sup>(3)</sup>	\$ 1.96	—	11,984,720
June 1, 2023 - June 30, 2023	64,353 <sup>(3)</sup>	\$ 4.10	—	11,984,720
	159,123		—	

- (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**

On May 25, 2023, Kathleen Weber, our Chief Product Officer, adopted a trading arrangement (the "Trading Plan") intended to satisfy the affirmative defense conditions of Securities Exchange Act Rule 10b5-1(c) with respect to the sale of up to an aggregate of 64,129 shares of our common stock between August 30 and May 17, 2024 pursuant to the terms of the Trading Plan. The Trading Plan was entered into during an open insider trading window and is intended to satisfy the affirmative defense of Rule 10b5-1(c) under the Exchange Act and the Company's policies regarding insider transactions.

The number of shares to be withheld, and thus the exact number of shares to be sold pursuant to Ms. Weber's Trading Plan, can only be determined upon the occurrence of the future vesting events. For purposes of this disclosure, without subtracting any shares to be withheld upon future vesting events, the aggregate number of shares to be sold pursuant to Ms. Weber's 10b5-1 Plan is 64,129 shares.

**Item 6. EXHIBITS**

<b>Exhibit Number</b>	<b>Exhibit</b>
10.1**	Amended and Restated OraSure Technologies, Inc. 2000 Stock Award Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K as filed.
31.1*	<a href="#">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.</a>
31.2*	<a href="#">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.</a>
32.1*+	<a href="#">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.</a>
32.2*+	<a href="#">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.</a>
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
104	Cover Page from Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in exhibits 101).

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\* 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: August 4, 2023

/s/ Kenneth J. McGrath

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

Date: August 4, 2023

/s/Michele M. Anthony

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

**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: August 4, 2023

*/s/ Carrie Eglinton Manner*

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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: August 4, 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 June 30, 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

August 4, 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 June 30, 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

August 4, 2023