

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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 October 31, 2023, the registrant had 73,484,272 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 the Company’s 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 the Company’s 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:

- The Company’s ability to market and sell products, whether through its internal, direct sales force or third parties;
 - The Company’s ability to fulfill its commitments under its contract 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 the Company’s products;
 - Significant customer concentrations that exist or may develop in the future;
 - The Company’s ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements;
 - The Company’s 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;
 - The Company’s 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 the Company’s 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;
 - The Company’s ability to meet increased demand for its products;
 - The impact of replacing distributors on the Company’s business;
 - Inventory levels at distributors and other customers;
 - The Company’s ability to achieve its financial and strategic objectives and continue to increase its revenues, including the ability to expand international sales;
 - The impact of competitors, competing products and technology changes on the Company’s business;
 - Reduction or deferral of public funding available to customers;
 - Competition from new or better technology or lower cost products;
 - The Company’s 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;
 - The Company's 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 the Company's products;
 - The impact of contracting with the U.S. government on the Company's business;
 - The impact of negative economic conditions on the Company's business;
 - The Company's ability to maintain sustained profitability;
 - The Company's ability to increase its gross margins;
 - The ability to utilize net operating loss carry forwards or other deferred tax assets;
 - Volatility of the Company's stock price;
 - Uncertainty relating to patent protection and potential patent infringement claims;
 - Uncertainty and costs of litigation relating to patents and other intellectual property;
 - Availability of licenses to patents or other technology;
 - Ability to enter into international manufacturing agreements;
 - Obstacles to international marketing and manufacturing of products;
 - The Company's 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;
 - The Company's ability to attract and retain qualified personnel;
 - The Company's 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;
 - Geopolitical tensions or the outbreak of hostilities or war, including from the Russia-Ukraine conflict and the evolving events in Israel and Gaza;
 - Cybersecurity breaches or other attacks involving our systems or those of our third-party IT service providers; and
 - General political, business and economic conditions, including inflationary pressures and banking instability.
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These and other factors that could affect the Company's 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 the Company's 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 the Company undertakes no duty to update these statements, unless it is required to do so by law. If the Company does update one or more forward-looking statements, no inference should be drawn that it will make updates with respect to other forward-looking statements or that it will make any further updates to those forward-looking statements at any future time.

Investors should also be aware that while the Company does, from time to time, communicate with securities analysts, it is against the Company's policy to disclose any material non-public information or other confidential commercial information. Accordingly, stockholders should not assume that the Company agrees with any statement or report issued by any analyst irrespective of the content of the statement or report. Furthermore, the Company has 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)

	September 30, 2023	December 31, 2022
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 217,533	\$ 83,980
Short-term investments	7,358	26,867
Accounts receivable, net of allowance of \$2,289 and \$2,365	53,402	70,797
Inventories	59,264	95,704
Prepaid expenses	6,423	6,273
Other current assets	12,484	41,569
Total current assets	356,464	325,190
Noncurrent Assets:		
Property, plant and equipment, net of accumulated depreciation of \$84,168 and \$69,881	48,027	59,413
Operating right-of-use assets, net	13,302	10,399
Finance right-of-use assets, net	793	1,293
Intangible assets, net of accumulated amortization of \$27,336 and \$31,077	3,793	11,694
Goodwill	35,033	35,104
Deferred tax asset	47	—
Other noncurrent assets	973	1,087
Total noncurrent assets	101,968	118,990
TOTAL ASSETS	\$ 458,432	\$ 444,180
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 14,966	\$ 38,020
Deferred revenue	1,824	2,273
Accrued expenses and other current liabilities	21,140	25,762
Finance lease liability	1,000	1,179
Operating lease liability	2,017	1,764
Acquisition-related contingent consideration obligation	—	65
Total current liabilities	40,947	69,063
Noncurrent Liabilities:		
Finance lease liability	247	503
Operating lease liability	11,758	9,101
Acquisition-related contingent consideration obligation	—	99
Other noncurrent liabilities	595	581
Deferred income taxes	—	408
Total noncurrent liabilities	12,600	10,692
TOTAL LIABILITIES	53,547	79,755
Commitments and contingencies (Note 12)		
STOCKHOLDERS' EQUITY		
Preferred stock, par value \$0.000001, 25,000 shares authorized, none issued	—	—
Common stock, par value \$0.000001, 120,000 shares authorized, 73,483 and 72,734 shares issued and outstanding	—	—
Additional paid-in capital	526,261	520,446
Accumulated other comprehensive loss	(17,372)	(18,435)
Accumulated deficit	(104,004)	(137,586)
Total stockholders' equity	404,885	364,425
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 458,432	\$ 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
NET REVENUES:				
Products and services	\$ 89,014	\$ 112,821	\$ 326,666	\$ 257,224
Other	173	3,642	2,925	7,177
	<u>89,187</u>	<u>116,463</u>	<u>329,591</u>	<u>264,401</u>
COST OF PRODUCTS AND SERVICES SOLD	<u>44,847</u>	<u>69,949</u>	<u>193,065</u>	<u>165,791</u>
Gross profit	44,340	46,514	136,526	98,610
OPERATING EXPENSES:				
Research and development	8,516	10,088	26,737	28,185
Sales and marketing	8,736	13,474	29,413	37,875
General and administrative	10,051	15,527	44,186	52,262
Loss on impairments	6,183	6,559	7,503	17,101
Change in the estimated fair value of acquisition-related contingent consideration	(40)	—	(99)	(36)
	<u>33,446</u>	<u>45,648</u>	<u>107,740</u>	<u>135,387</u>
Operating income (loss)	10,894	866	28,786	(36,777)
OTHER INCOME	<u>2,612</u>	<u>3,586</u>	<u>6,752</u>	<u>5,467</u>
Income (loss) before income taxes	13,506	4,452	35,538	(31,310)
INCOME TAX (BENEFIT) EXPENSE	<u>2,347</u>	<u>(1,143)</u>	<u>1,956</u>	<u>1,624</u>
NET INCOME (LOSS)	<u>\$ 11,159</u>	<u>\$ 5,595</u>	<u>\$ 33,582</u>	<u>\$ (32,934)</u>
INCOME (LOSS) PER SHARE:				
BASIC	\$ 0.15	\$ 0.08	\$ 0.46	\$ (0.45)
DILUTED	\$ 0.15	\$ 0.08	\$ 0.45	\$ (0.45)
WEIGHTED-AVERAGE SHARES OUTSTANDING:				
BASIC	<u>73,453</u>	<u>72,616</u>	<u>73,298</u>	<u>72,448</u>
DILUTED	<u>74,349</u>	<u>72,785</u>	<u>74,197</u>	<u>72,448</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 September 30,</u>		<u>Nine Months Ended September 30,</u>	
	2023	2022	2023	2022
NET INCOME (LOSS)	\$ 11,159	\$ 5,595	\$ 33,582	\$ (32,934)
OTHER COMPREHENSIVE INCOME				
Currency translation adjustments	(2,813)	(9,828)	843	(12,421)
Unrealized gain on marketable securities	—	11	220	167
COMPREHENSIVE INCOME (LOSS)	<u>\$ 8,346</u>	<u>\$ (4,222)</u>	<u>\$ 34,645</u>	<u>\$ (45,188)</u>

See accompanying notes to the consolidated financial statements.

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

	Nine Months Ended September 30,	
	2023	2022
OPERATING ACTIVITIES:		
Net income (loss)	\$ 33,582	\$ (32,934)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Stock-based compensation	7,602	9,100
Depreciation and amortization	17,372	11,391
Loss on impairments	7,503	17,101
Other non-cash amortization	3	411
Provision for credit losses	(75)	974
Unrealized foreign currency gain	(66)	(396)
Interest expense on finance leases	42	74
Deferred income taxes	(490)	542
Loss on sale of fixed assets	—	729
Change in the estimated fair value of acquisition-related contingent consideration	(99)	(36)
Payment of acquisition-related contingent consideration	(19)	—
Changes in assets and liabilities:		
Accounts receivable	17,468	(19,152)
Inventories	36,425	(26,240)
Prepaid expenses and other assets	10,530	(5,990)
Accounts payable	(25,122)	15,315
Deferred revenue	(449)	(312)
Accrued expenses and other liabilities	(3,990)	233
Net cash provided by (used in) operating activities	100,217	(29,190)
INVESTING ACTIVITIES:		
Purchases of short-term investments	(74,652)	(22,873)
Proceeds from maturities and redemptions of short-term investments	94,980	47,415
Purchases of property and equipment	(4,517)	(28,081)
Purchase of property and equipment under government contracts	(4,501)	(38,705)
Proceeds from funding under government contract	24,290	37,756
Net cash provided by (used in) investing activities	35,600	(4,488)
FINANCING ACTIVITIES:		
Cash payments for lease liabilities	(835)	(826)
Proceeds from exercise of stock options	76	15
Payment of acquisition-related contingent consideration	(46)	(208)
Repurchase of common stock	(1,863)	(2,008)
Net cash used in financing activities	(2,668)	(3,027)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	404	(4,852)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	133,553	(41,557)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	83,980	116,762
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 217,533	\$ 75,205
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash (refunds) paid for income taxes	\$ (5,733)	\$ 9,400
Non-cash investing and financing activities		
Accrued property and equipment purchases	\$ 155	\$ 1,463
Accrued property and equipment purchases under government contracts	\$ 2	\$ 2,374
Unrealized gain on marketable securities	\$ —	\$ 167

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
Notes to the Consolidated Financial Statements
(Unaudited)

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 nine months ended September 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 & Short-Term 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. Securities with maturities ninety days or less are considered cash equivalents. 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 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
September 30, 2023				
Guaranteed investment certificates	\$ 7,358	\$ —	\$ —	\$ 7,358
Corporate bonds	—	—	—	—
Total	<u>\$ 7,358</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 7,358</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 September 30, 2023, maturities of the Company’s available-for-sale securities were as follows:				
Less than one year	<u>\$ 7,358</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 7,358</u>
Greater than one year	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

Fair Value of Financial Instruments. As of September 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 September 30, 2023 and December 31, 2022.

Included in cash and cash equivalents at September 30, 2023 and December 31, 2022 was \$37.1 million and \$1.7 million, respectively, 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 September 30, 2023 was \$14.7 million 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 September 30, 2023 and December 31, 2022 was \$0.6 million and \$0.7 million, 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 \$(0.1) million and \$2.3 million for the three months ended September 30, 2023 and 2022, respectively. Net foreign exchange gains and (losses) resulting from foreign currency transactions for the nine months ended September 30, 2023 and 2022 were \$(0.7) million and \$2.4 million, respectively.

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

The Company identified a triggering event to test for the recoverability of intangible assets in the third quarter given the decline in the Company's market capitalization leading up to and as of its annual goodwill impairment testing date. The Company performed an undiscounted cash flow analysis and determined the carrying value of the developed technology, trade names, and customer relationships intangible assets could not be recovered through the sum of the undiscounted future cash flows. The Company used an income approach to determine the fair value of the developed technology and customer relationship intangible assets and the relief from royalty method for the trade names. For the three months ended September 30, 2023, the Company determined the developed technology, trade names, and customer relationships intangible assets associated with Diversigen and Novosanis were impaired as the fair value of the intangible assets did not exceed their carrying value. A full impairment loss of \$6.2 million is recorded on the consolidated statement of operations for the three months ended September 30, 2023.

There was no impairment of property, plant and equipment for the three months ended September 30, 2023 related to this triggering event. See Note 4 for discussion of equipment impairments recorded in the first half of 2023.

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

Accumulated Other Comprehensive Loss. Changes in accumulated other comprehensive loss by component is listed below (in thousands):

	Foreign Currency	Marketable Securities	Total
Balance at December 31, 2022	\$ (18,215)	\$ (220)	\$ (18,435)
Other comprehensive gain	843	220	1,063
Balance at September 30, 2023	<u>\$ (17,372)</u>	<u>\$ —</u>	<u>\$ (17,372)</u>

Immaterial Correction of Errors. Inventories, accounts payable and cost of products and services were reduced by \$0.5 million, \$1.3 million and \$0.8 million, 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 nine months ended September 30, 2022, cost of products and services sold was reduced by \$0.3 million and \$0.6 million, respectively. The respective operating activities on the consolidated statement of cash flows for the nine months ended September 30, 2022 has also been adjusted. Furthermore, stockholder's equity at September 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 nine months ended September 30, 2022, \$0.3 million and \$0.9 million 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 the Company's 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 IntelliSwab® production in Thailand. This reduction in useful lives resulted in \$6.9 million 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 \$109.0 million 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 IntelliSwab® 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 billed and funded until the completion of the final validation testing, which occurred in October 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 \$84.6 million, as of September 30, 2023. The remaining \$24.4 million was received in October 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 \$0.6 million of such income, which is reported as other income in the Company's consolidated statement of operations for both the three months ended September 30, 2023 and 2022. The Company recognized \$1.7 million of such income, for both the nine months ended September 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 September 30, 2023 and 2022, \$0.4 million and \$0.3 million, respectively, were recorded in research and development and other income. For the nine months ended September 30, 2023 and 2022, \$2.0 million and \$0.9 million, 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 (in thousands):

	<u>September 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
Other current assets:		
Billed receivables	\$ 4,365	\$ —
Unbilled receivables	5,956	27,013
Total other current assets	10,321	27,013
Accrued expenses and other current liabilities	\$ —	\$ (318)

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

	<u>September 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
Cost of assets, cumulative	\$ 86,993	\$ 83,359
Reduction for funding earned to date, not yet received	(1,841)	(22,497)
Reduction for funding received to date	(85,152)	(60,862)
Total property, plant and equipment, net	\$ —	\$ —

3. Inventories (in thousands)

	<u>September 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
Raw materials	\$ 26,115	\$ 42,445
Work in process	2,459	2,335
Finished goods	30,690	50,924
	<u>\$ 59,264</u>	<u>\$ 95,704</u>

4. Property, Plant and Equipment, net (in thousands)

	September 30, 2023	December 31, 2022
Land	\$ 1,118	\$ 1,118
Buildings and improvements	35,714	35,582
Machinery and equipment	65,371	60,725
Computer equipment and software	17,352	16,681
Furniture and fixtures	4,079	4,064
Construction in progress	8,561	11,124
	132,195	129,294
Accumulated depreciation	(84,168)	(69,881)
	<u>\$ 48,027</u>	<u>\$ 59,413</u>

During the nine months ended September 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 aggregate pre-tax asset impairment charges of \$1.3 million during the nine months ended September 30, 2023. No property, plant and equipment impairment charges were recorded during the three months ended September 30, 2023.

During the three and nine months ended September 30, 2022, the Company determined several manufacturing lines and associated supporting assets would not be utilized due to changes in forecasted demand for the products the lines are intended to produce. As a result of this decision, the Company determined that the carrying values of the equipment and supporting assets were not recoverable and recorded aggregate pre-tax asset impairment charges during the three and nine months ended September 30, 2022 of \$6.6 million and \$13.5 million, respectively.

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 (in thousands)

	September 30, 2023	December 31, 2022
Payroll and related benefits	\$ 12,213	\$ 14,103
Professional fees	2,730	4,685
Sales tax payable	1,344	1,519
Other	4,853	5,455
	<u>\$ 21,140</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 (in thousands):

	Nine Months Ended September 30, 2023	
Cost of products and services sold	\$	369
Research and development		566
Sales and marketing		1,543
General and administrative		787
Total	\$	3,265

As of September 30, 2023 the Company had \$0.9 million accrued and had paid \$2.4 million related to the reduction in workforce. No additional expense was incurred during the three months ended September 30, 2023.

7. Revenues

Revenues by product line. The following table represents total net revenues by product line (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
COVID-19 ⁽¹⁾	\$ 50,199	\$ 79,920	\$ 216,115	\$ 154,331
HIV	16,650	9,054	46,518	27,577
Molecular Products ⁽²⁾	15,238	15,829	41,230	51,344
HCV	2,901	3,234	9,957	10,182
Risk assessment testing	2,554	2,595	7,540	7,786
Molecular Services	834	1,957	3,567	4,895
Other product and service revenues	638	232	1,739	1,109
Net product and services revenues	89,014	112,821	326,666	257,224
Non-product and services revenues ⁽³⁾	173	3,642	2,925	7,177
Net revenues	\$ 89,187	\$ 116,463	\$ 329,591	\$ 264,401

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

⁽²⁾ Includes Genomics, Microbiome and Novosanis product revenues.

⁽³⁾ 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 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
United States	\$ 77,925	\$ 108,941	\$ 296,815	\$ 237,248
Europe	1,992	2,207	6,297	8,929
Other regions	9,270	5,315	26,479	18,224
	\$ 89,187	\$ 116,463	\$ 329,591	\$ 264,401

Customer and Vendor Concentrations. At September 30, 2023, one non-commercial customer accounted for 52% of the Company's consolidated accounts receivable. The same non-commercial customer accounted for 57% of the Company's consolidated accounts receivable as of December 31, 2022. The same non-commercial customer also accounted for 56% and 69% of net consolidated revenues for the three months ended September 30, 2023 and 2022, respectively. The same non-commercial customer also accounted for 66% and 53% of net consolidated revenues for the nine months ended September 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 September 30, 2023 and December 31, 2022 included customer prepayments of \$1.4 million and \$1.5 million, respectively. Deferred revenue as of September 30, 2023 and December 31, 2022 also included \$0.4 million and \$0.7 million, 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 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
State income tax expense (benefit)	\$ 1,131	\$ (40)	\$ 2,388	\$ 379
Foreign income tax expense (benefit)	1,216	(1,103)	(432)	(438)
Foreign withholding tax	—	—	—	1,683
	<u>\$ 2,347</u>	<u>\$ (1,143)</u>	<u>\$ 1,956</u>	<u>\$ 1,624</u>

Income taxes for the nine months ended September 30, 2022 includes \$1.7 million of Canadian withholding tax on the repatriation of \$65.0 million of unremitted earnings from Canada to the United States. The increase in income tax expense for three months ended September 30, 2023 is due to an increase in the income before taxes for both the U.S. and Canadian entities.

Income 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 September 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 September 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 and nine months ended September 30, 2023 outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 2,027 shares and 2,048 shares, respectively, were excluded from the computation of diluted earnings per share as their inclusion would have been anti-dilutive. For the nine months ended September 30, 2022 outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 1,734 shares, were excluded from the computation of diluted loss per share as their inclusion would have been

anti-dilutive. For the nine months ended September 30, 2022, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing, 383 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 nine months ended September 30, 2023 and 2022 (in thousands):

	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	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
Balance at June 30, 2023	73,413	\$ —	\$ 523,861	\$ (14,559)	\$ (115,163)	\$ 394,139
Common stock issued upon exercise of options	2	—	10	—	—	10
Vesting of restricted stock and performance stock units	99	—	—	—	—	—
Purchase and retirement of common shares	(31)	—	(200)	—	—	(200)
Stock-based compensation	—	—	2,590	—	—	2,590
Net income	—	—	—	—	11,159	11,159
Currency translation adjustments	—	—	—	(2,813)	—	(2,813)
Balance at September 30, 2023	73,483	\$ —	\$ 526,261	\$ (17,372)	\$ (104,004)	\$ 404,885

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balance at December 31, 2021	72,069	\$ —	\$ 511,063	\$ (10,077)	\$ (120,453)	\$ 380,533
Common stock issued upon exercise of options	2	—	15	—	—	15
Vesting of restricted stock and performance stock units	352	—	—	—	—	—
Purchase and retirement of common shares	(116)	—	(1,049)	—	—	(1,049)
Stock-based compensation	—	—	3,524	—	—	3,524
Net loss	—	—	—	—	(19,940)	(19,940)
Currency translation adjustments	—	—	—	1,756	—	1,756
Unrealized gain on marketable securities	—	—	—	74	—	74
Balance at March 31, 2022	72,307	\$ —	\$ 513,553	\$ (8,247)	\$ (140,393)	\$ 364,913
Vesting of restricted stock and performance stock units	407	—	—	—	—	—
Purchase and retirement of common shares	(142)	—	(905)	—	—	(905)
Stock-based compensation	—	—	3,280	—	—	3,280
Net loss	—	—	—	—	(18,589)	(18,589)
Currency translation adjustments	—	—	—	(4,349)	—	(4,349)
Unrealized gain on marketable securities	—	—	—	82	—	82
Balance at June 30, 2022	72,572	\$ —	\$ 515,928	\$ (12,514)	\$ (158,982)	\$ 344,432
Vesting of restricted stock and performance stock units	66	—	—	—	—	—
Purchase and retirement of common shares	(19)	—	(54)	—	—	(54)
Stock-based compensation	—	—	2,296	—	—	2,296
Net income	—	—	—	—	5,595	5,595
Currency translation adjustments	—	—	—	(9,828)	—	(9,828)
Unrealized gain on marketable securities	—	—	—	11	—	11
Balance at September 30, 2022	72,619	\$ —	\$ 518,170	\$ (22,331)	\$ (153,387)	\$ 342,452

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 the Company's Chief Executive Officer, whom the Company has determined to be its Chief Operating Decision Maker ("CODM"). The CODM reviews the business based on individual product success. Therefore, the Company's 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 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. Those motions remain pending. DNAG filed its opening appellate brief on September 28, 2023. Spectrum's responsive appellate brief is due December 22, 2023. Oral argument in the appeal has not been scheduled. An inter partes review is currently pending before the PTO regarding the second asserted patent. Oral argument in the inter partes review is currently scheduled for November 14, 2023. On September 15, 2023, Spectrum filed a petition for inter partes review of a third patent, which DNAG did not assert in the District Court. An optional preliminary patent owner response is due in December 2023.

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

The following discussion and analysis of the Company's financial condition and results of operations should be read in conjunction with (i) the Company's unaudited condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and (ii) the Company's audited consolidated financial statements and related notes and management's discussion and analysis of financial condition and results of operations included in the Company's 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 the Company's plans and strategy for its business and impact and potential impacts on its 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 the Company's 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, the Company's 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, the Company's business consisted of two segments: its "Diagnostics" segment, and its "Molecular Solutions" segment. In February 2023, the Company 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 September 30, 2023 compared to September 30, 2022.

CONSOLIDATED NET REVENUES

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

	Three Months Ended September 30,				
	Dollars			Percentage of Total Net Revenues	
	2023	2022	% Change	2023	2022
COVID-19 Diagnostics	\$ 50,145	\$ 79,559	(37)%	56 %	68 %
Diagnostics ⁽¹⁾	19,551	12,288	59	22	11
Molecular Products ⁽²⁾	15,238	15,829	(4)	17	14
Other products and services ⁽³⁾	3,192	2,827	13	4	2
Molecular Services	834	1,957	(57)	1	2
COVID-19 Molecular Products	54	361	(85)	—	—
Net product and services revenues	89,014	112,821	(21)	100	97
Non-product and services revenues ⁽⁴⁾	173	3,642	(95)	—	3
Net revenues	\$ 89,187	\$ 116,463	(23)%	100 %	100 %

⁽¹⁾ Includes HIV and HCV product revenues.

⁽²⁾ Includes Genomics, Microbiome and Novosanis product revenues.

⁽³⁾ Includes Risk assessment testing and other product and services revenues.

⁽⁴⁾ Non-product and services revenues include funded research and development contracts, royalty income and grant revenues.

Product and Services Revenues

Consolidated net revenues decreased 23% to \$89.2 million for the three months ended September 30, 2023 from \$116.5 million for the three months ended September 30, 2022.

COVID-19 Diagnostics revenues decreased by 37% to \$50.1 million for the three months ended September 30, 2023 compared to \$79.6 million in three months ended September 30, 2022 due to decreased sales of the Company's InteliSwab[®] tests through its U.S. government procurement contracts. We expect this decline in revenue to continue in the fourth quarter but at a lower rate.

Sales of the Company's Diagnostics products increased 59% to \$19.6 million for the three months ended September 30, 2023 from \$12.3 million for the three months ended September 30, 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 international markets due to customer ordering patterns.

Molecular Products revenues decreased 4% to \$15.2 million for the three months ended September 30, 2023 from \$15.8 million for the three months ended September 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 larger customers scaled down purchasing after they reorganized their business. These declines in revenues were partially offset by new customer sales in the animal and genetic testing markets.

Other products and services revenues increased 13% to \$3.2 million for the three months ended September 30, 2023 from \$2.8 million for the three months ended September 30, 2022.

Molecular Services revenues, which are largely derived from the Company's laboratory services, decreased 57% to \$0.8 million for the three months ended September 30, 2023 from \$2.0 million for the three months ended September 30, 2022. The decrease in services revenues was largely due to completion of a large customer's clinical trial project and increased competition.

Sales of the Company's COVID-19 Molecular Products collection kits decreased by 85% to \$0.05 million for the three months ended September 30, 2023 from \$0.4 million for the three months ended September 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 95% to \$0.2 million for the three months ended September 30, 2023 from \$3.6 million for the three months ended September 30, 2022 as a result lower funding for research and development activities and lower royalty income.

CONSOLIDATED OPERATING RESULTS

Consolidated gross profit margin increased to 49.7% for the three months ended September 30, 2023 from 39.9% for the three months ended September 30, 2022. This increase in margins was driven by IntelliSwab® sales which generated higher margins due to reduced costs associated with manufacturing efficiencies and a packaging change implemented during the first quarter of 2023. Also contributing to improved margins is lower product scrap expense, and improved overhead absorption. These improvement in margins were partially offset by a decrease in non-product revenues which contribute 100% to gross margin. Gross margins in the fourth quarter to are expected to moderate and not remain at this level due to product mix shifts, including the anticipated reduction in IntelliSwab volume

Consolidated operating income for the three months ended September 30, 2023 was \$10.9 million, a \$10.0 million improvement from the \$0.9 million operating income reported for the three months ended September 30, 2022. Results for the three months ended September 30, 2023 were positively impacted by lower operating expense and impairment losses. Results for the three months ended September 30, 2022 included \$6.6 million of impairment losses compared to \$6.2 million for the three months ended September 30, 2023. Impairment losses in the third quarter of 2023 were comprised of intangible impairments whereas impairment in the third quarter of 2022 was associated with idle manufacturing equipment.

Operating expenses in the third quarter of 2023, excluding the impairment charge, decreased \$11.8 million compared to the third quarter of 2022 reflecting the impact of the Company's cost saving measures and headcount reductions.

Research and development expenses decreased 16% to \$8.5 million for the three months ended September 30, 2023 from \$10.1 million for the three months ended September 30, 2022 largely due a decrease in spend on COVID-19 product development, a decrease in employee costs associated with a reduction in headcount, and lower spending on lab supplies.

Sales and marketing expenses decreased 35% to \$8.7 million for the three months ended September 30, 2023 from \$13.5 million for the three months ended September 30, 2022 due to lower employee costs associated with a decrease in headcount, decreased spend on advertising and consulting fees and a decrease in our provision for uncollectible accounts.

General and administrative expenses decreased 35% to \$10.1 million for the three months ended September 30, 2023 from \$15.5 million for the three months ended September 30, 2022 largely due to a decrease in legal fees as well as lower sales tax penalties, lower staffing costs due to a reduction in headcount, and lower project management fees related to our \$109 million manufacturing expansion contract.

All of the above contributed to the Company's operating income of \$10.9 million for the three months ended September 30, 2023, which included a non-cash impairment charge of \$6.2 million, non-cash charges of \$3.4 million for depreciation and amortization, and \$2.6 million for stock-based compensation. The Company's operating income of \$0.9 million for the three months ended September 30, 2022 included a non-cash impairment charge of \$6.6 million, non-cash charges of \$3.9 million for depreciation and amortization, and \$2.3 million for stock-based compensation.

OTHER INCOME

Other income for the three months ended September 30, 2023 was \$2.6 million compared to \$3.6 million for the three months ended September 30, 2022. This decrease is largely due to lower foreign currency gains 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 September 30, 2023, the Company recorded U.S. state income tax expense of \$1.1 million compared to \$40.0 thousand benefit for the three months ended September 30, 2022 and a foreign tax expense of \$1.2 million for the three months ended September 30, 2023 compared to \$1.1 million benefit for the three months ended September 30, 2022. The overall increase in tax expense is associated with a projected increase in earnings in both the U.S. and in Canada.

Results of Operations

Nine months ended September 30, 2023 compared to September 30, 2022.

CONSOLIDATED NET REVENUES

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

	Nine Months Ended September 30,				
	Dollars		% Change	Percentage of Total Net Revenues	
	2023	2022		2023	2022
COVID-19 Diagnostics	\$ 215,876	\$ 144,809	49 %	65 %	55 %
Diagnostics ⁽¹⁾	56,475	37,759	50	18	14
Molecular Products ⁽²⁾	41,230	51,344	(20)	13	19
Other products and services ⁽³⁾	9,279	8,895	4	3	3
Molecular Services	3,567	4,895	(27)	1	2
COVID-19 Molecular Products	239	9,522	(97)	—	4
Net product and services revenues	326,666	257,224	27	99	97
Non-product and services revenues ⁽⁴⁾	2,925	7,177	(59)	1	3
Net revenues	\$ 329,591	\$ 264,401	25 %	100 %	100 %

⁽¹⁾ Includes HIV and HCV product revenues.

⁽²⁾ Includes Genomics, Microbiome and Novosanis product revenues.

⁽³⁾ Includes Risk assessment testing and other product and services revenues.

⁽⁴⁾ Non-product and services revenues include funded research and development contracts, royalty income and grant revenues.

Product and Services Revenues

Consolidated net product and services revenues increased 25% to \$329.6 million for the nine months ended September 30, 2023 from \$264.4 million for the nine months ended September 30, 2022.

COVID-19 Diagnostics revenues increased 49% to \$215.9 million for the nine months ended September 30, 2023 compared to \$144.8 million for the nine months ended September 30, 2022 due to increased sales of the Company's InteliSwab® tests through its government procurement contracts.

Sales of the Company's Diagnostics products increased 50% to \$56.5 million for the nine months ended September 30, 2023 from \$37.8 million for the nine months ended September 30, 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 international markets.

Molecular Products revenues decreased 20% to \$41.2 million for the nine months ended September 30, 2023 from \$51.3 million for the nine months ended September 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 customer ordering patterns. These declines in revenue are being partially offset by new customer revenues in the animal, pharma, and genetic testing markets.

Other products and services revenues increased 4% to \$9.3 million for the nine months ended September 30, 2023 from \$8.9 million for the nine months ended September 30, 2022.

Molecular Services revenues, which are largely derived from the Company's laboratory services, decreased 27% to \$3.6 million for the nine months ended September 30, 2023 from \$4.9 million for the nine months ended September 30, 2022. The decline in services revenues was the result of the loss of two customers in 2022 : one customer ceased operations in 2022 and the other deprioritized microbiome studies coupled with the completion of certain large clinical trial studies and timing of research studies.

Sales of the Company's COVID-19 Molecular Products collection kits decreased significantly by 97% to \$0.2 million for the nine months ended September 30, 2023 from \$9.5 million for the nine months ended September 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 59% to \$2.9 million for the nine months ended September 30, 2023 from \$7.2 million for the nine months ended September 30, 2022 as a result of lower funding received on research and development activities and lower royalty income.

CONSOLIDATED OPERATING RESULTS

Consolidated gross profit margin increased to 41.4% for the nine months ended September 30, 2023 from 37.3% for the nine months ended September 30, 2022. This improvement in margins was driven by IntelliSwab® sales which generated higher margins due to reduced costs associated with improved manufacturing efficiencies and a packaging change implemented during the first quarter of 2023, and lower freight charges. Lower product scrap expense in 2023 compared to 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 the Company on-shores and automates the manufacturing of this product at its Pennsylvania facilities and lower COVID-19 Molecular Products revenue which historically generated higher margins.

Consolidated operating income for the nine months ended September 30, 2023 was \$28.8 million, a \$65.6 million improvement from the \$36.8 million operating loss reported for the nine months ended September 30, 2022. Results for the nine months ended September 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 nine months ended September 30, 2022 included \$17.1 million of impairment losses compared to \$7.5 million for the nine months ended September 30, 2023.

Operating expenses in the nine months ended September 30, 2023, excluding the impairment charges, decreased \$18.0 million compared to the nine months ended September 30, 2022.

Research and development expenses decreased to \$26.7 million for the nine months ended September 30, 2023 from \$28.2 million for the nine months ended September 30, 2022, largely due to a decline in spend on COVID-19 development and lower staffing costs due to a decrease in headcount, partially offset by increased engineering consulting spend associated with our \$109 million manufacturing expansion contract.

Sales and marketing expenses decreased 22% to \$29.4 million for the nine months ended September 30, 2023 from \$37.9 million for the nine months ended September 30, 2022 due to decreased employee costs associated with the reduction in headcount, a decrease in the Company's reserve for expected credit losses and lower advertising, marketing, sales meeting, and consulting spend.

General and administrative expenses decreased 15% to \$44.2 million for the nine months ended September 30, 2023 from \$52.3 million for the nine months ended September 30, 2022 largely due a decrease in consulting fees, lower project management fees associated with the \$109 million DOD manufacturing expansion contract, lower employee costs associated with lower headcount, severance, stock compensation expense and recruitment fees. In the first nine months of 2022, the Company incurred high severance and stock compensation expense associated with the accelerated vesting of shares under the Company's 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 \$28.8 million for the nine months ended September 30, 2023, which included non-cash impairment charges of \$7.5 million largely related to equipment that will no longer be used in production and intangible asset impairment, non-cash charges of \$17.4 million for depreciation and amortization, and \$7.6 million for stock-based compensation. The Company's operating loss of \$36.8 million for the nine months ended September 30, 2022 included a non-cash impairment charge of \$17.1 million, non-cash charges of \$11.4 million for depreciation and amortization, and \$9.1 million for stock-based compensation.

OTHER INCOME

Other income for the nine months ended September 30, 2023 was \$6.8 million compared to \$5.5 million for the nine months ended September 30, 2022. This increase is largely due to higher interest income and higher reimbursement of costs incurred under the Company's DOD expansion contract which are presented in research and development expenses offset by lower foreign currency gains.

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 nine months ended September 30, 2023, the Company recorded U.S. state tax expense of \$2.4 million, and a foreign tax benefit of \$0.4 million. For the nine months ended September 30, 2022, the Company recorded U.S. state tax expense of \$0.4 million, a foreign tax benefit of \$0.4 million, and foreign withholding tax of \$1.7 million associated with the Company's 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.

Liquidity and Capital Resources

	September 30, 2023	December 31, 2022
	(in thousands)	
Cash and cash equivalents	\$ 217,533	\$ 83,980
Available-for-sale securities	7,358	26,867
Working capital	315,517	256,127

The Company's cash and cash equivalents and available-for-sale securities increased to \$224.9 million at September 30, 2023 from \$110.8 million at December 31, 2022. \$78.9 million or 35% of the \$224.9 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 the Company's foreign subsidiaries.

The Company's working capital increased to \$315.5 million at September 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 the Company's Cash Flows

Operating Activities

During the nine months ended September 30, 2023, net cash provided by operating activities was \$100.2 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 \$33.6 million included non-cash charges of depreciation and amortization expense of \$17.4 million, stock-based compensation expense of \$7.6 million, impairment charges taken for idle equipment and intangible assets of \$7.5 million and a non-cash deferred tax benefit of \$0.5 million.

Cash provided by the working capital accounts included a decrease in inventory of \$36.4 million as the Company fulfilled demand for its IntelliSwab® product, a decrease in accounts receivable of \$17.5 million largely associated with collections of monies due from the U.S. government for IntelliSwab® shipments, a \$10.5 million decrease in prepaid and other assets as the Company received payment of its Employee Retention Credit filed for in 2021 and taxes refunds associated with Canadian income tax returns. Offsetting these increases in cash is a decrease in accounts payable of \$25.1 million associated with the timing of payment of vendor invoices and a decrease in accrued expenses of \$4.0 million.

Investing Activities

Net cash provided by investing activities was \$35.6 million for the nine months ended September 30, 2023, which reflects proceeds from the maturities of investments of \$95.0 million, \$24.3 million in reimbursement received under the Company's \$109 million contract with the U.S. government offset by \$74.7 in purchases of investments, \$4.5 million to build additional manufacturing capacity as required by the contract, and \$4.5 million to acquire property and equipment to support the normal operations of the business.

Financing Activities

Net cash used in financing activities was \$2.7 million for the nine months ended September 30, 2023, which is largely comprised of \$1.9 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 September 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 nine months ended September 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. We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and Rule 15d-15(e) under the Exchange Act that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized

and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2023. Based on the evaluation of our disclosure controls and procedures as of September 30, 2023, our Chief Executive Officer and Chief Financial Officer concluded that as of such date, our disclosure controls and procedures were not effective due to the existence of the material weakness described below. However, our management, including our Chief Executive Officer and our Chief Financial Officer, has concluded that, notwithstanding the identified material weakness in our internal control over financial reporting, the financial statements in this Quarterly Report fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with U.S. GAAP.

(b) Material Weakness in Internal Control Over Financial Reporting. In the third quarter of fiscal 2023, we identified a material weakness in our internal control over financial reporting related to customer pricing in the revenue recognition process. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. A control related to the validation of accurate pricing in customer sales orders did not operate effectively to detect an error in prices, which resulted in the recognition of revenue at an inaccurate price during the six months ended June 30, 2023. Although the resulting error was not material to those financial statements, we concluded that the control deficiency represents a material weakness. The financial statements for the nine months ended September 30, 2023 were not impacted by this material weakness and are not misstated. A remediation plan is being put in place to correct this control deficiency.

(c) Changes in Internal Control Over Financial Reporting. Except for the identification of and ongoing steps to remediate the material weakness in our internal control over financial reporting as described above, there was no change in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our 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 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. Those motions remain pending. DNAG filed its opening appellate brief on September 28, 2023. Spectrum's responsive appellate brief is due December 22, 2023. Oral argument in the appeal has not been scheduled. An inter partes review is currently pending before the PTO regarding the second asserted patent. Oral argument in the inter partes review is currently scheduled for November 14, 2023. On September 15, 2023, Spectrum filed a petition for inter partes review of a third patent, which DNAG did not assert in the District Court. An optional preliminary patent owner response is due in December 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.

We have identified a material weakness in our internal control over financial reporting. Failure to remediate such material weakness or any other material weakness that we may identify in the future could result in material misstatements in our financial statements or cause us to fail to meet our periodic reporting obligations.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, our management is required to report on, and our independent registered public accounting firm is required to attest to, the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to determine the adequacy of our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation if a deficiency is identified. Annually, we perform activities that include reviewing, documenting, and testing our internal control over financial reporting. If we fail to maintain the adequacy of our internal control over financial reporting, we will not be able to conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with legal requirements. Any failure to achieve and maintain an effective internal control environment could result in materially misstated consolidated financial statements and a failure to meet our reporting obligations, which would likely cause investors to lose confidence in our reported financial information. This could result in significant expenses to remediate any internal control deficiency and lead to a decline in our stock price.

Management identified a material weakness in our internal control over financial reporting related to customer pricing in the revenue recognition process and concluded that our disclosure controls and procedures were not effective due to the existence of the material weakness as of September 30, 2023. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The material

weakness will not be remediated until all necessary internal controls have been implemented, tested and determined to be operating effectively. In addition, we may need to take additional measures to address such material weakness or modify the planned remediation steps, and we cannot be certain that the measures we have taken, and expect to take, to improve our internal controls will be sufficient to address the issues identified, to ensure that our internal controls are effective or to ensure that the identified material weakness will not result in a material misstatement of our consolidated financial statements. Moreover, other material weaknesses or deficiencies may develop or be identified in the future. If we are unable to correct material weaknesses or deficiencies in internal controls in a timely manner, our ability to record, process, summarize and report financial information accurately and within the time periods specified in the rules and forms of the SEC, will be adversely affected. This failure could negatively affect the market price and trading liquidity of our common stock, cause investors to lose confidence in our reported financial information, subject us to civil and criminal investigations and penalties, and otherwise have a material adverse effect on our consolidated balance sheet, results of operations or our stock price.

For further discussion of this material weakness, see Item 4, Controls and Procures of Part II in this Quarterly report on Form 10-Q.

An Impairment of Goodwill Could Reduce the Company's Earnings.

Throughout the year, the Company's 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 the Company's common stock and market capitalization may suggest that the fair value of the Company's reporting unit has fallen below its carrying amount, indicating that an interim goodwill impairment test is required. The Company monitors changes in its stock price during interim periods between annual goodwill impairment tests and consider overall stock market conditions, the underlying reasons for the decline in the Company's stock price, the significance of the decline, and the duration of time that the Company's securities have been trading at a lower value.

The Company performed its annual goodwill impairment assessment as of July 31, 2023 using a quantitative assessment given the volatility in the Company's stock and the decline in its market capitalization. This assessment resulted in no impairment.

Security Breaches and Other Disruptions Could Compromise Our Information, Expose Us To Liability and Harm Our Reputation and Business.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, personal information, our proprietary business information and that of our customers, suppliers and business partners, and personally identifiable information of our employees in our data centers and on our networks. Secure maintenance and transmission of this information is critical to our operations business strategy. We generally rely on commercially available systems, software, tools and domestically available monitoring to provide security for processing, transmitting and storing this sensitive date.

Cyber-attacks could result in unauthorized access to our computer systems or our third-party IT service provider's systems and, if successful, misappropriate personal or confidential information. We have in the past and may in the future experience phishing and other security incidents, and such attacks are an ongoing threat. Due to the nature of some of these attacks, there is a risk that they may remain undetected for a period of time. If successful, these activities could lead to service interruptions, extortion, theft of confidential, personal or proprietary information, the compromise of data integrity or unauthorized information disclosure. Any technology service interruption or breach of our systems could adversely affect our business operations and/or result in the loss of personal data, confidential information or intellectual property. Such incidents could require disclosure to government authorities and/or regulators and could require notification to impacted individuals and any incident could result in financial, legal, business and reputational harm to us. We maintain cyber liability insurance; however, this insurance may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems.

We have outsourced significant elements of our IT infrastructure and, as a result, we manage relationships with third-party providers who may or could have access to our confidential information. We rely on technology developed, supplied and/or maintained by third-parties that may make us vulnerable to "supply chain" style cyber-attacks. Further, technology and security vulnerabilities of acquisitions, business partners or third-party providers may not be identified during due diligence or soon enough to mitigate exploitation. The size and complexity of our IT and information security systems, and those of our third-party providers (and the large amounts of confidential information that is present on them), make such systems potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by, but not limited to, our employees, service providers, business partners, customers or malicious attackers. In addition, a contractor or other third party with whom we do business may attempt to circumvent our security measures or obtain such

information, and may purposefully or inadvertently cause a breach involving sensitive information. While we will continue to evaluate and implement additional protective measures to reduce the risk and detect cyber incidents, cyberattacks are becoming more sophisticated and frequent and the techniques used in such attacks change rapidly. Despite our cybersecurity measures (including employee and third-party training, monitoring of networks and systems and maintenance of back up of protective systems) which are continuously reviewed and upgraded, our information technology networks and infrastructure may still be vulnerable to damage, disruptions or shutdowns due to attack by hackers or breaches, voyeur or malfeasance.

Even the most well protected IT networks, systems and facilities remain potentially vulnerable because the techniques used in attempted security breaches are continually evolving and generally are not recognized until launched against a target or, in some cases, are designed not to be detected and, in fact, may not be detected. Any such compromise of our or our third party's IT service providers' data security and access, public disclosure, or loss of personal or confidential business information, could result in legal claims and proceedings, liability under laws to protect privacy of personal information, and regulatory penalties, and could disrupt our operations, require significant management attention and resources to remedy any damages that result, and damage our reputation and customers willingness to transact business with us, any of which could adversely affect our business.

As our activities continue to evolve and expand, we may be subject to additional laws which impose further restrictions on the transfer, access, use, and disclosure of health and other personal information which may impact our business either directly or indirectly. Our failure to comply with applicable privacy or security laws or significant changes in these laws could significantly impact our business and future business plans.

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

Period	Total number of shares purchased	Average price paid per Share	Total number of shares purchased as part of publicly announced plans or programs	Maximum number (or approximate dollar value) of shares that may yet be repurchased under the plans or programs ^(1, 2)
July 1, 2023 - July 31, 2023	597 ⁽³⁾	\$ 4.57	—	11,984,720
August 1, 2023 - August 31, 2023	29,562 ⁽³⁾	\$ 6.49	—	11,984,720
September 1, 2023 - September 30, 2023	1,062 ⁽³⁾	\$ 5.71	—	11,984,720
	<u>31,221</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
31.1*	Certification of Carrie Eglinton-Manner required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.2*	Certification of Kenneth J. McGrath required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
32.1*+	Certification of Carrie Eglinton-Manner required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*+	Certification of 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.
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).

* Filed herewith

+ 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: November 7, 2023

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

Date: November 7, 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: November 7, 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: November 7, 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 September 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

November 7, 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 September 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

November 7, 2023