Table of Contents

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2024.

OR

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

For the transition period from _____to _____ .

Commission File Number 001-16537

ORASURE TECHNOLOGIES, INC.
(Exact Name of Registrant as Specified in Its Charter)

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

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

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

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

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

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

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

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

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

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

As of August 2, 2024, the registrant had 74,568,307 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:

- Market acceptance of, and the Company's ability to market and sell, its products and services, whether through its internal, direct sales force or third parties;
- 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 achieve the anticipated cost savings as a result of its business restructuring, including from in-sourcing third party manufacturing and exiting microbiome services;
- 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;
- 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;
- The Company's ability to fulfill its commitments under its contract with the U.S. government for InteliSwab® COVID-19 Rapid Tests;

- 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 (the "CDC") or other agencies;
- The Company's 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 achieve and maintain sustained profitability;
- The Company's ability to increase its gross margins;
- The Company's 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 impact of changes in international funding sources and testing algorithms on international sales;
- 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;
- The impact of terrorist attacks and civil unrest, hostilities and war;
- The impact of cybersecurity incidents and other disruptions involving our computer systems or those of our third-party IT service providers, suppliers and customers; and
- General political, business and economic conditions, including interest rates and inflationary pressures.

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 for the fiscal year ended December 31, 2023 filed with the Securities and Exchange Commission (the “SEC”) on March 11, 2024, and in subsequent 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

Item 1. FINANCIAL STATEMENTS

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

	June 30, 2024	December 31, 2023
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 258,239	$ 290,407
Short-term investments	9,142	—
Accounts receivable, net of allowance of $1,065 and $1,216	38,097	40,171
Inventories	38,255	47,614
Prepaid expenses	3,554	6,041
Other current assets	3,775	2,226
Total current assets	351,062	386,459
Noncurrent Assets:		
Property, plant and equipment, net of accumulated depreciation of $88,529 and $85,143	40,313	45,420
Operating right-of-use assets, net	10,241	12,270
Finance right-of-use assets, net	170	576
Intangible assets, net of accumulated amortization of $33,200 and $33,649	829	1,206
Goodwill	34,964	35,696
Investment in equity method investee	27,773	—
Other noncurrent assets	991	1,218
Total noncurrent assets	115,281	96,386
TOTAL ASSETS	**$ 466,343**	**$ 482,845**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 9,085	$ 13,151
Deferred revenue	1,445	1,559
Accrued expenses and other current liabilities	16,199	22,710
Finance lease liability	515	539
Operating lease liability	1,608	1,577
Total current liabilities	28,852	39,536
Noncurrent Liabilities:		
Finance lease liability	267	226
Operating lease liability	10,234	11,162
Other noncurrent liabilities	523	696
Deferred income taxes	627	554
Total noncurrent liabilities	11,651	12,638
TOTAL LIABILITIES	40,503	52,174
Commitments and contingencies (Note 11)		
STOCKHOLDERS' EQUITY		
Preferred stock, par value $0.000001, 25,000 shares authorized, none issued	—	—
Common stock, par value $0.000001, 120,000 shares authorized, 74,568 and 73,528 shares issued and outstanding	—	—
Additional paid-in capital	532,601	529,543
Accumulated other comprehensive loss	(18,631)	(14,941)
Accumulated deficit	(88,130)	(83,931)
Total stockholders' equity	425,840	430,671
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 466,343**	**$ 482,845**

See accompanying notes to the consolidated financial statements.

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2024	2023	2024	2023
NET REVENUES:				
Products and services	$ 53,949	$ 84,738	$ 107,728	$ 237,652
Other	386	703	739	2,752
	54,335	85,441	108,467	240,404
COST OF PRODUCTS AND SERVICES SOLD	29,646	59,070	59,713	148,218
Gross profit	24,689	26,371	48,754	92,186
OPERATING EXPENSES:				
Research and development	6,599	7,661	14,337	18,221
Sales and marketing	7,931	8,535	16,379	20,677
General and administrative	11,845	16,424	23,479	34,135
Loss on impairments	1,054	215	4,392	1,320
Change in the estimated fair value of acquisition-related contingent consideration	—	(35)	—	(59)
	27,429	32,800	58,587	74,294
Operating (loss) income	(2,740)	(6,429)	(9,833)	17,892
OTHER INCOME	3,066	1,467	6,557	4,140
(Loss) income before income taxes	326	(4,962)	(3,276)	22,032
INCOME TAX EXPENSE (BENEFIT)	381	(166)	363	(391)
LOSS ON EQUITY INVESTMENT	(560)	—	(560)	—
NET (LOSS) INCOME	$ (615)	$ (4,796)	$ (4,199)	$ 22,423
(LOSS) INCOME PER SHARE:				
BASIC	$ (0.01)	$ (0.07)	$ (0.06)	$ 0.31
DILUTED	$ (0.01)	$ (0.07)	$ (0.06)	$ 0.30
WEIGHTED-AVERAGE SHARES OUTSTANDING:				
BASIC	74,159	73,324	74,127	73,219
DILUTED	74,159	73,324	74,127	74,115

See accompanying notes to the consolidated financial statements.

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2024	2023	2024	2023
NET (LOSS) INCOME	$ (615)	$ (4,796)	$ (4,199)	$ 22,423
OTHER COMPREHENSIVE (LOSS) INCOME				
Currency translation adjustments	(1,134)	2,859	(3,690)	3,656
Unrealized gain on marketable securities	—	—	—	220
COMPREHENSIVE (LOSS) INCOME	$ (1,749)	$ (1,937)	$ (7,889)	$ 26,299

See accompanying notes to the consolidated financial statements.

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

	For the Six Months Ended June 30,	
	2024	**2023**
OPERATING ACTIVITIES:		
Net (loss) income	$ (4,199)	$ 22,423
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Stock-based compensation	6,290	5,012
Depreciation and amortization	5,331	14,011
Loss on impairments	4,392	1,320
Other non-cash amortization	(88)	1
Provision for credit losses	149	(478)
Unrealized foreign currency (gain) loss	(48)	106
Interest expense on finance leases	13	28
Loss on equity investment	560	—
Deferred income taxes	91	(1,815)
Change in the estimated fair value of acquisition-related contingent consideration	—	(59)
Payment of acquisition-related contingent consideration	—	(19)
Changes in assets and liabilities:		
Accounts receivable	1,802	18,652
Inventories	9,220	22,556
Prepaid expenses and other assets	1,727	5,495
Accounts payable	(3,469)	(22,187)
Deferred revenue	(105)	(450)
Accrued expenses and other liabilities	(7,083)	(1,326)
Net cash provided by operating activities	14,583	63,270
INVESTING ACTIVITIES:		
Purchases of short-term investments	(53,244)	—
Purchase of equity method investee	(28,333)	—
Proceeds from maturities and redemptions of short-term investments	43,908	27,305
Purchases of property and equipment	(3,196)	(2,893)
Purchase of property and equipment under government contracts	—	(4,034)
Proceeds from funding under government contract	—	17,793
Net cash provided by (used in) investing activities	(40,865)	38,171
FINANCING ACTIVITIES:		
Cash payments for lease liabilities	(107)	(320)
Proceeds from exercise of stock options	215	66
Payment of acquisition-related contingent consideration	—	(46)
Repurchase of common stock	(3,446)	(1,663)
Net cash used in financing activities	(3,338)	(1,963)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	(2,547)	2,478
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(32,168)	101,956
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	290,407	83,980
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 258,239	$ 185,936
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for income taxes	$ 1,607	$ 623
Non-cash investing and financing activities		
Accrued property and equipment purchases	$ 638	$ 314

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, 2023. Results of operations for the three and six months ended June 30, 2024 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, 2023 that have had a material impact on the consolidated financial statements and related notes except as discussed herein.

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 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 following is a summary of the Company's available-for-sale securities (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
June 30, 2024				
Guaranteed investment certificates	$ 9,142	$ —	$ —	$ 9,142
Total	$ 9,142	$ —	$ —	$ 9,142
At June 30, 2024, maturities of the Company's available-for-sale securities were as follows:				
Less than one year	$ 9,142	$ —	$ —	$ 9,142
Greater than one year	$ —	$ —	$ —	$ —

The Company had no available-for-sale securities as of December 31, 2023.

Fair Value of Financial Instruments

As of June 30, 2024 and December 31, 2023, 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 guaranteed investment certificates are measured as Level 1 instruments as of June 30, 2024.

Included in cash and cash equivalents at June 30, 2024 and December 31, 2023 was $60.3 million and $71.7 million, respectively, of guaranteed investment certificates. All of the Company's guaranteed investment certificates are measured as Level 1 instruments.

Also included in cash and cash equivalents at June 30, 2024 and December 31, 2023 was $115.6 million and $112.7 million, respectively, invested in money market funds. These money market funds have investments in U.S. government securities and are measured as Level 1 instruments.

The Company offers a nonqualified deferred compensation plan for certain eligible employees and members of its Board of Directors. The assets of the plan are held in the name of the Company at a third-party financial institution. Separate accounts are maintained for each participant to reflect the amounts deferred by the participant and all earnings and losses on those deferred amounts. The assets of the plan are held in mutual funds and company stock. The fair value of the plan assets as of both June 30, 2024 and December 31, 2023 was $0.7 million 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 financial 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.

Equity Method Investee

In January 2024, the Company lead the Series B financing and entered into wide-ranging strategic distribution agreements with KKR Sapphiros L.P. ("Sapphiros"), a privately held consumer diagnostic portfolio company, and certain of its related entities. Through this relationship, the Company expects to be able to offer a more comprehensive range of low-cost diagnostic tests and molecular sample management solutions to the Company's customers globally. As of June 30, 2024, the Company had funded $28.3 million for an interest in Sapphiros, with an aggregate commitment of up to $30.0 million, of which the remainder was funded in July 2024. The Company has recorded the investment using the equity method in accordance with Accounting Standards Codification ("ASC") Topic 323, *Investments—Equity Method and Joint Ventures—Overall.* In accordance with the equity method, the Company's equity investment is presented net of its share of any gains or losses of the investee. The Company has elected as its accounting policy to recognize its share of any income or loss in Sapphiros on a three-month lag. The investment in Sapphiros of $27.8 million as of June 30, 2024 is included in the investment in equity method investee line of the Company's balance sheet and is measured as a Level 3 investment. The Company has no unconditional obligations or guarantees to, or in support of, our equity method investee and its operations. In conjunction with the preparation of the Company's June 30, 2024 financial statements, the Company considered whether the carrying values of Sapphiros was impaired and concluded that no such impairment existed. There was no similar investment as of December 31, 2023.

Foreign Currency Transactions

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 $(0.5) million for the three months ended June 30, 2024 and 2023, respectively. Net foreign exchange gains and (losses) resulting from foreign currency transactions for the six months ended June 30, 2024 and 2023 were $0.3 million and $(0.5) million, respectively.

Impairment of Long-Lived Assets

Long-lived assets, which include property, plant and equipment, definite-lived intangible assets, as well as right-of-use assets (ROU assets) of operating and finance leases, 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.

During the first quarter of 2024, the Company identified a triggering event to test for the recoverability of all the property, plant, and equipment and ROU assets of both the Diversigen and Novosanis subsidiaries, given the Company's decision to initiate a strategic plan to transition away from the microbiome molecular sequencing services business and close its Belgian operations. The Company performed an undiscounted cash flow analysis and determined the carrying values of the property, plant and equipment and ROU assets could not be recovered through the sum of the undiscounted future cash flows and were impaired. During the six months ended June 30, 2024 the Company recognized aggregate pre-tax impairment charges of $1.2 million and $0.3 million to its operating and finance ROU assets, respectively. These charges are reported in the Company's consolidated statement of operations. The impact of the impairments on the Company's property, plant, equipment for the six months ended June 30, 2024 is discussed further in Note 4.

Accumulated Other Comprehensive Loss

Change in accumulated other comprehensive loss by component is listed below (in thousands):

	Foreign Currency	Total
Balance at December 31, 2023	$ (14,941)	$ (14,941)
Other comprehensive loss	(3,690)	(3,690)
Balance at June 30, 2024	$ (18,631)	$ (18,631)

Recent Accounting Pronouncements

In March 2024, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") No. 2024-01, *Compensation—Stock Compensation (Topic 718), Scope Application of Profits Interest and Similar Awards*. The purpose of this update was to provide illustrative examples to demonstrate how an entity should apply guidance to determine whether profits interests and similar awards should be accounted for in accordance with Topic 718. For public business entities, the amendments in this ASU are effective for fiscal years beginning after December 15, 2024, and interim periods within those fiscal periods. The amendments may be applied prospectively or retrospectively, and early adoption is permitted. Management is evaluating the impact on the Company's consolidated financial statements.

2. Government Capital Contracts

In September 2021, the Company entered into an agreement for $109.0 million in funding from the U.S. Department of Defense (the "DOD"), in coordination with the Department of Health and Human Services, to build additional manufacturing capacity in the United States for its InteliSwab® COVID-19 Rapid Test as part of the nation's pandemic preparedness plan. In accordance with the milestone payment schedule, 15% of the total was not billed and funded until the completion of the final validation testing, which occurred in October 2023. The Company began receiving funds from the DOD in January 2022 and has received $109.0 million as of December 31, 2023. In connection with the completion of the contract in the fourth quarter of 2023, all funds were received.

Activity for these capital contracts was accounted for pursuant to International Accounting Standards ("IAS") 20, *Accounting for Government Grants and Disclosure of Government Assistance,* as there is not direct US GAAP guidance for this type of transaction. Funding received in relation to capital-related costs incurred for government contracts was 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 were 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 covered project management costs were recognized straight-line in other income over the term of the government contract. The Company recognized no such income during the three and six months ended June 30, 2024. The Company recognized $0.6 million and $1.1 million of such income during the three and six months ended June 30, 2023, respectively.

The DOD also reimbursed the Company for certain engineering consulting costs. These expenses are reflected in research and development expenses as incurred with the corresponding amount presented in other income. The Company recognized no such costs during the three and six months ended June 30, 2024. The Company recognized $0.5 million and $1.6 million of such costs during the three and six months ended June 30, 2023, respectively.

The activity corresponding to the government contracts included in the Company's consolidated statements of cash flows for the cumulative period ended December 31, 2023 is as follows (in thousands):

	December 31, 2023
Cost of assets, cumulative	$ 86,993
Reduction for funding received to date	(86,993)
Total property, plant and equipment, net	$ —

3. Inventories (in thousands)

	June 30, 2024	December 31, 2023
Raw materials	$ 20,137	$ 20,727
Work in process	1,452	1,900
Finished goods	16,666	24,987
	$ 38,255	$ 47,614

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

	June 30, 2024	December 31, 2023
Land	$ 1,118	$ 1,118
Buildings and improvements	34,904	34,606
Machinery and equipment	62,344	64,156
Computer equipment and software	17,634	17,739
Furniture and fixtures	3,460	3,748
Construction in progress	9,382	9,196
	128,842	130,563
Accumulated depreciation	(88,529)	(85,143)
	$ 40,313	$ 45,420

During the first quarter of 2024, the Company initiated a strategic plan to transition away from the microbiome molecular sequencing services business and to exit operations at its Belgium location. As a result of these decisions, the Company determined that the carrying values of all the property, plant, and equipment of its Diversigen and Novosanis subsidiaries were not recoverable and recorded an aggregate pre-tax asset impairment charge of $1.8 million during the six months ended June 30, 2024.

During the second quarter of 2024, the Company determined a manufacturing line will no longer be utilized. As a result of this decision, the Company determined that the carrying value of the equipment was not recoverable and recorded an aggregate pre-tax impairment charge of $1.1 million during the six months ended June 30, 2024.

During the six months ended June 30, 2023, the Company determined several manufacturing lines will not be utilized due to changes in forecasted demand for the products the equipment is intended to produce. Additionally, the Company elected not to proceed with certain leasehold improvements to its research and development laboratories. As a result of these decisions, the Company determined that the carrying values of the equipment and leasehold improvements made to date were not recoverable and recorded an aggregate pre-tax asset impairment charge of $1.3 million during the six months ended June 30, 2023.

Due to the extremely specialized nature of the property, plant, and equipment in each triggering event noted above and due to various market data points, the estimated fair value of all assets was determined to be zero. These charges are reported within loss on impairments in the consolidated statement of operations.

5. Accrued Expenses and Other Current Liabilities (in thousands)

	June 30, 2024	December 31, 2023
Payroll and related benefits	$ 9,881	$ 14,654
Professional fees	1,591	2,827
Sales tax payable	1,359	1,245
Other	3,369	3,984
	$ 16,199	$ 22,710

6. Termination Benefits

2023 Reduction in Workforce

During the first and second quarters of 2023, the Company executed a reduction in workforce. This was accounted for pursuant to ASC 420, *Exit or Disposal Cost Obligations*. The charges for termination benefits included in the Company's consolidated statements of operations are as follows (in thousands):

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2024	2023	2024	2023
Cost of products and services sold	$ —	$ 334	$ —	$ 369
Research and development	—	—	—	566
Sales and marketing	—	94	—	1,542
General and administrative	—	201	—	787
	$ —	$ 629	$ —	$ 3,264

As of June 30, 2024 the Company had fully paid the $3.3 million related to the reduction in workforce. No additional expense associated with the 2023 reduction in workforce was incurred during the six months ended June 30, 2024. This plan was completed as of June 30, 2024.

Q1 2024 Reduction in Workforce

During the first quarter of 2024, the Company executed a reduction in workforce largely affecting its COVID-19 manufacturing workforce. This was accounted for pursuant to ASC 420, *Exit or Disposal Cost Obligations*. The charges for termination benefits included in the Company's consolidated statements of operations are as follows (in thousands):

	For the Six Months Ended June 30,
	2024
Cost of products and services sold	$ 231
Research and development	87
Sales and marketing	69
General and administrative	17
	$ 404

As of June 30, 2024 the Company had $51.8 thousand accrued and had paid $0.4 million related to the reduction in workforce. No additional expense associated with the Q1 2024 reduction in workforce was incurred during the three months ended June 30, 2024. The Company expects this plan to be completed by December 31, 2024.

Q2 2024 Reduction in Workforce

During the second quarter of 2024, the Company executed an additional reduction in workforce as the Company notified employees of its intention to consolidate its Novosanis site in Belgium into other locations by the end of December 31,

2024, discontinue the Diversigen molecular services line of business by the end of June 30, 2024, and consolidate facilities by third-party manufacturing activities into its Pennsylvania facilities by the end of the third quarter of 2025. This was accounted for pursuant to ASC 420, *Exit or Disposal Cost Obligations*. The charges for termination benefits included in the Company's consolidated statements of operations are as follows (in thousands):

	For the Three Months Ended June 30, 2024
Cost of products and services sold	$ 889
Research and development	478
Sales and marketing	125
General and administrative	160
Total	$ 1,652

As of June 30, 2024 the Company had $1.5 million accrued and had paid $0.2 million related to the reduction in workforce. The Company expects this plan to be completed by September 2025.

7. Revenues

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2024	2023	2024	2023
COVID-19 [1]	$ 18,939	$ 47,507	$ 42,067	$ 165,916
HIV	13,652	15,964	27,032	29,868
Molecular Sample Management Solutions [2]	12,609	13,050	23,431	25,992
HCV	4,734	3,870	7,734	7,056
Risk assessment testing [3]	2,308	2,358	4,352	4,986
Molecular Services	810	1,354	1,683	2,733
Other product and service revenues [4]	897	635	1,429	1,101
Net product and services revenues	53,949	84,738	107,728	237,652
Non-product and services revenues [5]	386	703	739	2,752
Net revenues	$ 54,335	$ 85,441	$ 108,467	$ 240,404

[1] Includes COVID-19 Diagnostics and COVID-19 Molecular revenues.
[2] Includes Genomics, Microbiome and Novosanis product revenues.
[3] Includes substance abuse testing products revenues.
[4] Includes Syphilis revenues.
[5] Includes 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):

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2024	2023	2024	2023
United States	$ 44,386	$ 73,871	$ 89,597	$ 218,890
Europe	2,164	2,453	3,766	4,305
Other regions	7,785	9,117	15,104	17,209
	$ 54,335	$ 85,441	$ 108,467	$ 240,404

Customer and Vendor Concentrations. At June 30, 2024, one non-commercial customer accounted for 22% of the Company's consolidated accounts receivable. The same non-commercial customer accounted for 40% of the Company's consolidated accounts receivable as of December 31, 2023. The same non-commercial customer also accounted for 33% and 56% of net consolidated revenues for the three months ended June 30, 2024 and 2023, respectively. The same non-

commercial customer also accounted for 37% and 70% of net consolidated revenues for the six months ended June 30, 2024 and 2023, respectively.

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

Deferred Revenue. The Company records deferred revenue when funds are received prior to the recognition of the associated revenue. Deferred revenue as of June 30, 2024 and December 31, 2023 included customer prepayments of $1.4 million and $1.2 million, respectively. Deferred revenue as of December 31, 2023 also included $0.4 million 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. The $0.4 million associated with the long-term contract met the criteria to be recognized as revenue during the six months ended June 30, 2024, and as such there is no equivalent balance remaining in deferred revenue at June 30, 2024. Deferred revenue recognized for the three months ended June 30, 2024 and 2023, was $2.0 million and $0.9 million, respectively. Deferred revenue recognized for the six months ended June 30, 2024 and 2023, was $2.7 million and $1.8 million, respectively.

8. Income Taxes

The components of income tax expense (benefit) are as follows (in thousands):

	For the Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
State income tax expense (benefit)	$ 3	$ 1,481	$ (228)	$ 1,257
Foreign income tax expense (benefit)	378	(1,647)	591	(1,648)
Foreign withholding tax	—	—	—	—
	$ 381	$ (166)	$ 363	$ (391)

During the three months ended June 30, 2024 and 2023, the Company recorded income tax expense and benefit of $0.4 million and $0.2 million, respectively. The three months ended June 30, 2024 net tax expense increase is due to having both U.S. and foreign pretax income in 2024 compared to a foreign pretax loss for the three months ended June 30, 2023. During the three months ended June 30, 2024, the state income taxes declined compared to the three months ended June 30, 2023 due to lower state pretax income in 2024. During the six months ended June 30, 2024 and 2023, the Company recorded income tax expense and benefit of $0.4 million and $0.4 million, respectively. Foreign pretax income increased during the six months ended June 30, 2024 compared to a foreign pretax loss offset by lower state pretax income for six months ended June 30, 2023.

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 liability as of June 30, 2024 and at December 31, 2023 relate to the tax effects of the basis difference between the intangible assets acquired in its acquisitions for financial reporting and for tax purposes along with basis differences arising from accelerated tax depreciation of fixed assets.

A valuation allowance is recorded to the extent it is more likely than not that some portion or all of the deferred tax assets will not be realized. A full valuation allowance was recorded on the Company’s U.S. deferred tax assets as of June 30, 2024 and December 31, 2023.

9. Income (Loss) Per Share

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

For the three months ended June 30, 2024 and 2023, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 1,010 shares and 966 shares, respectively, were excluded from the computation of diluted loss per share.

For the six months ended June 30, 2024, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 1,333 shares, were excluded from the computation of diluted loss per share. For the six months ended June 30, 2023, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 2,030 shares were excluded from the computation of diluted earnings per share as their inclusion would have been anti-dilutive.

10. Stockholders' Equity

Reconciliation of the changes in stockholders' equity for the three and six months ended June 30, 2024 and 2023:

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balance at December 31, 2023	73,528	$ —	$ 529,543	$ (14,941)	$ (83,931)	$ 430,671
Common stock issued upon exercise of options	32	—	214	—	—	214
Vesting of restricted stock and performance stock units	593	—	—	—	—	—
Purchase and retirement of common shares	(194)	—	(1,462)	—	—	(1,462)
Stock-based compensation	—	—	2,968	—	—	2,968
Net loss	—	—	—	—	(3,584)	(3,584)
Currency translation adjustments	—	—	—	(2,556)	—	(2,556)
Balance at March 31, 2024	73,959	$ —	$ 531,263	$ (17,497)	$ (87,515)	$ 426,251
Vesting of restricted stock and performance stock units	1,033	—	—	—	—	—
Purchase and retirement of common shares	(424)	—	(1,984)	—	—	(1,984)
Stock-based compensation	—	—	3,322	—	—	3,322
Net loss	—	—	—	—	(615)	(615)
Currency translation adjustments	—	—	—	(1,134)	—	(1,134)
Balance at June 30, 2024	74,568	$ —	$ 532,601	$ (18,631)	$ (88,130)	$ 425,840

	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

11. 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 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. The Company appealed the grant of summary judgment to the Court of Appeals on June 8, 2023. The Company is pursuing the appeal with respect to the first patent, with oral argument expected in the second half of 2024. Second, the Court denied Spectrum's motion to supplement 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. On February 7, 2024, the PTO issued a Final Written Decision regarding the second patent in the litigation, holding that claims 1, 3-8, 11 and 12 of U.S. Patent No. 11,002,646 B2 are unpatentable. On March 8, 2024, the Company filed a Request for Rehearing by the Director of the PTO of the Final Written Decision. On March 27, 2024, the Company's Request for Rehearing was denied. On September 15, 2023, Spectrum filed a separate petition for *inter partes* review of a third patent, which DNAG did not assert in the District Court. On March 26, 2024, the PTO issued a Decision Granting Institution of *Inter Partes* Review and scheduled oral argument for January 14, 2025. On July 2, 2024 the Company filed a Motion to Amend the claims of the third patent, which remains pending.

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, 2023 filed with the Securities and Exchange Commission on March 11, 2024. 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, 2023 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

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. These products include tests for diseases including COVID-19, HIV, Hepatitis C, and Syphilis that are performed on a rapid basis at the point of care, and tests for drugs of abuse that are processed in a laboratory. These products are sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations, and other public health organizations, distributors, government agencies, physicians' offices, and commercial and industrial entities. The Company's COVID-19 and HIV products are also sold in a consumer-friendly format in the over-the-counter ("OTC") market in the U.S. and, in the case of the HIV product, as a self-test to individuals in a number of other countries, including as an oral swab in-home test for HIV-1 and HIV-2 in Europe.

The Company's business also includes molecular sample management solutions and services that are used by clinical laboratories, direct-to-consumer laboratories, researchers, pharmaceutical companies, and animal health service and product providers. The revenues from sample management solutions 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, through its Diversigen subsidiary, the Company offered laboratory and bioinformatics services for both genomics and microbiome customers. These services were primarily provided to pharmaceutical, biotech companies, and research institutions. During the first quarter of 2024, the Company initiated steps to wind down and exit this line of business. Diversigen contributed $1.7 million to revenues during the six months ended June 30, 2024 and contributed $4.5 million to revenues for the full year of 2023.

Results of Operations

For the three months ended June 30, 2024 compared to June 30, 2023.

CONSOLIDATED NET REVENUES

The table below shows an outline of total consolidated net revenues (dollars in thousands) for the three months ended June 30, 2024 and 2023:

	For the Three Months Ended June 30,				
	Dollars			Percentage of Total Net Revenues	
	2024	2023	% Change	2024	2023
COVID-19 Diagnostics	$ 18,934	$ 47,477	(60)%	35 %	56 %
Diagnostics [1]	18,746	19,834	(5)	35	23
Molecular Sample Management Solutions [2]	12,609	13,050	(3)	23	15
Other products and services [3]	2,845	2,993	(5)	5	4
Molecular Services	810	1,354	(40)	1	2
COVID-19 Molecular Products	5	30	(83)	—	—
Net product and services revenues	53,949	84,738	(36)	99	99
Non-product and services revenues [4]	386	703	(45)	1	1
Net revenues	$ 54,335	$ 85,441	(36)%	100 %	100 %

[1] Includes HIV, HCV and Syphilis product revenues.
[2] Includes Genomics, Microbiome and Novosanis product revenues.
[3] Includes Risk assessment testing and other product and services revenues.
[4] Includes funded research and development contracts, royalty income and grant revenues.

Product and Services Revenues

Consolidated net revenues decreased 36% to $54.3 million for the three months ended June 30, 2024 from $85.4 million for the three months ended June 30, 2023.

COVID-19 Diagnostics revenues decreased by 60% to $18.9 million for the three months ended June 30, 2024 compared to $47.5 million for the three months ended June 30, 2023 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 throughout 2024 due to the fulfillment of these contracts and lower overall demand for COVID-19 testing.

Sales of the Company's Diagnostics products decreased 5% to $18.7 million for the three months ended June 30, 2024 from $19.8 million for the three months ended June 30, 2023. This decrease in revenues is largely due to lower domestic and international HIV revenues of approximately $2.3 million primarily driven by customer ordering patterns partially offset by a combined increase in global HCV revenues and Syphilis revenues of approximately $1.2 million. The increase in HCV revenues is primarily due to new customer orders and customer ordering patterns and the Syphilis revenues are generated from the Company's new distribution agreements.

Molecular Sample Management Solutions revenues decreased 3% to $12.6 million for the three months ended June 30, 2024 from $13.1 million for the three months ended June 30, 2023. Sales of the Company's Molecular Products are being impacted by reduced consumer demand for products in which our genomics collection devices are used, economic pressures, and the overall decline in the microbiome market.

Other products and services revenues decreased 5% to $2.8 million for the three months ended June 30, 2024 from $3.0 million for the three months ended June 30, 2023.

Molecular Services revenues, which are derived from the Company's microbiome molecular sequencing services, decreased 40% to $0.8 million for the three months ended June 30, 2024 from $1.4 million for the three months ended June 30, 2023. The decrease in services revenues was due to the decision to exit this line of business. We expect minimal molecular services revenues in the second half of 2024.

Non-Product and Services Revenues

Non-product and services revenues decreased 45% to $0.4 million for the three months ended June 30, 2024 from $0.7 million for the three months ended June 30, 2023 as a result of no royalty income in the second quarter of 2024 as the royalty agreement for sample collection kits expired in June 2023. Further reducing the Company's non-product and services revenue is lower funding for research and development activities largely as a result of the end of our agreement with Biomedical Advanced Research Authority ("BARDA") which provided funding to obtain clearance of a premarket notification ("510(k)") and Clinical Laboratory Improvement Amendments of 1988 waiver of our InteliSwab® tests. The Company has communicated to BARDA that it does not intend to pursue further development of this clearance.

CONSOLIDATED OPERATING RESULTS

Consolidated gross profit margin increased to 45.4% for the three months ended June 30, 2024 from 30.9% for the three months ended June 30, 2023. During the second quarter of 2023, the Company recorded $7.0 million of accelerated depreciation associated with the wind-down of InteliSwab® manual assembly in Thailand as the Company made the decision to onshore and automate manufacturing of this product at its Pennsylvania facilities. In addition, also contributing to the increased margins is improved overhead absorption and lower scrap expense partially offset by a negative impact in product mix caused by a higher volume of sales of lower margin products.

Consolidated operating loss for the three months ended June 30, 2024 was $2.7 million, a 57.4% improvement from the $6.4 million operating loss reported for the three months ended June 30, 2023. Results for the three months ended June 30, 2024 benefited from a $6.2 million reduction in operating expense offset by lower gross profit dollars driven by the decrease in revenues. Results for the three months ended June 30, 2024 included $1.1 million of impairment losses compared to $0.2 million for the three months ended June 30, 2023.

Operating expenses in the second quarter of 2024, excluding the impairment charge, decreased 19% to $26.4 million from $32.6 million in the second quarter of 2023 reflecting the impact of the Company's cost saving measures and headcount reductions.

Research and development expenses decreased 14% to $6.6 million for the three months ended June 30, 2024 from $7.7 million for the three months ended June 30, 2023 largely due to a decrease in employee costs associated with a reduction in headcount, decrease in spend on COVID-19 product development, and no related project management fees for our $109 million manufacturing expansion contract which ended during the fourth quarter of 2023, partially offset by an increase in severance costs for those employees impacted by the Company's decisions to exit the molecular services business offered by its Diversigen subsidiary and wind-down operations located in Belgium.

Sales and marketing expenses decreased 7% to $7.9 million for the three months ended June 30, 2024 from $8.5 million for the three months ended June 30, 2023 due to lower employee costs associated with a decrease in headcount, decreased advertising fees and lower amortization expense.

General and administrative expenses decreased 28% to $11.8 million for the three months ended June 30, 2024 from $16.4 million for the three months ended June 30, 2023 largely due to lower legal fees and lower staffing costs due to a reduction in headcount, partially offset by an increase in non-cash stock compensation expense.

All of the above contributed to the Company's operating loss of $2.7 million for the three months ended June 30, 2024, which included a non-cash impairment charge of $1.1 million, non-cash charges of $2.6 million for depreciation and amortization, and non-cash charges of $3.3 million for stock-based compensation. The Company's operating loss of $6.4 million for the three months ended June 30, 2023 included a non-cash impairment charge of $0.2 million, non-cash charges of $10.3 million for depreciation and amortization, and $2.4 million for stock-based compensation.

OTHER INCOME

Other income for the three months ended June 30, 2024 was $3.1 million compared to $1.5 million for the three months ended June 30, 2023. This increase is due to higher interest income partially offset by the absence of profit earned under our manufacturing expansion contract with the U.S. government which ended at the end of 2023.

CONSOLIDATED INCOME TAXES

The Company continues to believe the full valuation allowance established against its total U.S. deferred tax asset is appropriate as the facts and circumstances necessitating the allowance have not changed. For the three months ended June 30, 2024 and 2023, the Company recorded U.S. state income tax expense of $3.0 thousand and $1.5 million, respectively. For the three months ended June 30, 2024 and 2023, the state income tax expense was partially offset by foreign income tax expense and benefit of $0.4 million and $1.6 million, respectively.

Results of Operations

For the six months ended June 30, 2024 compared to June 30, 2023.

CONSOLIDATED NET REVENUES

The table below shows an outline of total consolidated net revenues (dollars in thousands) for the six months ended June 30, 2024 and 2023:

	For the Six Months Ended June 30,				
	Dollars			Percentage of Total Net Revenues	
	2024	2023	% Change	2024	2023
COVID-19 Diagnostics	$ 42,031	$ 165,731	(75)%	39 %	69 %
Diagnostics [1]	35,139	36,924	(5)	33	15
Molecular Sample Management Solutions [2]	23,431	25,992	(10)	22	11
Other products and services [3]	5,408	6,087	(11)	5	3
Molecular Services	1,683	2,733	(38)	2	1
COVID-19 Molecular Products	36	185	(81)	—	—
Net product and services revenues	107,728	237,652	(55)	99	99
Non-product and services revenues [4]	739	2,752	(73)	1	1
Net revenues	$ 108,467	$ 240,404	(55)%	100 %	100 %

[1] Includes HIV, HCV and Syphilis product revenues.
[2] Includes Genomics, Microbiome and Novosanis product revenues.
[3] Includes Risk assessment testing and other product and services revenues.
[4] Includes funded research and development contracts, royalty income and grant revenues.

Product and Services Revenues

Consolidated net product and services revenues decreased 55% to $108.5 million for the six months ended June 30, 2024 from $240.4 million for the six months ended June 30, 2023.

COVID-19 Diagnostics revenues decreased 75% to $42.0 million for the six months ended June 30, 2024 compared to $165.7 million for the six months ended June 30, 2023 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 throughout 2024 due to the fulfillment of these contracts and lower overall demand for COVID-19 testing.

Sales of the Company's Diagnostics products decreased 5% to $35.1 million for the six months ended June 30, 2024 from $36.9 million for the six months ended June 30, 2023. This decrease in revenue was primarily driven by lower HIV revenues in both the domestic and international markets of $2.8 million as a result of fluctuations in customer ordering patterns. The decline in HIV revenue was partially offset by a combined increase in HCV and Syphilis revenues of $1.1 million .

Molecular Sample Management Solutions revenues decreased 10% to $23.4 million for the six months ended June 30, 2024 from $26.0 million for the six months ended June 30, 2023. Sales of the Company's Molecular Sample Management Solutions Products are being impacted by reduced consumer demand for products in which our genomics collection devices are used, economic pressures and reduction on funding for programs in which our collection devices are used, and the overall decline in the microbiome market.

Other products and services revenues decreased 11% to $5.4 million for the six months ended June 30, 2024 from $6.1 million for the six months ended June 30, 2023. This decrease is driven by lower Risk Assessment testing revenue due to the loss of customers to competing products.

Molecular Services revenues, which are largely derived from the Company's laboratory services, decreased 38% to $1.7 million for the six months ended June 30, 2024 from $2.7 million for the six months ended June 30, 2023. The decrease in services revenues was due to the decision to exit this line of business. We expect minimal molecular services revenues in the second half of 2024.

Non-Product and Services Revenues

Non-product and services revenues decreased 73% to $0.7 million for the six months ended June 30, 2024 from $2.8 million for the six months ended June 30, 2023 as a result of lower royalty income in the first half of 2024 as one of the Company's royalty agreement for sample collection kits expired in June 2023. Further reducing the Company's non-product and services revenue is a result of lower funding for research and development activities largely as a result of the end of our agreement with Biomedical Advanced Research Authority ("BARDA") which provided funding to obtain clearance of a premarket notification ("510(k)") and Clinical Laboratory Improvement Amendments of 1988 waiver of our InteliSwab® tests. The Company has communicated to BARDA that it does not intend to pursue further development of this clearance.

CONSOLIDATED OPERATING RESULTS

Consolidated gross profit margin increased to 44.9% for the six months ended June 30, 2024 from 38.3% for the six months ended June 30, 2023. This improvement in margins was due to $7.0 million of accelerated depreciation recorded in the second quarter of 2023 associated with the wind-down of InteliSwab® manual assembly in Thailand as the Company on-shores and automates the manufacturing of this product at its Pennsylvania facilities. In addition, reduced salary and benefits due to the reduction in workforce experienced in 2023 contributed to improved overhead absorption and lower product scrap expense also contributed to the increased margins in the first half of 2024. These improvement in margins were partially offset by the decline in other non-product revenues which contribute 100% to gross margin and a shift in product mix of increased revenues from lower margin products.

Consolidated operating loss for the six months ended June 30, 2024 was $9.8 million, compared to $17.9 million operating income reported for the six months ended June 30, 2023. Results for the six months ended June 30, 2024 were negatively impacted by the decrease in revenues and were positively impacted by reduced operating expense and negatively impacted by the higher impairment losses. Results for the six months ended June 30, 2024 included $4.4 million of impairment losses compared to $1.3 million for the six months ended June 30, 2023.

Operating expenses for the six months ended June 30, 2024, excluding the impairment charge, decreased 25.7% to $54.2 million from $73.0 million for the six months ended June 30, 2023 reflecting the impact of the Company's cost saving measures and headcount reductions.

Research and development expenses decreased 21% to $14.3 million for the six months ended June 30, 2024 from $18.2 million for the six months ended June 30, 2023, largely due to lower staffing costs due to a decrease in headcount, decrease in spend on COVID-19 product development, and no related project management fees for our $109 million manufacturing expansion contract which ended during the fourth quarter of 2023, partially offset by an increase in severance costs for those employees impacted by the Company's decisions to exit the molecular services business offered by its Diversigen subsidiary and wind-down operations located in Belgium.

Sales and marketing expenses decreased 21% to $16.4 million for the six months ended June 30, 2024 from $20.7 million for the six months ended June 30, 2023 primarily due to decreased employee costs associated with the reduction in headcount and lower advertising, consulting, and amortization expense.

General and administrative expenses decreased 31% to $23.5 million for the six months ended June 30, 2024 from $34.1 million for the six months ended June 30, 2023 largely due to lower legal fees relating to the Spectrum litigation (discussed further in Part II. Other Information, Item 1. Legal Proceedings, below) and lower employee costs associated with reduced headcount partially offset by an increase in non-cash stock compensation expense.

All of the above contributed to the Company's operating loss of $9.8 million for the six months ended June 30, 2024, which included non-cash impairment charges of $4.4 million, non-cash charges of $5.3 million for depreciation and amortization, and $6.3 million for stock-based compensation. The Company's operating income of $17.9 million for the six months ended June 30, 2023 included a non-cash impairment charge of $1.3 million, non-cash charges of $14.0 million for depreciation and amortization, and $5.0 million for stock-based compensation.

OTHER INCOME

Other income for the six months ended June 30, 2024 was $6.6 million compared to $4.1 million for the six months ended June 30, 2023. This increase is largely due to higher interest income and offset by absence of profit earned under our manufacturing expansion contract with the U.S. government which ended at the end of 2023.

CONSOLIDATED INCOME TAXES

The Company continues to believe the full valuation allowance established against its total U.S. deferred tax asset is appropriate as the facts and circumstances necessitating the allowance have not changed. For the six months ended June 30, 2024 and 2023, the Company recorded U.S. state tax benefit and expense of $0.2 million and $1.3 million, respectively. For the six months ended June 30, 2024 and 2023, the state tax expense was partially offset by foreign tax expense and benefit of $0.6 million and $1.6 million.

Liquidity and Capital Resources

	June 30, 2024	December 31, 2023
	(in thousands)	
Cash and cash equivalents	$ 258,239	$ 290,407
Short-term investments	9,142	—
Working capital	322,210	346,923

The Company's cash and cash equivalents and short-term investments decreased to $267.4 million at June 30, 2024 from $290.4 million at December 31, 2023. $87.1 million or 33% of the $267.4 million in cash and cash equivalents and short-term investments is held by DNAG, the Company's Canadian subsidiary.

The Company's working capital decreased to $322.2 million at June 30, 2024 from $346.9 million at December 31, 2023. The decrease in cash and cash equivalents and working capital was primarily due to the investment in Sapphiros of $28.3 million during the six months ended June 30, 2024.

Analysis of the Company's Cash Flows

Operating Activities

During the six months ended June 30, 2024, net cash provided by operating activities was $14.6 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 loss of $4.2 million included non-cash charges of depreciation and amortization expense of $5.3 million, stock-based compensation expense of $6.3 million, impairment losses of $4.4 million, and loss on equity investment of $0.6 million. Cash provided by the working capital accounts included a decrease in accounts receivable of $1.8 million largely associated with lower overall sales and collections of balances due, a decrease in inventory of $9.2 million as the Company fulfilled demand for its InteliSwab® product, and a decrease in prepaid expense and other current assets of $1.7 million. Uses of cash included a decrease in accounts payable of $3.5 million due to lower inventory purchases and timing of vendor invoice payments and a decrease in accrued expenses of $7.1 million as the Company paid out year-end bonuses in March 2024.

Investing Activities

Net cash used in investing activities was $40.9 million for the six months ended June 30, 2024, which reflects proceeds from the maturities of investments of $43.9 million, offset by $53.2 million in purchases of investments. Investing

activities also include a $28.3 million investment in Sapphiros, and $3.2 million to acquire property and equipment to support the normal operations of the business.

Financing Activities

Net cash used in financing activities was $3.3 million for the six months ended June 30, 2024, which is largely comprised of $3.4 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 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, 2023 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, 2023. As of June 30, 2024, 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, 2023 filed with the SEC. No material changes have been made to such critical accounting policies during the six months ended June 30, 2024.

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, 2023.

Item 4. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures. The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) as of June 30, 2024. Based on that evaluation, the Company's management, including such officers, concluded that the Company's disclosure controls and procedures were effective as of June 30, 2024 to provide reasonable assurance that material information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act of 1934 was accumulated and communicated to the Company's management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure and was recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission.

(b) Changes in Internal Control Over Financial Reporting. There was no change in the Company's internal control over financial reporting that occurred during the three months ended June 30, 2024 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

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

Spectrum Patent Litigation

In March 2021, the Company filed a complaint against Spectrum Solutions, LLC ("Spectrum") in the United States District Court for the Southern District of California alleging that certain saliva collection devices manufactured and sold by Spectrum infringe a patent held by DNAG. Spectrum filed an answer 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. The Company appealed the grant of summary judgment to the Court of Appeals on June 8, 2023. The Company is pursuing the appeal with respect to the first patent, with oral argument expected in the second half of 2024. Second, the Court denied Spectrum's motion to supplement 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. On February 7, 2024, the PTO issued a Final Written Decision regarding the second patent in the litigation, holding that claims 1, 3-8, 11 and 12 of U.S. Patent No. 11,002,646 B2 are unpatentable. On March 8, 2024, the Company filed a Request for Rehearing by the Director of the PTO of the Final Written Decision. On March 27, 2024, the Company's Request for Rehearing was denied. On September 15, 2023, Spectrum filed a separate petition for *inter partes* review of a third patent, which DNAG did not assert in the District Court. On March 26, 2024, the PTO issued a Decision Granting Institution of *Inter Partes* Review and scheduled oral argument for January 14, 2025. On July 2, 2024 the Company filed a Motion to Amend the claims of the third patent, which remains pending.

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, 2023.

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

Period	Total number of shares purchased	Average price paid per Share	Total number of shares purchased as part of publicly announced plans or programs	Maximum number (or approximate dollar value) of shares that may yet be repurchased under the plans or programs [1, 2]
April 1, 2024 - April 30, 2024	— [3]	$ —	—	$ 11,984,720
May 1, 2024 - May 31, 2024	20,907 [3]	$ 5.27	—	$ 11,984,720
June 1, 2024 - June 30, 2024	403,077 [3]	$ 4.65	—	$ 11,984,720
	423,984		—	

(1) On August 5, 2008, the Company's Board of Directors approved a share repurchase program pursuant to which the Company is permitted to acquire up to $25.0 million of outstanding shares. This share repurchase program may be discontinued at any time.

(2) This column represents the amount that remains available under the $25.0 million repurchase plan, as of the period indicated. The Company has made no commitment to purchase any shares under this plan.

(3) Pursuant to the OraSure Technologies, Inc. Stock Award Plan, and in connection with the vesting of restricted and performance shares, these shares were retired to satisfy minimum tax withholdings.

Item 3. DEFAULTS UPON SENIOR SECURITIES

None

Item 4. MINE SAFETY DISCLOSURES

Not applicable

Item 5. OTHER INFORMATION

On May 31, 2024, Kathleen Weber, our Chief Product Officer, adopted a trading arrangement (the “Trading Plan”) intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act with respect to the sale of an aggregate of up to 75,000 shares of our common stock between August 30, 2024 and May 30, 2025 pursuant to the terms of the Trading Plan.

Item 6. EXHIBITS

Exhibit Number	Exhibit
3.1	Certificate of Amendment to the Company's Certificate of Incorporation (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on May 17, 2024).
10.1**	Amended and Restated OraSure Technologies, Inc. 2000 Stock Award Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 17, 2024)
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

** Management contract or compensatory plan or arrangement.

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned thereunto duly authorized.

ORASURE TECHNOLOGIES, INC.

/s/ Kenneth J. McGrath

Date: August 6, 2024

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

/s/Michele M. Anthony

Date: August 6, 2024

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

Exhibit 31.1

Certification

I, Carrie Eglinton Manner, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 6, 2024

/s/ Carrie Eglinton Manner

Carrie Eglinton Manner

President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification

I, Kenneth J. McGrath, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 6, 2024

/s/ Kenneth J. McGrath

Kenneth J. McGrath

Chief Financial Officer

(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of OraSure Technologies, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Carrie Eglinton Manner, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Carrie Eglinton Manner

Carrie Eglinton Manner
President and Chief Executive Officer

August 6, 2024

Exhibit 32.2

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

In connection with the Quarterly Report of OraSure Technologies, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Kenneth J. McGrath, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Kenneth J. McGrath

Kenneth J. McGrath
Chief Financial Officer

August 6, 2024