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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2024.

OR

o **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 x No o

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 x No o

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	o	Accelerated filer	x
Non-accelerated filer	o	Smaller reporting company	o
		Emerging growth company	o

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. o

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

As of May 2, 2024, the registrant had 73,959,289 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; 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 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;
- The impact of cybersecurity incidents and other disruptions involving our computer systems or those of our third-party IT service providers; 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 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

Item 1. FINANCIAL STATEMENTS

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

	March 31, 2024	December 31, 2023
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 247,145	$ 290,407
Short-term investments	16,627	—
Accounts receivable, net of allowance of $1,065 and $1,216	34,037	40,171
Inventories	43,180	47,614
Prepaid expenses	4,691	6,041
Other current assets	2,825	2,226
Total current assets	348,505	386,459
Noncurrent Assets:		
Property, plant and equipment, net of accumulated depreciation of $86,332 and $85,143	42,597	45,420
Operating right-of-use assets, net	10,570	12,270
Finance right-of-use assets, net	158	576
Intangible assets, net of accumulated amortization of $33,261 and $33,649	1,010	1,206
Goodwill	35,172	35,696
Investment in equity method investee	28,333	—
Other noncurrent assets	1,213	1,218
Total noncurrent assets	119,053	96,386
TOTAL ASSETS	**$ 467,558**	**$ 482,845**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 12,683	$ 13,151
Deferred revenue	1,597	1,559
Accrued expenses and other current liabilities	12,715	22,710
Finance lease liability	517	539
Operating lease liability	1,593	1,577
Total current liabilities	29,105	39,536
Noncurrent Liabilities:		
Finance lease liability	204	226
Operating lease liability	10,676	11,162
Other noncurrent liabilities	727	696
Deferred income taxes	595	554
Total noncurrent liabilities	12,202	12,638
TOTAL LIABILITIES	41,307	52,174
Commitments and contingencies (Note 12)		
STOCKHOLDERS' EQUITY		
Preferred stock, par value $0.000001, 25,000 shares authorized, none issued	—	—
Common stock, par value $0.000001, 120,000 shares authorized, 73,959 and 73,528 shares issued and outstanding	—	—
Additional paid-in capital	531,263	529,543
Accumulated other comprehensive loss	(17,497)	(14,941)
Accumulated deficit	(87,515)	(83,931)
Total stockholders' equity	426,251	430,671
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 467,558**	**$ 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 March 31,	
	2024	**2023**
NET REVENUES:		
Products and services	$ 53,779	$ 152,914
Other	353	2,049
	54,132	154,963
COST OF PRODUCTS AND SERVICES SOLD	30,067	89,148
Gross profit	24,065	65,815
OPERATING EXPENSES:		
Research and development	7,738	10,560
Sales and marketing	8,448	12,142
General and administrative	11,634	17,711
Loss on impairments	3,338	1,105
Change in the estimated fair value of acquisition-related contingent consideration	—	(24)
	31,158	41,494
Operating income (loss)	(7,093)	24,321
OTHER INCOME	3,491	2,673
Income (loss) before income taxes	(3,602)	26,994
INCOME TAX BENEFIT	(18)	(225)
NET INCOME (LOSS)	$ (3,584)	$ 27,219
INCOME (LOSS) PER SHARE:		
BASIC	$ (0.05)	$ 0.37
DILUTED	$ (0.05)	$ 0.37
WEIGHTED-AVERAGE SHARES OUTSTANDING:		
BASIC	73,947	73,112
DILUTED	73,947	73,966

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 March 31,	
	2024	2023
NET INCOME (LOSS)	$ (3,584)	$ 27,219
OTHER COMPREHENSIVE INCOME		
Currency translation adjustments	(2,556)	797
Unrealized gain on marketable securities	—	220
COMPREHENSIVE INCOME (LOSS)	$ (6,140)	$ 28,236

See accompanying notes to the consolidated financial statements.

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

	For the Three Months Ended March 31,	
	2024	**2023**
OPERATING ACTIVITIES:		
Net income (loss)	$ (3,584)	$ 27,219
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Stock-based compensation	2,968	2,655
Depreciation and amortization	2,725	3,696
Loss on impairments	3,338	1,105
Other non-cash amortization	6	—
Provision for credit losses	(85)	(67)
Unrealized foreign currency (gain) loss	(119)	44
Interest expense on finance leases	7	15
Deferred income taxes	53	—
Change in the estimated fair value of acquisition-related contingent consideration	—	(24)
Payment of acquisition-related contingent consideration	—	(19)
Changes in assets and liabilities:		
Accounts receivable	6,199	(36,613)
Inventories	4,337	18,540
Prepaid expenses and other assets	603	5,299
Accounts payable	(68)	(12,097)
Deferred revenue	47	(279)
Accrued expenses and other liabilities	(9,688)	(3,472)
Net cash provided by operating activities	6,738	6,002
INVESTING ACTIVITIES:		
Purchases of short-term investments	(25,850)	(22,330)
Purchase of equity method investee	(28,333)	—
Proceeds from maturities and redemptions of short-term investments	9,234	27,304
Purchases of property and equipment	(1,579)	(1,191)
Purchase of property and equipment under government contracts	—	(2,767)
Net cash provided by (used in) investing activities	(46,528)	1,016
FINANCING ACTIVITIES:		
Cash payments for lease liabilities	(50)	(148)
Proceeds from exercise of stock options	215	66
Payment of acquisition-related contingent consideration	—	(46)
Repurchase of common stock	(1,462)	(1,203)
Net cash used in financing activities	(1,297)	(1,331)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	(2,175)	527
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(43,262)	6,214
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	290,407	83,980
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 247,145	$ 90,194
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash (refunds) paid for income taxes	$ 592	$ (10)
Non-cash investing and financing activities		
Accrued property and equipment purchases	$ 471	$ 733

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 months ended March 31, 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
March 31, 2024				
Guaranteed investment certificates	$ 16,627	$ —	$ —	$ 16,627
Total	$ 16,627	$ —	$ —	$ 16,627
At March 31, 2024, maturities of the Company's available-for-sale securities were as follows:				
Less than one year	$ 16,627	$ —	$ —	$ 16,627
Greater than one year	$ —	$ —	$ —	$ —

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

Fair Value of Financial Instruments

As of March 31, 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 March 31, 2024.

Included in cash and cash equivalents at March 31, 2024 and December 31, 2023 was $ 114.1 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. Included in cash and cash equivalents at March 31, 2024 and December 31, 2023 was $53.6 million and $71.7 million, respectively, of guaranteed investment certificates, which are also measured as Level 1 instruments.

In January 2024, the Company lead the Series B financing and have entered 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 test and molecular sample management solutions to the Company's customers globally. The Company has funded $28.3 million for an interest in Sapphiros, with an aggregate commitment of up to $ 30.0 million to be funded by June 2024, contingent on certain terms and conditions being met. The Company has recorded the investment using the equity method in accordance with Accounting Standards Codification Topic 323, *Investments-Equity Method and Joint Ventures - Overall.* The investment in Sapphiros L.P. of $ 28.3 million as of March 31, 2024 is included in the equity method investee line of the Company's balance sheet and is measured as Level 3 investments. There is no similar investment as of December 31, 2023.

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 March 31, 2024 and December 31, 2023 was $0.8 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 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 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 $0.2 million and $(0.05) million for the three months ended March 31, 2024 and 2023, 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.

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 during the three months ended March 31, 2024, 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 three months ended March 31, 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 three months ended March 31, 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	(2,556)	(2,556)
Balance at March 31, 2024	$ (17,497)	$ (17,497)

Recent Accounting Pronouncements

In March 2024, the Financial Accounting Standards Board (FASB) issued Accounting Standard Update ("ASU") No. 2024-01, Topic 718, *Compensation-Stock Compensation*. 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 Tests 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 is 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 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 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 months ended March 31, 2024 and $ 0.6 million during the three months ended March 31, 2023.

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 months ended March 31, 2024 and $ 1.1 million during the three months ended March 31, 2023.

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)

	March 31, 2024	December 31, 2023
Raw materials	$ 17,621	$ 20,727
Work in process	1,340	1,900
Finished goods	24,219	24,987
	$ 43,180	$ 47,614

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

	March 31, 2024	December 31, 2023
Land	$ 1,118	$ 1,118
Buildings and improvements	35,013	34,606
Machinery and equipment	62,308	64,156
Computer equipment and software	17,681	17,739
Furniture and fixtures	3,468	3,748
Construction in progress	9,341	9,196
	128,929	130,563
Accumulated depreciation	(86,332)	(85,143)
	$ 42,597	$ 45,420

During the three months ended March 31, 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 three months ended March 31, 2024.

During the three months ended March 31, 2023, the Company determined several manufacturing lines will not be utilized due to changes in forecasted demand for the products the equipment is intended to produce. As a result of this decision, the Company determined that the carrying value of the equipment was not recoverable and recorded an aggregate pre-tax asset impairment charge of $1.1 million during the three months ended March 31, 2023.

Due to the extremely specialized nature of the equipment and various market data points, the estimated fair value was zero. These charges are reported within loss on impairments in the consolidated statements of operations.

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

	March 31, 2024	December 31, 2023
Payroll and related benefits	$ 5,475	$ 14,654
Professional fees	1,980	2,827
Sales tax payable	1,268	1,245
Other	3,992	3,984
	$ 12,715	$ 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 Accounting Standards Codification ("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 March 31,	
	2024	2023
Cost of products and services sold	$ —	$ 35
Research and development	—	566
Sales and marketing	—	1,448
General and administrative	—	586
	$ —	$ 2,635

As of March 31, 2024 the Company had $ 0.1 million accrued and had paid $ 3.2 million related to the reduction in workforce. No additional expense was incurred during the three months ended March 31, 2024. The Company expects this plan to be completed by September 30, 2024.

Q1 2024 Reduction in Workforce

During the three months ended March 31, 2024, the Company executed a reduction in workforce largely affect its COVID-19 manufacturing workforce. This was accounted for pursuant to Accounting Standards Codification ("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 March 31,
	2024
Cost of products and services sold	$ 231
Research and development	87
Sales and marketing	69
General and administrative	17
Total	$ 404

As of March 31, 2024 the Company had $0.3 million accrued and had paid $ 0.1 million related to the reduction in workforce. The Company expects this plan to be completed by December 31, 2024.

7. Revenues

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

	Three Months Ended March 31,	
	2024	2023
COVID-19 [1]	$ 23,128	$ 118,409
HIV	13,380	13,904
Molecular Sample Management Solutions [2]	10,822	12,942
HCV	3,000	3,186
Risk assessment testing [3]	2,080	2,628
Molecular Services	873	1,379
Other product and service revenues	496	466
Net product and services revenues	53,779	152,914
Non-product and services revenues [4]	353	2,049
Net revenues	$ 54,132	$ 154,963

[1] Includes COVID-19 Diagnostics and COVID-19 Molecular Products.

[2] Includes Genomics, Microbiome and Novosanis product revenues.

[3] Includes substance abuse testing products.

[4] 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 March 31,	
	2024	2023
United States	$ 45,211	$ 145,019
Europe	1,602	1,852
Other regions	7,319	8,092
	$ 54,132	$ 154,963

Customer and Vendor Concentrations. At March 31, 2024, one non-commercial customer accounted for 29% 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 40% and 78% of net consolidated revenues for the three months ended March 31, 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 March 31, 2024 and December 31, 2023 included customer prepayments of $1.3 million and $1.2 million, respectively. Deferred revenue as of March 31, 2024 and December 31, 2023 also included $0.3 million and $0.4 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. Deferred revenue recognized for the three months ended March 31, 2024, and 2023, was $0.7 million and $0.9 million, respectively.

8. Income Taxes

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

	Three Months Ended March 31,	
	2024	2023
State income tax expense (benefit)	$ (230)	$ (225)
Foreign income tax expense (benefit)	212	—
Foreign withholding tax	—	—
	$ (18)	$ (225)

During the three months ended March 31, 2024 and 2023, the Company recorded an income tax benefit of $ 0.0 million and $0.2 million, respectively. The income tax benefit for the three months ended March 31, 2024 and 2023 is primarily composed of a U.S. state tax benefit.

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 March 31, 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 March 31, 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 March 31, 2024, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 1,697 shares, were excluded from the computation of diluted loss per share. For the three months ended March 31, 2023 outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 2,237 shares, respectively, 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 three months ended March 31, 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)
Unrealized gain on marketable securities	—	—	—	—	—	—
Balance at March 31, 2024	73,959	$ —	$ 531,263	$ (17,497)	$ (87,515)	$ 426,251

	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

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 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 appealed the grant of summary judgment to the Court of Appeals on June 8, 2023. The appeal is pending, 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. The Company is considering its appellate options. 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.

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 and Hepatitis C that are performed on a rapid basis at the point of care, and tests for drugs of abuse that are processed in a laboratory. These products are sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations, and other public health organizations, distributors, government agencies, physicians' offices, and commercial and industrial entities. The Company's COVID-19 and HIV products are also sold in a consumer-friendly format in the over-the-counter ("OTC") market in the U.S. and, in the case of the HIV product, as a self-test to individuals in a number of other countries, 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, the Company offers laboratory and bioinformatics services for both genomics and microbiome customers. These services are primarily provided to pharmaceutical, biotech companies, and research institutions.

Recent Developments

Novosanis

During the three months ended March 31, 2024, the Company made a strategic decision to commence wind-down of its operations at its Novosanis subsidiary located in Belgium. The Company intends to continue to sell and manufacture its Colli-Pee® product under the DNAG product line of collection devices. In addition, during the three months ended March 31, 2024, the Company initiated steps to wind down and exit the molecular services business offered by its Diversigen subsidiary while providing transition continuity for clients. This business contributed $0.9 million to revenues during the three months ended March 31, 2024 and contributed $4.5 million for the full year of 2023.

Sapphiros

In January 2024, the Company announced that it is leading the Series B financing and have entered wide-ranging strategic distribution agreements with KKR Sapphiros L.P. ("Sapphiros"), a privately held consumer diagnostics portfolio company based in Boston, and certain of its related entities. Through this strategic 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.

The Company has funded approximately $28.3 million an interest in Sapphiros, with an aggregate commitment of up to $30.0 million to be funded by June 2024, contingent on certain terms and conditions being met.

Results of Operations

For the three months ended March 31, 2024 compared to March 31, 2023.

CONSOLIDATED NET REVENUES

The table below shows an outline of total consolidated net revenues (dollars in thousands) for the three months ended March 31, 2024 and 2023:

	Three Months Ended March 31,				
	Dollars			Percentage of Total Net Revenues	
	2024	2023	% Change	2024	2023
COVID-19 Diagnostics	$ 23,097	$ 118,254	(80) %	43 %	76 %
Diagnostics [1]	16,380	17,090	(4)	30	11
Molecular Sample Management Solutions [2]	10,822	12,942	(16)	20	8
Other products and services [3]	2,576	3,094	(17)	5	2
Molecular Services	873	1,379	(37)	2	1
COVID-19 Molecular Products	31	155	(80)	—	—
Net product and services revenues	53,779	152,914	(65)	99	99
Non-product and services revenues [4]	353	2,049	(83)	1	1
Net revenues	$ 54,132	$ 154,963	(65) %	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 65% to $54.1 million for the three months ended March 31, 2024 from $155.0 million for the three months ended March 31, 2023.

COVID-19 Diagnostics revenues decreased by 80% to $23.1 million for the three months ended March 31, 2024 compared to $118.3 million in three months ended March 31, 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 4% to $16.4 million for the three months ended March 31, 2024 from $17.1 million for the three months ended March 31, 2023. This decrease in revenues was primarily driven by customer ordering patterns.

Molecular Sample Management Solutions revenues decreased 16% to $10.8 million for the three months ended March 31, 2024 from $12.9 million for the three months ended March 31, 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 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 17% to $2.6 million for the three months ended March 31, 2024 from $3.1 million for the three months ended March 31, 2023.

Molecular Services revenues, which are derived from the Company's microbiome molecular sequencing services, decreased 37% to $0.9 million for the three months ended March 31, 2024 from $1.4 million for the three months ended March 31, 2023. The decrease in services revenues was largely due to discontinuance of customer's clinical trial projects.

Non-Product and Services Revenues

Non-product and services revenues decreased 83% to $0.4 million for the three months ended March 31, 2024 from $2.0 million for the three months ended March 31, 2023 as a result 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 ("CLIA") 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 44.5% for the three months ended March 31, 2024 from 42.5% for the three months ended March 31, 2023. This increase in margins was driven by increased average selling price on InteliSwab® sales and lower scrap expense. These improvement in margins were partially offset by a decrease in non-product revenues which contribute 100% to gross margin.

Consolidated operating loss for the three months ended March 31, 2024 was $7.1 million, a $31.4 million decline from the $24.3 million operating income reported for the three months ended March 31, 2023. Results for the three months ended March 31, 2024 were negatively impacted by lower revenues and higher impairment losses offset by increased gross profit margins and lower operating expense spend. Results for the three months ended March 31, 2024 included $3.3 million of impairment losses compared to $1.1 million for the three months ended March 31, 2023. Impairment losses in the first quarter of 2024 were comprised of the impairment of Novosanis and Diversigen property plant and equipment, including leased assets while impairment losses in 2023 were associated with idle manufacturing lines.

Operating expenses in the first quarter of 2024, excluding the impairment charge, decreased $12.6 million compared to the first quarter of 2023 reflecting the impact of the Company's cost saving measures and headcount reductions.

Research and development expenses decreased 27% to $7.7 million for the three months ended March 31, 2024 from $10.6 million for the three months ended March 31, 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.

Sales and marketing expenses decreased 30% to $8.4 million for the three months ended March 31, 2024 from $12.1 million for the three months ended March 31, 2023 due to lower employee costs associated with a decrease in headcount, and decreased spend on advertising and consulting fees.

General and administrative expenses decreased 34% to $11.6 million for the three months ended March 31, 2024 from $17.7 million for the three months ended March 31, 2023 largely due to lower legal fees and lower staffing costs due to a reduction in headcount.

All of the above contributed to the Company's operating loss of $7.1 million for the three months ended March 31, 2024, which included a non-cash impairment charge of $3.3 million, non-cash charges of $2.7 million for depreciation and amortization, and non-cash charges of $3.0 million for stock-based compensation. The Company's operating income of $24.3 million for the three months ended March 31, 2023 included a non-cash impairment charge of $1.1 million, non-cash charges of $3.7 million for depreciation and amortization, and $2.7 million for stock-based compensation.

OTHER INCOME

Other income for the three months ended March 31, 2024 was $3.5 million compared to $2.7 million for the three months ended March 31, 2023. This increase is due to 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 March 31, 2024 and 2023, the Company recorded a U.S. state income tax benefit of $0.2 million. For the three months ended March 31, 2024 the state tax benefit was partially offset by foreign tax expense of $0.2 million. No foreign taxes were recorded for the three months ended March 31, 2023 due to it being more likely than not that the Canadian subsidiary would not produce sufficient income to receive a tax benefit for the year to date loss.

Liquidity and Capital Resources

	March 31, 2024	December 31, 2023
	(in thousands)	
Cash and cash equivalents	$ 247,145	$ 290,407
Short-term investments	16,627	—
Working capital	319,400	346,923

The Company's cash and cash equivalents and short-term investments decreased to $263.8 million at March 31, 2024 from $290.4 million at December 31, 2023. $84.5 million or 32% of the $263.8 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 $319.4 million at March 31, 2024 from $346.9 million at December 31, 2023. Working capital decreased primarily due to the decrease in cash and cash equivalents. 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 three months ended March 31, 2024, net cash provided by operating activities was $6.7 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 $3.6 million included non-cash charges of depreciation and amortization expense of $2.7 million, stock-based compensation expense of $3.0 million, and impairment losses of $3.3 million. Cash provided by the working capital accounts included a decrease in accounts receivable of $6.2 million largely associated with lower overall sales and collections of balances due, a decrease in inventory of $4.3 million as the Company fulfilled demand for its InteliSwab® product, and a decrease in accrued expenses of $9.7 million as the Company paid out year end bonuses in March 2024.

Investing Activities

Net cash used in investing activities was $46.5 million for the three months ended March 31, 2024, which reflects proceeds from the maturities of investments of $9.2 million, offset by $25.9 million in purchases of investments. Investing activities also include a $28.3 million investment in Sapphiros, and $1.6 million to acquire property and equipment to support the normal operations of the business.

Financing Activities

Net cash used in financing activities was $1.3 million for the three months ended March 31, 2024, which is largely comprised of $1.5 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 March 31, 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 three months ended March 31, 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 March 31, 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 March 31, 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 March 31, 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 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 appealed the grant of summary judgment to the Court of Appeals on June 8, 2023. The appeal is pending, 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. The Company is considering its appellate options. 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.

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]
January 1, 2024 - January 31, 2024	59,151 [3]	$ 8.19	—	$ 11,984,720
February 1, 2024 - February 29, 2024	55,620 [3]	$ 7.40	—	$ 11,984,720
March 1, 2024 - March 31, 2024	78,707 [3]	$ 7.18	—	$ 11,984,720
	193,478		—	

(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.

/s/ Kenneth J. McGrath

Date: May 9, 2024

Kenneth J. McGrath

Chief Financial Officer

(Principal Financial Officer)

/s/Michele M. Anthony

Date: May 9, 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: May 9, 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: May 9, 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 March 31, 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

May 9, 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 March 31, 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

May 9, 2024