

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

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended **March 31, 2025**.

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission File Number **001-16537**

**ORASURE TECHNOLOGIES, INC.**

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**

(State or Other Jurisdiction of  
Incorporation or Organization)

**36-4370966**

(IRS Employer Identification No.)

**220 East First Street, Bethlehem, Pennsylvania**

(Address of Principal Executive Offices)

**18015**

(Zip code)

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

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

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

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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

Indicate by checkmark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No   
As of May 2, 2025, the registrant had 74,800,131 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 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 (the "FDA"), 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 IntelliSwab<sup>®</sup> 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;
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- 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, trade secrets 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, inflationary pressures, capital market disruptions, changes in governmental agencies, international tariffs, trade protection measures, economic sanctions and economic slowdowns or recession.

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, 2024 filed with the Securities and Exchange Commission (the "SEC") on March 7, 2025, 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

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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.

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**PART I. FINANCIAL INFORMATION**

	<b>Page No.</b>
<b>Item 1. Financial Statements (Unaudited)</b>	
<a href="#">Consolidated Balance Sheets at March 31, 2025 and December 31, 2024</a>	3
<a href="#">Consolidated Statements of Operations for the Three Months Ended March 31, 2025 and 2024</a>	4
<a href="#">Consolidated Statements of Comprehensive Loss for the Three Months Ended March 31, 2025 and 2024</a>	5
<a href="#">Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2025 and 2024</a>	6
<a href="#">Notes to the Consolidated Financial Statements</a>	7
<b><a href="#">Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</a></b>	23
<b><a href="#">Item 3. Quantitative and Qualitative Disclosures About Market Risk</a></b>	27
<b><a href="#">Item 4. Controls and Procedures</a></b>	27

**PART II. OTHER INFORMATION**

<b><a href="#">Item 1. Legal Proceedings</a></b>	28
<b><a href="#">Item 1A. Risk Factors</a></b>	28
<b><a href="#">Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</a></b>	30
<b><a href="#">Item 3. Defaults Upon Senior Securities</a></b>	30
<b><a href="#">Item 4. Mine Safety Disclosures</a></b>	30
<b><a href="#">Item 5. Other Information</a></b>	30
<b><a href="#">Item 6. Exhibits</a></b>	31
<a href="#">Signatures</a>	32

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**Item 1. FINANCIAL STATEMENTS**

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

	March 31, 2025	December 31, 2024
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 247,569	\$ 267,763
Accounts receivable, net of allowance of \$348 and \$773	21,516	23,816
Inventories	35,677	34,197
Prepaid expenses	5,888	3,956
Other current assets	3,131	3,488
Total current assets	313,781	333,220
Noncurrent Assets:		
Property, plant and equipment, net of accumulated depreciation of \$68,027 and \$65,918	43,164	45,105
Operating right-of-use assets	12,998	13,442
Finance right-of-use assets	132	145
Intangible assets, net of accumulated amortization of \$25,990 and \$32,413	17,307	17,435
Goodwill	40,449	40,330
Investment in equity method investee	27,776	28,300
Deferred tax asset	540	156
Other noncurrent assets	1,460	1,526
Total noncurrent assets	143,826	146,439
<b>TOTAL ASSETS</b>	<b>\$ 457,607</b>	<b>\$ 479,659</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 7,820	\$ 8,173
Deferred revenue	2,510	2,961
Accrued expenses and other current liabilities	12,960	20,179
Finance lease liability	42	41
Operating lease liability	2,090	2,129
Total current liabilities	25,422	33,483
Noncurrent Liabilities:		
Finance lease liability	102	113
Operating lease liability	11,968	12,321
Acquisition-related contingent consideration obligation	23,388	22,910
Other noncurrent liabilities	445	494
Total noncurrent liabilities	35,903	35,838
<b>TOTAL LIABILITIES</b>	<b>61,325</b>	<b>69,321</b>
Commitments and contingencies (Note 12)		
<b>STOCKHOLDERS' EQUITY</b>		
Preferred stock, par value \$.000001, 25,000 shares authorized, none issued	—	—
Common stock, par value \$.000001, 120,000 shares authorized, 75,114 and 74,598 shares issued and outstanding	—	—
Additional paid-in capital	539,875	538,129
Accumulated other comprehensive loss	(24,122)	(24,360)
Accumulated deficit	(119,471)	(103,431)
Total stockholders' equity	396,282	410,338
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 457,607</b>	<b>\$ 479,659</b>

See accompanying notes to the consolidated financial statements.

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

	For the Three Months Ended March 31,	
	2025	2024
<b>NET REVENUES:</b>		
Products and services	\$ 28,997	\$ 53,779
Other	934	353
	<u>29,931</u>	<u>54,132</u>
<b>COST OF PRODUCTS AND SERVICES SOLD</b>	<u>17,632</u>	<u>30,067</u>
Gross profit	12,299	24,065
<b>OPERATING EXPENSES:</b>		
Research and development	9,603	7,738
Sales and marketing	6,859	8,448
General and administrative	14,102	11,634
Loss on impairments	—	3,338
Change in the estimated fair value of acquisition-related contingent consideration	478	—
Gain on sale of assets	(993)	—
	<u>30,049</u>	<u>31,158</u>
Operating loss	(17,750)	(7,093)
<b>OTHER INCOME</b>	1,778	3,491
Loss before income taxes	(15,972)	(3,602)
<b>INCOME TAX BENEFIT</b>	(456)	(18)
<b>LOSS ON EQUITY INVESTMENT</b>	(524)	—
<b>NET LOSS</b>	<u>\$ (16,040)</u>	<u>\$ (3,584)</u>
<b>LOSS PER SHARE:</b>		
BASIC	<u>\$ (0.21)</u>	<u>\$ (0.05)</u>
DILUTED	<u>\$ (0.21)</u>	<u>\$ (0.05)</u>
<b>SHARES USED IN COMPUTING LOSS PER SHARE:</b>		
BASIC	<u>74,867</u>	<u>73,947</u>
DILUTED	<u>74,867</u>	<u>73,947</u>

See accompanying notes to the consolidated financial statements.

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

	<b>For the Three Months Ended March 31,</b>	
	<b>2025</b>	<b>2024</b>
NET LOSS	\$ (16,040)	\$ (3,584)
OTHER COMPREHENSIVE INCOME (LOSS)		
Currency translation adjustments	238	(2,556)
COMPREHENSIVE LOSS	<u>\$ (15,802)</u>	<u>\$ (6,140)</u>

See accompanying notes to the consolidated financial statements.

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

	For the Three Months Ended March 31,	
	2025	2024
<b>OPERATING ACTIVITIES:</b>		
Net loss	\$ (16,040)	\$ (3,584)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities		
Stock-based compensation	2,687	2,968
Depreciation and amortization	2,808	2,725
Loss on impairments	—	3,338
Other non-cash amortization	(37)	6
Provision for credit losses	(248)	(85)
Unrealized foreign currency loss (gain)	194	(119)
Interest expense on finance leases	2	7
Loss on equity investment	524	—
Deferred income taxes	(384)	53
Gain on sale of fixed assets	(780)	—
Change in the estimated fair value of acquisition-related contingent consideration	478	—
Changes in assets and liabilities:		
Accounts receivable	2,413	6,199
Inventories	(1,482)	4,337
Prepaid expenses and other assets	(2,075)	603
Accounts payable	(726)	(68)
Deferred revenue	(451)	47
Accrued expenses and other liabilities	(6,616)	(9,688)
Net cash (used in) provided by operating activities	(19,733)	6,739
<b>INVESTING ACTIVITIES:</b>		
Purchases of investments	—	(25,850)
Purchase of equity method investee	—	(28,333)
Proceeds from maturities and redemptions of investments	—	9,234
Proceeds from sale of assets	790	—
Purchases of property and equipment	(420)	(1,579)
Net cash provided by (used in) in investing activities	370	(46,528)
<b>FINANCING ACTIVITIES:</b>		
Cash payments for finance lease liabilities	(12)	(50)
Proceeds from exercise of stock options	—	214
Withholding and retirement of common stock	(941)	(1,462)
Net cash used in financing activities	(953)	(1,298)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	122	(2,175)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(20,194)	(43,262)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	267,763	290,407
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 247,569	\$ 247,145
<b>SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION</b>		
Cash paid for income taxes	\$ 1,796	\$ 592
Non-cash investing and financing activities		
Accrued property and equipment purchases	\$ 163	\$ 471

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"), Novosanis NV ("Novosanis"), and Sherlock Biosciences, Inc. ("Sherlock"). 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, 2024. Results of operations for the three months ended March 31, 2025 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, 2024 that have had a material impact on the consolidated financial statements and related notes except as discussed herein.

*Change in Accounting Principle*

During the three months ended March 31, 2025, the Company changed its methodology for valuing certain inventories to the average cost method from the first-in, first-out ("FIFO") cost method. The change was applicable to all inventories. The Company concluded that the average cost basis of accounting is preferable as it results in greater precision in the calculation of acquisition cost of inventory on the balance sheet. The effect of this change in accounting principle was immaterial. Therefore, retroactive application was not determined to be necessary and a cumulative adjustment of \$.08 million was recorded in the statement of operations for the three months ended March 31, 2025.

*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 Company records an allowance for credit loss for the Company's available-for-sale securities when a decline in investment market value is due to credit-related factors. When evaluating an investment for impairment, the Company reviews factors such as the severity of the impairment, changes in underlying credit ratings, forecasted recovery, the Company's intent to sell or the likelihood that it would be required to sell the investment before its anticipated recovery in market value, and the probability that the scheduled cash payments will continue to be made.

The Company had no available-for-sale securities as of March 31, 2025 and December 31, 2024.

The Company maintains cash balances in the United States in excess of the federally insured limits. The Company periodically evaluates financial institutions and believe the risk of loss to be remote due to this evaluation.

*Fair Value of Financial Instruments*

As of March 31, 2025 and December 31, 2024, 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).

To the extent that valuation is based on models or inputs that are unobservable in the market, determining fair value requires more judgment. Because of the inherent uncertainty of valuation, estimated values may be materially higher or lower than the values that would have been used had a ready market for the investments existed. Therefore, the degree of judgment exercised in determining fair value is greatest for assets or liabilities categorized in Level 3.

	Level	March 31, 2025	December 31, 2024
Guaranteed investment certificates	1	\$ 66,538	\$ 66,584
Contingent consideration	3	\$ 23,388	\$ 22,910

All of the Company's guaranteed investment certificates are measured as Level 1 instruments as of March 31, 2025.

Included in cash and cash equivalents at March 31, 2025 and December 31, 2024 was \$66.5 million and \$66.6 million, respectively, of guaranteed investment certificates.

Also included in cash and cash equivalents at March 31, 2025 and December 31, 2024 was \$119.8 million and \$118.5 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 March 31, 2025 and December 31, 2024 was \$0.8 million and \$0.7 million, respectively, and was calculated using the quoted market prices of the assets as of those dates. All investments in the plan are classified as trading securities and measured as Level 1 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.

*Contingent Consideration*

As further discussed in Note 11, Business Combinations, the Company has identified its contingent consideration obligations as Level 3 liabilities due to significant inputs that are required to measure the fair value of these obligations. The contingent consideration is comprised of two different tranches: milestone payments and royalty payments. The significant quantitative unobservable inputs for the milestone payments are the discount rate and probability achievement of a milestone of a regulatory approval.

The fair value methodology for royalty payments is based on a discounted cash flow model. Significant quantitative unobservable inputs are internally developed future expected cash flows, discount rate and probability achievement of a

milestone of a regulatory approval. The royalty payments represent a mid-single digit percentage of the net sales through 2034 associated with the acquired in-process and research developed intangible asset.

There was an increase of \$0.5 million in the fair value of the Company's contingent consideration from date of acquisition to March 31, 2025.

#### *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 March 31, 2025, the Company had funded \$30.0 million for its interest in Sapphiros. The Company 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 March 31, 2025 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, its equity method investee and its operations. In conjunction with the preparation of the Company's March 31, 2025 financial statements, the Company considered whether the carrying value of the investment in Sapphiros was impaired and concluded that no such impairment existed. The Company's investment in Sapphiros was valued at \$28.3 million as of December 31, 2024.

#### *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 \$(0.4) million and \$0.2 million for the three months ended March 31, 2025 and 2024, respectively.

#### *Accumulated Other Comprehensive Loss*

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

	Foreign Currency	Total
<b>Balance at December 31, 2024</b>	\$ (24,360)	\$ (24,360)
Other comprehensive gain	238	238
<b>Balance at March 31, 2025</b>	<u>\$ (24,122)</u>	<u>\$ (24,122)</u>

#### *Recent Accounting Pronouncements*

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740), Improvements to Income Tax Disclosures*. The purpose of the update was to address investor requests for more transparency about income tax information through improvements to income tax disclosures primarily related to the rate reconciliation and income taxes paid information. The amendments in this ASU are effective for annual periods beginning after December 15, 2024. The amendments may be applied prospectively or retrospectively, and early adoption is permitted. Management determined the annual disclosures required under the new guidance will have a significant impact on the Company's consolidated financial statements.

In November 2024, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") No. 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40), Disaggregation of Income Statement Expenses*. The purpose of this update was to require disclosure, in the notes to financial statements, of specified information about certain costs and expenses on a disaggregated basis. The amendments in the ASU are effective for all public business entities for annual periods beginning after December 15, 2026, and interim periods beginning after December 15, 2027, with early adoption permitted. The amendments are to be applied either prospectively to financial statements issued for reporting periods after the effective date of the update or retrospectively to

any or all prior periods presented in the financial statements. Management is evaluating the impact on the Company's consolidated financial statements.

In March 2024, the FASB issued 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 does not expect an impact on the Company's consolidated financial statements.

**2. Inventories (in thousands)**

	<u>March 31,</u> <u>2025</u>	<u>December 31,</u> <u>2024</u>
Raw materials	\$ 16,228	\$ 17,002
Work in process	1,193	420
Finished goods	18,256	16,775
	<u>\$ 35,677</u>	<u>\$ 34,197</u>

**3. Property, Plant and Equipment, net (in thousands)**

	<u>March 31,</u> <u>2025</u>	<u>December 31,</u> <u>2024</u>
Land	\$ 1,118	\$ 1,118
Buildings and improvements	38,719	36,152
Machinery and equipment	56,660	51,015
Computer equipment and software	11,995	11,502
Furniture and fixtures	1,621	1,621
Construction in progress	1,078	9,615
	111,191	111,023
Accumulated depreciation	(68,027)	(65,918)
	<u>\$ 43,164</u>	<u>\$ 45,105</u>

**4. Accrued Expenses and Other Current Liabilities (in thousands)**

	<u>March 31,</u> <u>2025</u>	<u>December 31,</u> <u>2024</u>
Payroll and related benefits	\$ 5,810	\$ 11,147
Professional fees	3,229	2,469
Sales tax payable	1,048	1,339
Other	2,873	5,224
	<u>\$ 12,960</u>	<u>\$ 20,179</u>

## 5. Termination Benefits

### *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):

	<b>For the Three Months Ended March 31,</b>	
	<b>2024</b>	
Cost of products and services sold	\$	231
Research and development		87
Sales and marketing		69
General and administrative		17
	\$	404

As of March 31, 2025, the Company had fully paid the \$0.4 million related to the reduction in workforce. This reduction in workforce was 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 bringing 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*.

As of March 31, 2025 the Company had \$0.3 million accrued and had paid \$1.3 million related to the reduction in workforce. No additional expense was incurred during the three months ended March 31, 2025. The Company expects this plan to be completed by September 2025.

### *Q3 2024 Reduction in Workforce*

During the third quarter of 2024, the Company executed a reduction in workforce largely as the Company notified certain employees of its intention to discontinue its risk assessment business. Additional employees were notified in the fourth quarter of 2024 and additional severance costs will be incurred. This was accounted for pursuant to ASC 420, *Exit or Disposal Cost Obligations*.

As of March 31, 2025 the Company had \$0.7 million accrued and had paid \$0.5 million related to the reduction in workforce. No additional expense was incurred during the three months ended March 31, 2025. The Company expects this plan to be completed by the third quarter of 2026.

## 6. Revenues

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

	For the Three Months Ended March 31,	
	2025	2024
HIV	\$ 12,900	\$ 13,380
Sample Management Solutions <sup>(1)</sup>	9,110	10,822
HCV	4,333	3,000
Risk Assessment Testing <sup>(2)</sup>	1,420	2,080
Other product and services revenues <sup>(3)</sup>	773	496
COVID-19 <sup>(4)</sup>	461	23,128
Molecular Services	—	873
Net product and services revenues	\$ 28,997	\$ 53,779
Non-product and services revenues <sup>(5)</sup>	934	353
Net revenues	\$ 29,931	\$ 54,132

<sup>(1)</sup> Includes Genomics, Microbiome and Colli-Pee product revenues.

<sup>(2)</sup> Includes substance abuse testing product revenues.

<sup>(3)</sup> Includes Syphilis revenues.

<sup>(4)</sup> Includes COVID-19 Diagnostics and COVID-19 Sample Management Solutions revenues.

<sup>(5)</sup> 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 March 31,	
	2025	2024
United States	\$ 20,335	\$ 45,211
Africa	7,189	5,704
Europe	1,637	1,602
Other regions	770	1,615
	\$ 29,931	\$ 54,132

*Customer Concentration.* The following table represents customer concentration risk:

	For the Three Months Ended March 31,	
	2025	2024
<i>Net Revenues</i>		
Non-commercial customer	N/A	40%
	<b>March 31,</b>	<b>December 31,</b>
	<b>2025</b>	<b>2024</b>
<i>Accounts Receivable</i>		
Commercial customer <sup>(1)</sup>	15%	10%
Commercial customer <sup>(1)</sup>	11%	N/A

<sup>(1)</sup> Each commercial customer is different.

*Vendor Concentration.* 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, 2025 and December 31, 2024 was comprised of customer prepayments of \$2.5 million and \$3.0 million, respectively.

The following table represents deferred revenue recognized:

<i>Deferred Revenue Recognized</i>	<b>For the Three Months Ended March 31,</b>	
	<b>2025</b>	<b>2024</b>
Accrued at beginning of period	\$ 771	\$ 723
From current period	1,333	834
	<u>\$ 2,104</u>	<u>\$ 1,557</u>

## 7. Income Taxes

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

	For the Three Months Ended March 31,	
	2025	2024
Federal income tax expense	\$ 8	\$ —
State income tax expense (benefit)	9	(230)
Foreign income tax (benefit) expense	(473)	212
	<u>\$ (456)</u>	<u>\$ (18)</u>

During the three months ended March 31, 2025 and 2024, the Company recorded an income tax benefit of \$0.5 million and \$0.02 million, respectively. The three months ended March 31, 2025 net tax benefit increase is due to having a U.S. and foreign pretax loss in 2025 compared to a U.S. pretax loss and foreign pretax income for the three months ended March 31, 2024.

Income tax expense reflects taxes due to the taxing authorities and the tax effects of temporary differences between the basis of assets and liabilities recognized for financial reporting and tax purposes, and net operating loss and tax credit carryforwards. The significant components of the Company's total deferred tax asset as of March 31, 2025 and at December 31, 2024 relate to the tax effects of the basis difference of acquired intangible 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. and U.K. deferred tax assets as of March 31, 2025 and December 31, 2024.

## 8. Income (Loss) Per Share

Basic earnings (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, 2025 and 2024, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 689 shares and 1,697 shares, respectively, were excluded from the computation of diluted loss per share.

## 9. Stockholders' Equity

In March 2025, the Company's Board of Directors authorized a stock repurchase program (the "Repurchase Program") effective March 21, 2025, whereby the Company may purchase up to \$40.0 million in shares of its common stock over a period of up to two years. The amount and timing of share repurchases under the Repurchase Program may be carried out at the discretion of the Company's management through various methods in compliance with applicable state and federal securities laws. The Company did not repurchase any shares of the Company's common stock under the Repurchase Program during the three months ended March 31, 2025.

The reconciliation of the changes in stockholders' equity for the three months ended March 31, 2025 and 2024 is as follows (in thousands):

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
<b>Balance at December 31, 2024</b>	74,598	\$ —	\$ 538,129	\$ (24,360)	\$ (103,431)	\$ 410,338
Vesting of restricted stock and performance stock units	768	—	—	—	—	—
Purchase and retirement of common shares	(252)	—	(941)	—	—	(941)
Stock-based compensation	—	—	2,687	—	—	2,687
Net loss	—	—	—	—	(16,040)	(16,040)
Currency translation adjustments	—	—	—	238	—	238
<b>Balance at March 31, 2025</b>	<u>75,114</u>	<u>\$ —</u>	<u>\$ 539,875</u>	<u>\$ (24,122)</u>	<u>\$ (119,471)</u>	<u>\$ 396,282</u>

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
<b>Balance at December 31, 2023</b>	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)
<b>Balance at March 31, 2024</b>	<u>73,959</u>	<u>\$ —</u>	<u>\$ 531,263</u>	<u>\$ (17,497)</u>	<u>\$ (87,515)</u>	<u>\$ 426,251</u>

## 10. Business Segment Information

The Company is organized on the basis of products and services into a single reportable segment. All products and services reside under the same reporting hierarchy. Historically, there was separate management leading the Company's Diagnostics and Molecular Solutions businesses. In February 2023, the Company announced a corporate restructuring to combine the commercial and innovation teams across the Diagnostics and Molecular Solutions businesses into one operating segment with sales, marketing, product development and research teams covering all product lines and reporting to a Chief Product Officer ("CPO").

The Company's reportable segment derives its revenues from the sale of diagnostics products and sample management solutions, as described in Note 1 Summary of Significant Accounting Policies. As the Company has only one reportable segment, there are no inter-segment sales or transfers.

The Company's Chief Operating Decision Maker ("CODM") is its Chief Executive Officer. The CODM uses consolidated net income (loss) as reported in the consolidated statement of operations as the primary measure of the reportable segment's profit or loss. The CODM uses consolidated net income (loss) to assess the performance of the segment and make decisions about resource allocation. Consolidated gross profit and consolidated operating income (loss), as reported in the consolidated statement of operations, are also used by the CODM as measures of segment profit or loss. The CODM uses gross profit to assess the impact of the Company's efforts to achieve manufacturing efficiencies and consolidate its production activities. The CODM uses operating income (loss) to assess the impact of the Company's recent restructurings, reduction in workforce, and efforts to streamline its operations to achieve cost savings. The CODM uses consolidated total assets as the measure of segment assets, as reported on the consolidated balance sheet.

The accounting policies of the Company's reportable segment are the same as those described in Note 1 Summary of Significant Accounting Policies.

The following table represents total long-lived assets by geographic area:

	<u>March 31,</u> <u>2025</u>	<u>December 31,</u> <u>2024</u>
United States	\$ 39,265	\$ 40,286
United Kingdom	11,463	12,849
Canada	5,189	5,468
Other regions	377	89
	<u>\$ 56,294</u>	<u>\$ 58,692</u>

The following table represents reported segment revenues, segment loss, and significant segment expenses:

	For the Three Months Ended March 31,	
	2025	2024
Net revenues	29,931	54,132
Cost of products and services sold <sup>(2)</sup>	17,632	30,067
Gross profit	12,299	24,065
Research and development <sup>(2)</sup>	9,603	7,738
Sales and marketing <sup>(2)</sup>	6,859	8,448
General and administrative <sup>(2)</sup>	14,102	11,634
Loss on impairments	—	3,338
Change in the estimated fair value of acquisition-related contingent consideration	478	—
Gain on sale of assets	(993)	—
Operating loss	(17,750)	(7,093)
Other (expense) income	(21)	271
Interest revenue	2,156	3,022
Other segment items <sup>(1)</sup>	(357)	198
Loss before income taxes	(15,972)	(3,602)
Income tax benefit	(456)	(18)
Loss on equity investment	(524)	—
Net loss	\$ (16,040)	(3,584)

<sup>(1)</sup> Includes interest expense and foreign currency gains (losses).

<sup>(2)</sup> The following tables represent additional significant segment expense categories:

	For the Three Months Ended March 31,	
	2025	2024
<i>Stock-based Compensation</i>		
Cost of products and services sold	\$ 169	\$ 151
Research and development	203	266
Sales and marketing	218	257
General and administrative	2,097	2,294
	\$ 2,687	\$ 2,968

	For the Three Months Ended March 31,	
	2025	2024
<i>Depreciation and Amortization</i>		
Cost of products and services sold	\$ 1,389	\$ 1,547
Research and development	485	242
Sales and marketing	27	48
General and administrative	907	888
	\$ 2,808	\$ 2,725

## 11. Business Combinations

### *Sherlock Biosciences*

On December 19, 2024, the Company acquired all of the outstanding stock of Sherlock, pursuant to the terms of a merger agreement (the "Merger Agreement"). The Company began operating this entity as of the December 19, 2024 closing date.

The primary reason for the acquisition was Sherlock's first test for Chlamydia Trachomatis (CT) and Neisseria Gonorrhoeae (NG), which is in clinical studies and is expected to be submitted to the FDA for approval by the end of 2025. Subject to regulatory approvals, this test is expected to expand the Company's portfolio for rapid diagnostics for sexually transmitted infections.

The initial aggregate purchase price of this transaction was funded with cash on hand as shown in the table below:

Milestone contingent consideration	\$	15,910
Royalty based contingent consideration		7,000
Cash paid to Sherlock		5,000
Legal expenses		389
Insurance policy expense		50
Initial aggregate purchase price	\$	<u>28,349</u>

Pursuant to the Merger Agreement, the Company agreed to pay up to \$20.0 million of contingent consideration based on the achievement of a regulatory milestone on or before December 31, 2026 as defined in the Merger Agreement. The fair value of the milestone contingent consideration was \$15.9 million. The range of outcome for the milestone contingent consideration is zero to \$20.0 million. There is also a mid-single digits quarterly royalty fee based on future sales until 2034 as defined in the Merger Agreement, the fair value of which was determined as part of the contingent consideration. The estimated acquisition-date fair value of the royalty fee acquisition-related contingent consideration was \$7.0 million. The range of outcome for the royalty payment cannot be determined due to the fact it is based on future sales associated with the acquired in-process research and development technology through 2034 and thus does not have an upper limit.

During the year ended December 31, 2024, the Company incurred a total of \$1.0 million of acquisition related costs, including accounting, legal, and other professional fees, all of which were expensed and reported as a component of general and administrative expenses in the consolidated statement of operations for the year ended December 31, 2024.

The following table summarizes the estimated fair values of the assets acquired and liabilities assumed as of the acquisition date:

<b>Assets Acquired</b>	
Other current assets	2,570
Property, plant, and equipment, net	9,244
Other noncurrent assets	462
Operating right-of-use assets	4,080
In-process research and development technology intangible asset	17,000
Goodwill	6,382
Total assets acquired	39,738
<b>Liabilities Assumed</b>	
Accounts payable	2,449
Current liabilities	3,621
Deferred revenue	1,641
Operating lease liability	4,080
Total liabilities assumed	11,791
<b>Net Assets Acquired</b>	27,947
Estimated fair value of contingent consideration	(22,910)
<b>Net Cash Paid (net of cash acquired of (\$402))</b>	<b>\$ 5,037</b>

The purchase price was allocated to the tangible assets and identifiable intangible assets acquired and liabilities assumed based on their acquisition-date estimate fair values. The identifiable intangible assets included in-process research and development technology ("IPR&D Technology"), which is an indefinite lived asset.

The Company, with the assistance of an independent valuation specialist, assessed the fair value of the assets and contingent consideration of Sherlock. The income approach was used to value the acquired intangibles and the fair value measurements were primarily based on significant inputs that are not observable in the market and are considered Level 3 fair value measurements. The income approach estimates fair value for an asset based on the present value of cash flows projected to be generated by the asset. Projected cash flows are discounted at a required rate of return that reflects the relative risk of achieving the cash flows and the time value of money.

The regulatory milestone scenario based model was used to value the assumed milestone contingent consideration, were primarily based on significant unobservable inputs and are considered Level 3 fair value measurements. The regulatory milestone scenario based model estimates fair value for contingent consideration based on the probability of on the achievement of a certain milestone as defined under the agreements and the discount rate.

The income approach was used to value the royalty based contingent consideration, were primarily based on significant unobservable inputs and are considered Level 3 fair value measurements. The fair value of contingent payments approach were primarily based on projected cash flows, probability of on the achievement of a regulatory milestone as defined under the agreements, and discount rate.

Goodwill is calculated as the difference between the acquisition date fair value of the consideration transferred and the fair value of the net assets acquired, and represents the future economic benefits that we expect to achieve as a result of the acquisition. The Company believes the goodwill related to the acquisition was a result of Sherlock providing a product offering that will enable the Company to leverage those products with existing and new customers. The goodwill is not deductible for income tax purposes.

The Company continues to evaluate the fair value of certain assets acquired and liabilities assumed. Additional information, which existed as of the acquisition date, but was at that time unknown to the Company, may become known during the remainder of the measurement period. Changes to amounts recorded as a result of the final determination may result in a corresponding adjustment to these assets and liabilities, including goodwill. The determination of the estimated fair values of all assets acquired is expected to be completed within one year from the date of acquisition.

Revenues from Sherlock primarily consist of grant revenues for research and development purposes. Effective as of December 19, 2024, the financial results of Sherlock are included in the consolidated financial results of the Company.

*Unaudited Pro Forma Financial Information*

The unaudited pro forma results presented below include the results of the Sherlock acquisition as if it had been consummated as of January 1, 2024. The unaudited pro forma results include depreciation of the acquired property plant and equipment and the estimated tax effect of adjustments to income before income taxes but do not include changes in the fair value of the Company's contingent consideration obligations. Material nonrecurring charges, directly attributable to the transactions, including direct acquisition costs, are also excluded. In addition, the unaudited pro forma results do not include any expected benefits of the acquisitions. Accordingly, the unaudited pro forma results are not necessarily indicative of either future results of operations or results that might have been achieved had the acquisition been consummated as of January 1, 2024.

	<b>For the Three Months Ended March 31,</b>	
	<b>2024</b>	
Net revenues	\$	54,464
Net loss	\$	(14,338)

## 12. Commitments and Contingencies

### *Litigation*

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

In March 2021, the Company filed a complaint against Spectrum Solutions, LLC ("Spectrum") in the United States District Court for the Southern District of California alleging that certain saliva collection devices manufactured and sold by Spectrum infringe a patent held by DNAG. Spectrum filed an answer 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. 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. The Company appealed the grant of summary judgment to the Court of Appeals on June 8, 2023. On February 14, 2025, the Court of Appeals affirmed the District Court's judgment. The Court of Appeals mandate issued on March 24, 2025. 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. On July 2, 2024, the Company filed a Motion to Amend the claims of the third patent and oral argument in this IPR took place on January 24, 2025. On February 19, 2025, the PTO issued a Final Written Decision regarding the third patent in the litigation, granting the Company's Motion to Amend as to cancelling the original claims, but denying the Company's Motion to Amend as to adding proposed substitute claims.

On November 14, 2024 the Company filed a complaint against NowDiagnostics, Inc. ("NowDx"), Jody Berry ("Berry") and Janean Young ("Young") in the United States District Court for the Eastern District of Pennsylvania alleging misappropriation and misuse of the Company's proprietary information and trade secrets by NowDx, Berry and Young in violation of the Federal Defend Trade Secrets Act and the Pennsylvania Uniform Trade Secrets Act. The complaint also alleges breach of contract and duty of loyalty by Young, unfair competition by NowDx, and tortious interference with contractual relations by Berry and NowDx. NowDx filed Counterclaims against the Company on January 13, 2025 and the Company filed its Answer to the Counterclaims on February 3, 2025. Young filed a Motion to Dismiss the claims against her, which was denied by the court on February 4, 2025. NowDx, Berry, and Young agreed to a preliminary injunction which the Court entered on February 27, 2025. The trial is scheduled for March 9, 2026.

## **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, 2024 filed with the Securities and Exchange Commission on March 7, 2025. 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, 2024 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 HIV, Hepatitis C, Syphilis, and COVID-19 that are performed on a rapid basis at the point of care. 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 HIV and COVID-19 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 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.

### **Recent Developments**

#### *Risk Assessment Testing*

In the third quarter of 2024, the Company announced the discontinuance of sales of its risk assessment product line which was expected to be completed in the second quarter of 2025. Sales of its risk assessment products contributed \$1.4 million and \$2.1 million to revenues during the three months ended March 31, 2025 and 2024, respectively. During the first quarter of 2025, the Company sold certain assets that made up the risk assessment product line including certain intellectual property, contracts, permits, and equipment.

## Results of Operations

For the three months ended March 31, 2025 compared to March 31, 2024.

### CONSOLIDATED NET REVENUES

The table below shows total consolidated net revenues (dollars in thousands) for the three months ended March 31, 2025 and 2024:

	For the Three Months Ended March 31,				
	Dollars		% Change	Percentage of Total Net Revenues	
	2025	2024		2025	2024
Diagnostics <sup>(1)</sup>	\$ 17,689	\$ 16,380	8 %	59 %	30 %
Sample Management Solutions <sup>(2)</sup>	9,110	10,822	(16)	30	20
Risk Assessment Testing <sup>(3)</sup>	1,420	2,080	(32)	5	3
COVID-19 Diagnostics	457	23,097	(98)	2	43
Other products and services <sup>(4)</sup>	321	527	(39)	1	1
Molecular Services	—	873	(100)	—	2
Net product and services revenues	28,997	53,779	(46)	97	99
Non-product and services revenues <sup>(5)</sup>	934	353	165	3	1
Net revenues	\$ 29,931	\$ 54,132	(45)%	100 %	100 %

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

<sup>(2)</sup> Includes Genomics, Microbiome and Colli-Pee product revenues.

<sup>(3)</sup> Includes substance abuse testing product revenues.

<sup>(4)</sup> Includes COVID-19 Sample Management Solutions product revenues.

<sup>(5)</sup> Includes funded research and development contracts, royalty income and grant revenues.

## Product and Services Revenues

Consolidated net revenues decreased 45% to \$29.9 million for the three months ended March 31, 2025 from \$54.1 million for the three months ended March 31, 2024.

Sales of the Company's Diagnostics products increased 8% to \$17.7 million for the three months ended March 31, 2025 from \$16.4 million for the three months ended March 31, 2024. This increase in revenues is largely due to higher international HIV and HCV revenues of approximately \$1.2 million primarily driven by customer ordering patterns. Sales of a syphilis product, which were first sold in the second quarter of 2024 are also partially responsible for the increase. This increase in revenues was offset by decrease in revenues under the CDC "Together Take me Home," HIV self-test program.

Sample Management Solutions revenues decreased 16% to \$9.1 million for the three months ended March 31, 2025 from \$10.8 million for the three months ended March 31, 2024. Sales of the Company's genomics products are being impacted by customer bankruptcy and economic pressures.

Risk assessment revenue decreased 32% to \$1.4 million for the three months ended March 31, 2025 from \$2.1 million for the three months ended March 31, 2024. The Company discontinued this line of business at the end of 2024 and business is winding down in early 2025.

COVID-19 Diagnostics revenues decreased 98% to \$0.5 million for the three months ended March 31, 2025 compared to \$23.1 million for the three months ended March 31, 2024 due to decreased sales of the Company's IntelliSwab<sup>®</sup> tests through its U.S. government procurement contracts. We expect this decline in revenue to continue throughout the remainder of 2025 and for the foreseeable future due to the fulfillment of these contracts and lower overall demand for COVID-19 testing.

Molecular Services revenues, which are derived from the Company's microbiome molecular sequencing services, were zero during the three months ended March 31, 2025 compared to \$0.9 million during the three months ended March 31, 2024. The decrease in services revenues was due to the Company's decision to exit this line of business in 2024.

## **Non-Product and Services Revenues**

Non-product and services revenues increased 165% to \$0.9 million for the three months ended March 31, 2025 from \$0.4 million for the three months ended March 31, 2024 primarily due to the recognition of revenue under funded R&D contracts that were assumed by the Company as a result of the Sherlock acquisition at the end of 2024.

## **CONSOLIDATED OPERATING RESULTS**

Consolidated gross profit margin decreased to 41.1% for the three months ended March 31, 2025 from 44.5% for the three months ended March 31, 2024. The largest driver of the margin decline was driven by product mix of lower volume InteliSwab® sales that generate higher gross margins. Gross margin was also negatively impacted by the decrease in genomics sales that also generate higher gross margin coupled with increased international product sales which generate lower margins. This negative impact to gross margin was offset by improved overhead absorption and the termination of the microbiome molecular sequencing services business which historically dragged down the gross margin rate.

Consolidated operating loss for the three months ended March 31, 2025 was \$17.8 million, a \$10.7 million decline from the operating loss reported for the three months ended March 31, 2024. The increase in the operating loss reported in the first quarter of 2025 was largely a result of the lower revenues and lower gross margins generated on sales of the Company's products during the three months ended March 31, 2025.

Research and development expenses increased 24% to \$9.6 million for the three months ended March 31, 2025 from \$7.7 million for the three months ended March 31, 2024 largely due the additional R&D spend incurred by the newly acquired Sherlock companies.

Sales and marketing expenses decreased 19% to \$6.9 million for the three months ended March 31, 2025 from \$8.4 million for the three months ended March 31, 2024 due to lower spend on consulting fees and lower employee costs associated with a decrease in headcount.

General and administrative expenses increased 21% to \$14.1 million for the three months ended March 31, 2025 from \$11.6 million for the three months ended March 31, 2024 largely due an increase in legal fees and the additional general and administrative costs associated with the newly acquired Sherlock companies.

As discussed above in Recent Developments, the Company sold certain assets, including certain intellectual property, contracts, permits and equipment during the first quarter of 2025 related to its risk assessment product line. The Company recorded a \$0.75 million gain on the sales of those assets in addition to the sale of other assets for an approximately \$0.2 million gain.

During the first quarter of 2025, the Company recorded a non-cash adjustment of \$0.5 million, reflecting the change in the estimated fair value of the Sherlock acquisition-related contingent consideration. The Sherlock acquisition was completed in December 2024 and there is no comparable amount in the first quarter of 2024.

All of the above contributed to the Company's operating loss of \$17.8 million for the three months ended March 31, 2025, which included non-cash charges of \$2.8 million for depreciation and amortization, and non-cash charges of \$2.7 million for stock-based compensation. The Company's operating loss of \$7.1 million for the three months ended March 31, 2024 included a non-cash impairment charge of \$3.3 million, non-cash charges of \$2.7 million for depreciation and amortization, and \$3.0 million for stock-based compensation.

## **OTHER INCOME**

Other income for the three months ended March 31, 2025 was \$1.8 million compared to \$3.5 million for the three months ended March 31, 2024 due to lower interest income and foreign currency gains.

## **CONSOLIDATED INCOME TAXES**

The Company continues to believe the full valuation allowance established against its total U.S. deferred tax asset is appropriate as the facts and circumstances necessitating the allowance have not changed. For the three months ended March 31, 2025 and 2024, the Company recorded an income tax benefit of \$0.5 million and \$0.02 million, respectively. The increase in the income tax benefit is largely due to a higher foreign income tax benefit as a result of higher projected foreign losses.

## Liquidity and Capital Resources

	March 31, 2025	December 31, 2024
	(in thousands)	
Cash and cash equivalents	\$ 247,569	\$ 267,763
Working capital	288,359	299,737

The Company's cash and cash equivalents decreased to \$247.6 million at March 31, 2025 from \$267.8 million at December 31, 2024. The Company's Canadian subsidiary, DNAG, held \$82.5 million or 33% of the \$247.6 million in cash and cash equivalents.

The Company's working capital decreased to \$288.4 million at March 31, 2025 from \$299.7 million at December 31, 2024.

### Analysis of the Company's Cash Flows

#### *Operating Activities*

During the three months ended March 31, 2025, net cash used in operating activities was \$19.7 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 \$16.0 million included non-cash charges of depreciation and amortization expense of \$2.8 million, stock-based compensation expense of \$2.7 million, and other non-cash income of \$0.3 million mostly consisting of a gain on the sale of assets offset by the non-cash adjustment to the contingent consideration liabilities. Cash used by the working capital accounts included an increase in inventory of \$1.5 million due to the lower revenues and reduced shipments, an increase in prepaid expense and other current assets of \$2.1 million due to foreign tax installment payments, and a decrease in accrued expenses of \$6.6 million as the Company paid out year-end bonuses in March 2025. Cash provided by the working capital accounts included a decrease in accounts receivable of \$2.4 million largely associated with lower overall sales and collections of balances due.

#### *Investing Activities*

Net cash provided by investing activities was \$0.4 million for the three months ended March 31, 2025, which was due to proceeds from sale of property and equipment offset by the acquisition of new property and equipment.

#### *Financing Activities*

Net cash used in financing activities was \$1.0 million for the three months ended March 31, 2025, which was largely comprised of \$0.9 million used for the repurchase of common stock to satisfy withholding taxes related to the vesting of restricted shares awarded to the Company's employees.

#### *Resources*

The Company expects existing cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements over the next twelve months. The Company's cash requirements, however, may vary materially from those now planned due to many factors, including, but not limited to, the 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, 2024 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, 2024. As of March 31, 2025, 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, 2024 filed with the SEC. No material changes have been made to such critical accounting policies during the three months ended March 31, 2025.

### **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, 2024.

### **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, 2025. 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, 2025 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, 2025 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. 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. The Company appealed the grant of summary judgment to the Court of Appeals on June 8, 2023. On February 14, 2025, the Court of Appeals affirmed the District Court's judgment. The Court of Appeals mandate issued on March 24, 2025. 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. On July 2, 2024, the Company filed a Motion to Amend the claims of the third patent and oral argument in this IPR took place on January 24, 2025. On February 19, 2025, the PTO issued a Final Written Decision regarding the third patent in the litigation, granting the Company's Motion to Amend as to cancelling the original claims, but denying the Company's Motion to Amend as to adding proposed substitute claims.

#### NowDiagnostics Litigation

On November 14, 2024 the Company filed a complaint against NowDiagnostics, Inc. ("NowDx"), Jody Berry ("Berry") and Janean Young ("Young") in the United States District Court for the Eastern District of Pennsylvania alleging misappropriation and misuse of the Company's proprietary information and trade secrets by NowDx, Berry and Young in violation of the Federal Defend Trade Secrets Act and the Pennsylvania Uniform Trade Secrets Act. The complaint also alleges breach of contract and duty of loyalty by Young, unfair competition by NowDx, and tortious interference with contractual relations by Berry and NowDx. NowDx filed Counterclaims against the Company on January 13, 2025 and the Company filed its Answer to the Counterclaims on February 3, 2025. Young filed a Motion to Dismiss the claims against her, which was denied by the court on February 4, 2025. NowDx, Berry, and Young agreed to a preliminary injunction which the Court entered on February 27, 2025. The trial is scheduled for March 9, 2026.

### 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, 2024 filed with the SEC on March 7, 2025, other than as set forth below.

Adding the following new risk factors:

#### **Share Repurchases Could Increase the Volatility of the Trading Price of Our Common Stock and Diminish Our Cash Reserves, and We Cannot Guarantee That Our Stock Repurchase Program Will Enhance Long-Term Stockholder Value.**

On March 21, 2025, our Board authorized the repurchase of up to \$40.0 million in shares of our common stock pursuant to a stock repurchase program (the "Repurchase Program"). The Repurchase Program does not obligate us to repurchase any

minimum dollar amount or number of shares, and can be modified, terminated or suspended at any time. Repurchases of shares of our common stock could affect the trading price of our common stock and increase volatility of such securities. Similarly, the future announcement of the modification, suspension or termination of the Repurchase Program, or our decision not to utilize the full authorized repurchase amount under the Repurchase Program, could result in a decrease in the trading price of our common stock. In addition, the Repurchase Program could have the impact of reducing our cash reserves, which may impact our ability to finance our growth, fund working capital, strategic acquisitions or business opportunities, and other general corporate purposes and execute our strategic plan. Although the Repurchase Program is intended to enhance long-term stockholder value, there can be no assurance that it will do so because the trading price of our common stock may decline below the levels at which we repurchased our shares and short-term stock price fluctuations could reduce the effectiveness of the Repurchase Program.

**Disruptions at the FDA and Other Government Agencies Caused By Reduction in Staffing or Funding Shortages Could Hinder Their Ability to Hire and Retain Key Leadership and Other Personnel, Prevent New Products and Services From Being Developed or Commercialized In A Timely Manner, or Otherwise Prevent Those Agencies From Performing Normal Business Functions, Which Could Negatively Impact Our Business and Our Timelines.**

Currently, federal agencies in the United States are operating under a continuing resolution that is set to expire on September 30, 2025. Without appropriation of additional funding to federal agencies, our business operations related to our product development for the U.S. market could be impacted. Inadequate funding for the FDA, the SEC and other government agencies, including from government shut downs, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The Trump administration has issued executive orders seeking to greatly reduce the size of the federal workforce, including through layoffs and severance packages offered to employees of federal agencies within the executive branch and independent agencies, including the FDA. Any such reduction in personnel may result in longer review times by the FDA, the SEC and other agencies.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, shifting policy priorities as a result of changes in the Presidential administration and political appointees tasked to oversee the agency, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies on which our operations may rely is subject to the impacts of political events, which are inherently fluid and unpredictable.

Disruptions and personnel turnover, as a result of leadership changes, staff reductions or otherwise, at the FDA and other agencies may slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which could adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, or if staffing changes prevent the FDA, the SEC or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, including formal and informal interactions with product developers, it could significantly impact the ability of the FDA, the SEC or other regulatory authority to timely review and process our regulatory submissions, which could have a material adverse effect on our business and our timelines.

Supplementing the following risk factor:

**Increasing Geopolitical and Economic Risk and Tariffs Could Negatively Affect Our Ability to Maintain Sales at Existing Levels.**

The imposition of tariffs, non-tariff barriers, and other import and export restrictions have contributed to increased global economic uncertainty. For example, on April 2, 2025, the United States imposed substantial tariffs on most countries throughout the world. The new U.S. administration has indicated that it is considering broadly imposing tariffs, which could lead to corresponding punitive actions by countries with which the United States trades. These actions could make it more difficult for us to attract new customers, retain existing customers, continue to produce and source in an optimal manner, maintain our supply chain, or maintain sales at existing levels, both in the United States and in other countries. Geopolitical and economic risks, together with trade protectionism have increased over the past few years in many regions of the world, including in the United States. Any of these risks, ensuing retaliation, or the further deterioration of trade

relations between countries could make our offerings more expensive or non-competitive in the affected countries. Growing tensions, protectionist trade policies, and tariffs may also lead to a fragmentation of the global economy, a general reduction of international trade in goods and services, and a reduction in the integration of financial markets, any of which could materially and adversely affect our business results, cash flows, financial condition, or prospects.

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

Period	Total number of shares purchased	Average price paid per share	Total number of shares purchased as part of publicly announced plans or programs	Maximum number (or approximate dollar value) of shares that may yet be repurchased under the plans or programs <sup>(1,2)</sup>
January 1, 2025 - January 31, 2025	52,740 <sup>(3)</sup>	\$ 3.78	—	\$ 11,984,720
February 1, 2025 - February 28, 2025	50,009 <sup>(3)</sup>	\$ 3.95	—	\$ 11,984,720
March 1, 2025 - March 31, 2025	149,609 <sup>(3)</sup>	\$ 3.63	—	\$ 40,000,000
	<u>252,358</u>		<u>—</u>	

- (1) On August 5, 2008, the Company's Board of Directors approved a share repurchase program (the "Prior Repurchase Program") pursuant to which the Company was permitted to acquire up to \$25.0 million of outstanding shares of the Company's common stock. This share repurchase program was discontinued on March 21, 2025. In March 2025, the Company's board of directors authorized a stock repurchase program (the "Repurchase Program") effective March 21, 2025, whereby the Company may purchase up to \$40.0 million in shares of our common stock over a period of up to two years. The amount and timing of share repurchases under the Repurchase Program may be carried out at the discretion of management through various methods in compliance with applicable state and federal securities laws. We did not repurchase any shares of our common stock under the Repurchase Program during the three months ended March 31, 2025.
- (2) This column represents the amount that remains available under the \$25.0 million Prior Repurchase Program, 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**

**Rule 10b5-1 Trading Plans**

The disclosure set forth in Part II - Item 2 above is incorporated herein by reference.

During the three months ended March 31, 2025, none of our directors or officers adopted, amended, or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

**Item 6. EXHIBITS**

<b>Exhibit Number</b>	<b>Exhibit</b>
31.1*	<a href="#">Certification of Carrie Eglinton-Manner required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.</a>
31.2*	<a href="#">Certification of Kenneth J. McGrath required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.</a>
32.1*+	<a href="#">Certification of Carrie Eglinton-Manner required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
32.2*+	<a href="#">Certification of Kenneth J. McGrath required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
18.1*	<a href="#">Preferability Letter</a>
101.INS	Inline XBRL Instance Document – the Instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page from Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in exhibits 101).

\* Filed herewith

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

**SIGNATURES**

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

ORASURE TECHNOLOGIES, INC.

Date: May 7, 2025

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

Date: May 7, 2025

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

May 7, 2025

Board of Directors  
OraSure Technologies, Inc.  
220 E 1<sup>st</sup> St. Bethlehem, PA18015

Dear Directors:

We are providing this letter solely for inclusion as an exhibit to OraSure Technologies Inc. (the “Company”) Form 10-Q filing pursuant to Item 601 of Regulation S-K.

As stated in Note 1 to the unaudited consolidated financial statements included in the Company’s Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2025, the Company changed its accounting for inventory costing from the first-in, first-out (“FIFO”) method to average cost. Note 1 also states management’s belief that the newly adopted accounting principle is preferable in the circumstances as it results in greater precision in the calculation of acquisition cost of inventory on the balance sheet.

With regard to the aforementioned accounting change, it should be understood that authoritative criteria have not been established for evaluating the preferability of one acceptable method of accounting over another acceptable method and, in expressing our concurrence below, we have relied on management’s business planning and judgment and on management’s determination that this change in accounting principle is preferable.

Based on our reading of management’s stated reasons and justification for this change in accounting principle in the Form 10-Q, and our discussions with management as to their judgment about the relevant business planning factors relating to the change, we concur with management that the newly adopted method of accounting is preferable in the Company’s circumstances.

We have not audited the application of the aforementioned accounting change to the financial statements included in Part I of the Company’s Form 10-Q. We also have not audited any consolidated financial statements of the Company as of any date or for any period subsequent to December 31, 2024. Accordingly, we do not express an opinion on whether the accounting for the change in accounting principle has been properly applied or whether the aforementioned financial statements are fairly presented in conformity with accounting principles generally accepted in the United States of America.

Sincerely,

/s/ GRANT THORNTON LLP  
Philadelphia, Pennsylvania

**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 7, 2025

*/s/ Carrie Eglinton Manner*

\_\_\_\_\_  
Carrie Eglinton Manner

President and Chief Executive Officer  
( *Principal Executive Officer* )

**Certification**

I, Kenneth J. McGrath, certify that:

1. I have reviewed this report on Form 10-Q of OraSure Technologies, Inc.
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2025

*/s/ Kenneth J. McGrath*

Kenneth J. McGrath

Chief Financial Officer

( *Principal Financial Officer* )

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

In connection with the Quarterly Report of OraSure Technologies, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2025 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 7, 2025

**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, 2025 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 7, 2025