

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended **June 30, 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 July 31, 2025, the registrant had 73,136,987 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;
 - Changes in market acceptance of products based on product performance or other factors, including changes in testing guidelines, algorithms or other recommendations by the Centers for Disease Control and Prevention (the "CDC") or other agencies;
 - The Company's ability to fund research and development and other products and operations;
 - The Company's ability to obtain and maintain new or existing product distribution channels;
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- 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 reliable. Readers are cautioned not to place undue reliance on the forward-looking statements. The forward-looking statements are made as of the date of this report and the Company undertakes no duty to update these statements, unless it

is required to do so by law. If the Company does update one or more forward-looking statements, no inference should be drawn that it will make updates with respect to other forward-looking statements or that it will make any further updates to those forward-looking statements at any future time.

Investors should also be aware that while the Company does, from time to time, communicate with securities analysts, it is against the Company's policy to disclose any material non-public information or other confidential commercial information. Accordingly, stockholders should not assume that the Company agrees with any statement or report issued by any analyst irrespective of the content of the statement or report. Furthermore, the Company has a policy against issuing or confirming financial forecasts or projections issued by others. Thus, to the extent that reports issued by securities analysts contain any projections, forecasts or opinions, such reports are not the responsibility of OraSure.

PART I. FINANCIAL INFORMATION

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Item 1. FINANCIAL STATEMENTS

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

	June 30, 2025	December 31, 2024
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 234,578	\$ 267,763
Accounts receivable, net of allowance of \$329 and \$773	25,900	23,816
Inventories	33,375	34,197
Prepaid expenses	3,336	3,956
Other current assets	4,249	3,488
Total current assets	301,438	333,220
Noncurrent Assets:		
Property, plant and equipment, net of accumulated depreciation of \$71,100 and \$65,918	42,155	45,105
Operating right-of-use assets	12,703	13,442
Finance right-of-use assets	181	145
Intangible assets, net of accumulated amortization of \$27,234 and \$32,413	17,266	17,435
Goodwill	41,745	40,330
Investment in equity method investee	26,974	28,300
Deferred tax asset	—	156
Other noncurrent assets	2,573	1,526
Total noncurrent assets	143,597	146,439
TOTAL ASSETS	\$ 445,035	\$ 479,659
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 6,380	\$ 8,173
Deferred revenue	2,446	2,961
Accrued expenses and other current liabilities	14,395	20,179
Finance lease liability	62	41
Operating lease liability	2,086	2,129
Acquisition-related contingent consideration obligation	16,981	—
Total current liabilities	42,350	33,483
Noncurrent Liabilities:		
Finance lease liability	133	113
Operating lease liability	11,844	12,321
Acquisition-related contingent consideration obligation	7,140	22,910
Other noncurrent liabilities	2,847	494
Total noncurrent liabilities	21,964	35,838
TOTAL LIABILITIES	64,314	69,321
Commitments and contingencies (Note 12)		
STOCKHOLDERS' EQUITY		
Preferred stock, par value \$.000001, 25,000 shares authorized, none issued	—	—
Common stock, par value \$0.000001, 120,000 shares authorized, 73,735 and 74,598 shares issued and outstanding	—	—
Additional paid-in capital	537,256	538,129
Accumulated other comprehensive loss	(17,371)	(24,360)
Accumulated deficit	(139,164)	(103,431)
Total stockholders' equity	380,721	410,338
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 445,035	\$ 479,659

See accompanying notes to the consolidated financial statements.

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2025	2024	2025	2024
NET REVENUES:				
Products and services	\$ 29,847	\$ 53,949	\$ 58,844	\$ 107,728
Other	1,395	386	2,329	739
	<u>31,242</u>	<u>54,335</u>	<u>61,173</u>	<u>108,467</u>
COST OF PRODUCTS AND SERVICES SOLD	<u>18,083</u>	<u>29,646</u>	<u>35,715</u>	<u>59,713</u>
Gross profit	13,159	24,689	25,458	48,754
OPERATING EXPENSES:				
Research and development	11,401	6,599	21,004	14,337
Sales and marketing	6,375	7,931	13,234	16,379
General and administrative	12,676	11,845	26,778	23,479
Loss on impairments	—	1,054	—	4,392
Change in the estimated fair value of acquisition-related contingent consideration	733	—	1,211	—
Gain on sale of assets	—	—	(993)	—
	<u>31,185</u>	<u>27,429</u>	<u>61,234</u>	<u>58,587</u>
Operating loss	(18,026)	(2,740)	(35,776)	(9,833)
OTHER INCOME	<u>1,135</u>	<u>3,066</u>	<u>2,913</u>	<u>6,557</u>
(Loss) income before income taxes and equity investment	(16,891)	326	(32,863)	(3,276)
INCOME TAX EXPENSE	<u>2,000</u>	<u>381</u>	<u>1,544</u>	<u>363</u>
LOSS BEFORE EQUITY INVESTMENT	<u>(18,891)</u>	<u>(55)</u>	<u>(34,407)</u>	<u>(3,639)</u>
LOSS ON EQUITY INVESTMENT	<u>(802)</u>	<u>(560)</u>	<u>(1,326)</u>	<u>(560)</u>
NET LOSS	<u>\$ (19,693)</u>	<u>\$ (615)</u>	<u>\$ (35,733)</u>	<u>\$ (4,199)</u>
LOSS PER SHARE:				
BASIC	<u>\$ (0.26)</u>	<u>\$ (0.01)</u>	<u>\$ (0.48)</u>	<u>\$ (0.06)</u>
DILUTED	<u>\$ (0.26)</u>	<u>\$ (0.01)</u>	<u>\$ (0.48)</u>	<u>\$ (0.06)</u>
SHARES USED IN COMPUTING LOSS PER SHARE:				
BASIC	<u>74,541</u>	<u>74,159</u>	<u>74,703</u>	<u>74,127</u>
DILUTED	<u>74,541</u>	<u>74,159</u>	<u>74,703</u>	<u>74,127</u>

See accompanying notes to the consolidated financial statements.

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

	<u>For the Three Months Ended June 30,</u>		<u>For the Six Months Ended June 30,</u>	
	2025	2024	2025	2024
NET LOSS	\$ (19,693)	\$ (615)	\$ (35,733)	\$ (4,199)
OTHER COMPREHENSIVE INCOME (LOSS)				
Currency translation adjustments	6,751	(1,134)	6,989	(3,690)
COMPREHENSIVE LOSS	<u>\$ (12,942)</u>	<u>\$ (1,749)</u>	<u>\$ (28,744)</u>	<u>\$ (7,889)</u>

See accompanying notes to the consolidated financial statements.

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

	For the Six Months Ended June 30,	
	2025	2024
OPERATING ACTIVITIES:		
Net loss	\$ (35,733)	\$ (4,199)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities		
Stock-based compensation	5,852	6,290
Depreciation and amortization	5,334	5,331
Loss on impairments	—	4,392
Other non-cash amortization	(147)	(88)
Provision for credit losses	(296)	149
Unrealized foreign currency loss (gain)	470	(48)
Interest expense on finance leases	4	13
Loss on equity investment	1,326	560
Deferred income taxes	(820)	91
Gain on sale of fixed assets	(780)	—
Change in the estimated fair value of acquisition-related contingent consideration	1,211	—
Changes in assets and liabilities:		
Accounts receivable	(1,563)	1,802
Inventories	1,009	9,220
Prepaid expenses and other assets	(683)	1,727
Accounts payable	(1,548)	(3,469)
Deferred revenue	(520)	(105)
Accrued expenses and other liabilities	(3,072)	(7,083)
Net cash (used in) provided by operating activities	(29,956)	14,583
INVESTING ACTIVITIES:		
Purchases of investments	—	(53,244)
Purchase of equity method investee	—	(28,333)
Proceeds from maturities and redemptions of investments	—	43,908
Proceeds from sale of assets	790	—
Purchases of property and equipment	(2,356)	(3,196)
Net cash used in investing activities	(1,566)	(40,865)
FINANCING ACTIVITIES:		
Cash payments for finance lease liabilities	(26)	(107)
Proceeds from exercise of stock options	—	214
Repurchase of common stock	(5,000)	—
Payment of taxes related to net share settlement of equity awards	(1,725)	(3,446)
Net cash used in financing activities	(6,751)	(3,339)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	5,088	(2,547)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(33,185)	(32,168)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	267,763	290,407
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 234,578	\$ 258,239
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION		
Cash paid for income taxes	\$ 2,579	\$ 1,607
Non-cash investing and financing activities		
Accrued property and equipment purchases	\$ 182	\$ 638

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 and six months ended June 30, 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

Effective January 1, 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 six months ended June 30, 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 June 30, 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 June 30, 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	June 30, 2025	December 31, 2024
Guaranteed investment certificates	1	\$ 68,447	\$ 66,584
Contingent consideration:	3		
Current portion		16,981	—
Long-term portion		7,140	22,910
		\$ 24,121	\$ 22,910

All of the Company's guaranteed investment certificates are measured as Level 1 instruments as of June 30, 2025.

Included in cash and cash equivalents at June 30, 2025 and December 31, 2024 was \$68.4 million and \$66.6 million, respectively, of guaranteed investment certificates.

Also included in cash and cash equivalents at June 30, 2025 and December 31, 2024 was \$121.1 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 June 30, 2025 and December 31, 2024 was \$0.5 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 \$1.2 million in the fair value of the Company's contingent consideration from date of acquisition to June 30, 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 June 30, 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 \$27.0 million as of June 30, 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 June 30, 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 (losses) resulting from foreign currency transactions that are included in other income in the Company's consolidated statements of operations were \$(0.9) million and \$0.1 million for the three months ended June 30, 2025 and 2024, respectively.

Net foreign exchange gains (losses) resulting from foreign currency transactions for the six months ended June 30, 2025 and 2024 were \$(1.3) million and \$0.3 million respectively.

Accumulated Other Comprehensive Loss

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

	Foreign Currency	Total
Balance at December 31, 2024	\$ (24,360)	\$ (24,360)
Other comprehensive gain	6,989	6,989
Balance at June 30, 2025	<u>\$ (17,371)</u>	<u>\$ (17,371)</u>

Uncertain Tax Positions

Assets and liabilities are established for uncertain tax positions taken or positions expected to be taken in income tax returns when such positions fail to meet the "more likely than not" threshold based on the technical merits of the positions. We assess whether previously unrecognized tax benefits may be recognized when tax positions is (1) more likely than not of being sustained based on its technical merits, (2) effectively settled through examination, negotiation or litigation, or (3) settled through actual expiration of the relevant tax statutes. The assessment of an uncertain tax position requires significant judgement.

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>June 30,</u> <u>2025</u>	<u>December 31,</u> <u>2024</u>
Raw materials	\$ 15,334	\$ 17,002
Work in process	559	420
Finished goods	17,482	16,775
	<u>\$ 33,375</u>	<u>\$ 34,197</u>

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

	<u>June 30,</u> <u>2025</u>	<u>December 31,</u> <u>2024</u>
Land	\$ 1,118	\$ 1,118
Buildings and improvements	39,076	36,152
Machinery and equipment	57,527	51,015
Computer equipment and software	12,337	11,502
Furniture and fixtures	1,660	1,621
Construction in progress	1,537	9,615
	<u>113,255</u>	<u>111,023</u>
Accumulated depreciation	<u>(71,100)</u>	<u>(65,918)</u>
	<u>\$ 42,155</u>	<u>\$ 45,105</u>

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

	<u>June 30,</u> <u>2025</u>	<u>December 31,</u> <u>2024</u>
Payroll and related benefits	\$ 9,028	\$ 11,147
Professional fees	1,564	2,469
Sales tax payable	1,089	1,339
Other	2,714	5,224
	<u>\$ 14,395</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):

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

As of June 30, 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*.

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

As of June 30, 2025 the Company had \$0.3 million accrued and had paid \$1.4 million related to the reduction in workforce. No additional expense was incurred during the six months ended June 30, 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 June 30, 2025 the Company had \$0.5 million accrued and had paid \$0.7 million related to the reduction in workforce. No additional expense was incurred during the six months ended June 30, 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 June 30,		For the Six Months Ended June 30,	
	2025	2024	2025	2024
HIV	\$ 14,398	\$ 13,652	\$ 27,298	\$ 27,032
Sample Management Solutions ⁽¹⁾	9,855	12,609	18,965	23,431
HCV	4,126	4,734	8,459	7,734
Risk Assessment Testing ⁽²⁾	446	2,308	1,866	4,352
Other product and services revenues ⁽³⁾	994	897	1,767	1,429
COVID-19 ⁽⁴⁾	28	18,939	489	42,067
Molecular Services	—	810	—	1,683
Net product and services revenues	\$ 29,847	\$ 53,949	\$ 58,844	\$ 107,728
Non-product and services revenues ⁽⁵⁾	1,395	386	2,329	739
Net revenues	\$ 31,242	\$ 54,335	\$ 61,173	\$ 108,467

⁽¹⁾ Includes Genomics, Microbiome and Colli-Pee® product revenues.

⁽²⁾ Includes substance abuse testing product revenues.

⁽³⁾ Includes Syphilis revenues.

⁽⁴⁾ Includes COVID-19 Diagnostics and COVID-19 Sample Management Solutions revenues.

⁽⁵⁾ Includes funded research and development contracts, royalty income and grant revenues.

Revenues by Geographic Area. The following table represents total net revenues by geographic area, based on the location of the customer (in thousands):

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2025	2024	2025	2024
United States	\$ 19,852	\$ 44,386	\$ 40,187	\$ 89,597
Africa	8,027	6,366	15,216	12,070
Europe	2,117	2,164	3,754	3,766
Other regions	1,246	1,419	2,016	3,034
	\$ 31,242	\$ 54,335	\$ 61,173	\$ 108,467

Customer Concentration. The following table represents customer concentration risk:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2025	2024	2025	2024
<i>Net Revenues</i>				
Non-commercial customer	N/A	33%	N/A	37%
			June 30,	December 31,
			2025	2024
<i>Accounts Receivable</i>				
Commercial customer			19%	10%

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 June 30, 2025 and December 31, 2024 was comprised of customer prepayments of \$2.4 million and \$3.0 million, respectively.

The following table represents deferred revenue recognized:

<i>Deferred Revenue Recognized</i>	<u>For the Three Months Ended June 30,</u>		<u>For the Six Months Ended June 30,</u>	
	<u>2025</u>	<u>2024</u>	<u>2025</u>	<u>2024</u>
Accrued at beginning of period	\$ 974	\$ 774	\$ 1,461	\$ 1,194

7. Income Taxes

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2025	2024	2025	2024
Federal income tax expense	\$ 157	\$ —	\$ 165	\$ —
State income tax expense (benefit)	2,394	3	2,403	(228)
Foreign income tax (benefit) expense	(551)	378	(1,024)	591
	<u>\$ 2,000</u>	<u>\$ 381</u>	<u>\$ 1,544</u>	<u>\$ 363</u>

During the three months ended June 30, 2025 and 2024, the Company recorded income tax expense of \$2.0 million and \$0.4 million, respectively. During the six months ended June 30, 2025 and 2024, the Company recorded income tax expense of \$1.5 million and \$0.4 million, respectively. The net tax expense increase in both periods is largely due to recording an uncertain tax position for certain tax matters, including penalties and interest.

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 June 30, 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 June 30, 2025 and December 31, 2024.

As of December 31, 2024 and June 30, 2025, uncertain tax positions were approximately \$0.0 million and \$2.5 million. The Company's uncertain tax position relates to U.S. federal and other jurisdictions. Due to various factors, including the inherent complexities and uncertainties of the judicial, administrative, and regulatory processes in certain jurisdictions, the timing of the resolution of income tax controversies is highly uncertain, and the amounts ultimately paid, if any, upon resolution of the issues raised by the taxing authorities may differ from the amounts accrued. Any assessments or settlements could result in changes to our contingencies related to positions on prior years' tax filings.

On July 4, 2025, Congress enacted the One Big Beautiful Bill Act ("OBBBA"), which includes several changes to the Internal Revenue Code which may result in changes to the Company's income tax expense. The Company is currently evaluating the impacts of the OBBBA but does not believe that changes in tax law will materially affect the Company's operating performance or financial position.

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 June 30, 2025 and 2024, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 581 shares and 1,010 shares, respectively, were excluded from the computation of diluted loss per share.

For the six months ended June 30, 2025 and 2024, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 618 shares and 1,333 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 repurchased 1.8 million shares of its common stock under the Repurchase Program during the six months ended June 30, 2025.

The reconciliation of the changes in stockholders' equity for the three and six months ended June 30, 2025 and 2024 is as follows (in thousands):

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balance at December 31, 2024	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
Balance at March 31, 2025	75,114	\$ —	\$ 539,875	\$ (24,122)	\$ (119,471)	\$ 396,282
Vesting of restricted stock and performance stock units	713	—	—	—	—	—
Purchase and retirement of common shares	(271)	—	(784)	—	—	(784)
Stock-based compensation	—	—	3,165	—	—	3,165
Repurchase of common stock	(1,821)	—	(5,000)	—	—	(5,000)
Net loss	—	—	—	—	(19,693)	(19,693)
Currency translation adjustments	—	—	—	6,751	—	6,751
Balance at June 30, 2025	<u>73,735</u>	<u>\$ —</u>	<u>\$ 537,256</u>	<u>\$ (17,371)</u>	<u>\$ (139,164)</u>	<u>\$ 380,721</u>

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

10. Business Segment Information

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>June 30,</u> <u>2025</u>	<u>December 31,</u> <u>2024</u>
United States	\$ 38,418	\$ 40,286
United Kingdom	11,037	12,849
Canada	5,237	5,468
Other regions	347	89
	<u>\$ 55,039</u>	<u>\$ 58,692</u>

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2025	2024	2025	2024
Net revenues	31,242	54,335	61,173	108,467
Cost of products and services sold ⁽²⁾	18,083	29,646	35,715	59,713
Gross profit	13,159	24,689	25,458	48,754
Research and development ⁽²⁾	11,401	6,599	21,004	14,337
Sales and marketing ⁽²⁾	6,375	7,931	13,234	16,379
General and administrative ⁽²⁾	12,676	11,845	26,778	23,479
Loss on impairments	—	1,054	—	4,392
Change in the estimated fair value of acquisition-related contingent consideration	733	—	1,211	—
Gain on sale of assets	—	—	(993)	—
Operating (loss) income	(18,026)	(2,740)	(35,776)	58,587
Other (expense) income	—	(43)	(16)	241
Interest revenue	2,073	3,031	4,228	6,052
Other segment items ⁽¹⁾	(938)	78	(1,299)	264
(Loss) income before income taxes	(16,891)	326	(32,863)	(3,276)
Income tax expense	2,000	381	1,544	363
Loss on equity investment	(802)	(560)	(1,326)	(560)
Net loss	\$ (19,693)	(615)	(35,733)	(4,199)

⁽¹⁾ Includes interest expense and foreign currency gains (losses).

⁽²⁾ The following tables represent additional significant segment expense categories:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2025	2024	2025	2024
<i>Stock-based Compensation</i>				
Cost of products and services sold	\$ 207	\$ 193	\$ 376	\$ 344
Research and development	279	264	482	530
Sales and marketing	217	313	435	570
General and administrative	2,462	2,552	4,559	4,846
	\$ 3,165	\$ 3,322	\$ 5,852	\$ 6,290

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2025	2024	2025	2024
<i>Depreciation and Amortization</i>				
Cost of products and services sold	\$ 1,060	\$ 1,507	\$ 2,449	\$ 3,054
Research and development	569	243	1,054	485
Sales and marketing	30	47	57	95
General and administrative	868	809	1,775	1,697
	\$ 2,526	\$ 2,606	\$ 5,334	\$ 5,331

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:

Assets Acquired	
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	<u>39,738</u>
Liabilities Assumed	
Accounts payable	2,449
Current liabilities	3,621
Deferred revenue	1,641
Operating lease liability	4,080
Total liabilities assumed	<u>11,791</u>
Net Assets Acquired	<u>27,947</u>
Estimated fair value of contingent consideration	(22,910)
Net Cash Paid (net of cash acquired of (\$402))	<u>\$ 5,037</u>

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.

	<u>For the Three Months Ended June 30,</u>		<u>For the Six Months Ended June 30,</u>	
	<u>2024</u>		<u>2024</u>	
Net revenues	\$	54,575	\$	109,038
Net loss	\$	(9,865)	\$	(24,203)

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.

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 completed in the second quarter of 2025. Sales of its risk assessment products contributed \$0.4 million and \$2.3 million to revenues during the three months ended June 30, 2025 and 2024, respectively. Sales of its risk assessment products contributed \$1.9 million and \$4.4 million to revenues during the six months ended June 30, 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 June 30, 2025 compared to June 30, 2024.

CONSOLIDATED NET REVENUES

The table below shows total consolidated net revenues (dollars in thousands) for the three months ended June 30, 2025 and 2024:

	For the Three Months Ended June 30,				
	Dollars		% Change	Percentage of Total Net Revenues	
	2025	2024		2025	2024
Diagnostics ⁽¹⁾	\$ 19,222	\$ 18,746	3 %	62 %	35 %
Sample Management Solutions ⁽²⁾	9,855	12,609	(22)	32	23
Risk Assessment Testing ⁽³⁾	446	2,308	(81)	1	3
Other products and services ⁽⁴⁾	296	542	(45)	1	1
COVID-19 Diagnostics	28	18,934	(100)	—	35
Molecular Services	—	810	(100)	—	1
Net product and services revenues	29,847	53,949	(45)	96	98
Non-product and services revenues ⁽⁵⁾	1,395	386	261	4	2
Net revenues	\$ 31,242	\$ 54,335	(43)%	100 %	100 %

⁽¹⁾ Includes HIV, HCV, Syphilis, and SureQuick® product revenues.

⁽²⁾ Includes Genomics, Microbiome, and Colli-Pee® product revenues.

⁽³⁾ Includes substance abuse testing product revenues.

⁽⁴⁾ Includes COVID-19 Sample Management Solutions product revenues.

⁽⁵⁾ Includes funded research and development contracts, royalty income and grant revenues.

Product and Services Revenues

Consolidated net revenues decreased 43% to \$31.2 million for the three months ended June 30, 2025 from \$54.3 million for the three months ended June 30, 2024.

Sales of the Company's Diagnostics products increased 3% to \$19.2 million for the three months ended June 30, 2025 from \$18.7 million for the three months ended June 30, 2024. This increase in revenues is largely due to higher international HIV revenues of approximately \$1.3 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 partially offset by decrease in domestic revenues of the Company's HIV product and a decline in international HCV revenues.

Sample Management Solutions revenues decreased 22% to \$9.9 million for the three months ended June 30, 2025 from \$12.6 million for the three months ended June 30, 2024. Sales of the Company's genomics products are being impacted by a large customer's bankruptcy proceedings.

Risk assessment revenue decreased 81% to \$0.4 million for the three months ended June 30, 2025 from \$2.3 million for the three months ended June 30, 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 100% to \$0.03 million for the three months ended June 30, 2025 compared to \$18.9 million for the three months ended June 30, 2024 due to decreased sales of the Company's InteliSwab® tests through its U.S. government procurement contracts. We expect this level of 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 June 30, 2025 compared to \$0.8 million during the three months ended June 30, 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 261% to \$1.4 million for the three months ended June 30, 2025 from \$0.4 million for the three months ended June 30, 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 42.1% for the three months ended June 30, 2025 from 45.4% for the three months ended June 30, 2024. The largest driver of the margin decline was a negative product mix driven by lower InteliSwab® sales that generate higher gross margins, lower genomics sales that also generate higher gross margins, and higher international product sales which generate lower margins. The termination of the microbiome molecular sequencing services business which historically dragged down the gross margin rate helped to improve the gross margin rate during the quarter. Higher scrap expense also contributed to the lower margins in the quarter but was partially offset by improved overhead absorption as the Company brings more production in-house to its Opus Way facility.

Consolidated operating loss for the three months ended June 30, 2025 was \$18.0 million, a \$15.3 million increase from the operating loss reported for the three months ended June 30, 2024. The increase in the operating loss reported in the second 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 June 30, 2025 coupled with the increase spend on clinical trials. Results for the three months ended June 30, 2025 included change in the estimated fair value of acquisition-related contingent consideration of \$0.7 million.

Research and development expenses increased 73% to \$11.4 million for the three months ended June 30, 2025 from \$6.6 million for the three months ended June 30, 2024 largely due to higher spend incurred for clinical trials associated with the Chlamydia Trachomatis (CT) and Neisseria Gonorrhoeae (NG) device and additional R&D expense layered in from the newly acquired Sherlock companies.

Sales and marketing expenses decreased 20% to \$6.4 million for the three months ended June 30, 2025 from \$7.9 million for the three months ended June 30, 2024 due to decreased bad debt expense, lower employee costs associated with a decrease in headcount and a decrease in consulting costs.

General and administrative expenses increased 7% to \$12.7 million for the three months ended June 30, 2025 from \$11.8 million for the three months ended June 30, 2024 largely due an increase in legal fees and severance expense associated with an executive's departure.

During the three months ended June 30, 2025, the Company recorded a non-cash adjustment of \$0.7 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 \$18.0 million for the three months ended June 30, 2025, which included non-cash charges of \$3.2 million for stock-based compensation, \$2.5 million for depreciation and amortization, and \$0.7 million of change in the estimated fair value of acquisition-related contingent consideration. The Company's operating loss of \$2.7 million for the three months ended June 30, 2024 included a non-cash impairment charge of \$1.1 million, non-cash charges of \$2.6 million for depreciation and amortization, and \$3.3 million for stock-based compensation.

OTHER INCOME

Other income for the three months ended June 30, 2025 was \$1.1 million compared to \$3.1 million for the three months ended June 30, 2024 due to lower interest income and higher foreign currency losses.

CONSOLIDATED INCOME TAXES

The Company continues to believe the full valuation allowance established against its total U.S. deferred tax asset is appropriate as the facts and circumstances necessitating the allowance have not changed. For the three months ended June 30, 2025 and 2024, the Company recorded income tax expense of \$2.0 million and \$0.4 million, respectively. The increase in the income tax expense is largely due to recording an uncertain tax position for certain tax matters, including penalties and interest.

Results of Operations

For the six months ended June 30, 2025 compared to June 30, 2024.

CONSOLIDATED NET REVENUES

The table below shows an outline of total consolidated net revenues (dollars in thousands) for the six months ended June 30, 2025 and 2024:

	For the Six Months Ended June 30,				
	Dollars		% Change	Percentage of Total Net Revenues	
	2025	2024		2025	2024
Diagnostics ⁽¹⁾	\$ 36,911	\$ 35,139	5 %	60 %	32 %
Sample Management Solutions ⁽²⁾	18,965	23,431	(19)	31	22
Risk Assessment Testing ⁽³⁾	1,866	4,352	(57)	3	4
Other products and services ⁽⁴⁾	617	1,092	(43)	1	1
COVID-19 Diagnostics	485	42,031	(99)	1	39
Molecular Services	—	1,683	(100)	—	2
Net product and services revenues	58,844	107,728	(45)	96	99
Non-product and services revenues ⁽⁵⁾	2,329	739	215	4	1
Net revenues	\$ 61,173	\$ 108,467	(44)%	100 %	100 %

⁽¹⁾ Includes HIV, HCV, Syphilis, and SureQuick® product revenues.

⁽²⁾ Includes Genomics, Microbiome and Colli-Pee® product revenues.

⁽³⁾ Includes substance abuse testing product revenues.

⁽⁴⁾ Includes COVID-19 Sample Management Solutions product revenues.

⁽⁵⁾ Includes funded research and development contracts, royalty income and grant revenues.

Product and Services Revenues

Consolidated net product and services revenues decreased 45% to \$58.8 million for the six months ended June 30, 2025 from \$107.7 million for the six months ended June 30, 2024.

Sales of the Company's Diagnostics products increased 5% to \$36.9 million for the six months ended June 30, 2025 from \$35.1 million for the six months ended June 30, 2024. This increase in revenue was primarily driven by higher HIV and HCV revenues in international markets of \$1.9 million as a result of customer ordering patterns. Also contributing to the diagnostic revenue increase is a combined increase in HCV domestic and Syphilis revenues of \$0.9 million. A decline in our HIV domestic revenue resulting from funding delays or reductions in funding for HIV products and customer order patterns partially offset the increased revenues from the other product lines.

Sample Management Solutions revenues decreased 19% to \$19.0 million for the six months ended June 30, 2025 from \$23.4 million for the six months ended June 30, 2024. Sales of the Company's Sample Management Solutions Products are being impacted by customer bankruptcy and economic pressures.

Risk assessment revenues decreased 57% to \$1.9 million for the six months ended June 30, 2025, compared to \$4.4 million for the six months ended June 30, 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 99% to \$0.5 million for the six months ended June 30, 2025 compared to \$42.0 million for the six months ended June 30, 2024 due to decreased sales of the Company's InteliSwab® tests through its U.S. government procurement contracts. We expect this level of revenue to continue for 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 were largely derived from the Company's laboratory services, were zero for six months ended June 30, 2025 compared to \$1.7 million for the six months ended June 30, 2024. The decrease in service 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 215% to \$2.3 million for the six months ended June 30, 2025 from \$0.7 million for the six months ended June 30, 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 of 2024. The increase is also due to funded R&D contracts with BARDA which did not commence until after the first half of 2024.

CONSOLIDATED OPERATING RESULTS

Consolidated gross profit margin decreased to 41.6% for the six months ended June 30, 2025 from 44.9% for the six months ended June 30, 2024. The largest driver of the margin decline was a negative product mix driven by lower InteliSwab® sales that generate higher gross margins, lower genomics sales that also generate higher gross margins, and higher international product sales which generate lower margins. The termination of the microbiome molecular sequencing services business which historically dragged down the gross margin rate helped to improve the gross margin rate during the period along with the higher non-product revenues which contribute 100% to gross margin. Lastly, improved overhead absorption helped to offset the negative impact to margins as the Company brings more production in-house to its Opus Way facility.

Consolidated operating loss for the six months ended June 30, 2025 was \$35.8 million, compared to \$9.8 million operating loss reported for the six months ended June 30, 2024. Results for the six months ended June 30, 2025 were negatively impacted by the decrease in revenues and lower gross margins generated on sales of the Company's products coupled with higher clinical trial spend. Results for the six months ended June 30, 2025 included change in the estimated fair value of acquisition-related contingent consideration of \$1.2 million offset by gain on sale of assets of \$1.0 million.

Research and development expenses increased 47% to \$21.0 million for the six months ended June 30, 2025 from \$14.3 million for the six months ended June 30, 2024, largely due to higher spend incurred for clinical trials for the Chlamydia Trachomatis (CT) and Neisseria Gonorrhoeae (NG) device and additional R&D expense layered in from the newly acquired Sherlock companies.

Sales and marketing expenses decreased 19% to \$13.2 million for the six months ended June 30, 2025 from \$16.4 million for the six months ended June 30, 2024 primarily due to decreased employee costs associated with the reduction in headcount, lower consulting spend, and a decrease in bad debt expense.

General and administrative expenses increased 14% to \$26.8 million for the six months ended June 30, 2025 from \$23.5 million for the six months ended June 30, 2024 largely due to an increase in legal and accounting fees and the additional general and administrative costs associated with the newly acquired Sherlock companies.

All of the above contributed to the Company's operating loss of \$35.8 million for the six months ended June 30, 2025, which included non-cash charges \$5.9 million for stock-based compensation, \$5.3 million for depreciation and amortization, and \$1.2 million for change in the estimated fair value of acquisition-related contingent consideration. The Company's operating loss of \$9.8 million for the six months ended June 30, 2024 included a non-cash impairment charge of \$4.4 million, non-cash charges of \$6.3 million for stock-based compensation and non-cash charges of \$5.3 million for depreciation and amortization.

OTHER INCOME

Other income for the six months ended June 30, 2025 was \$2.9 million compared to \$6.6 million for the six months ended June 30, 2024. This decrease is largely due to lower interest income and higher foreign currency losses.

CONSOLIDATED INCOME TAXES

The Company continues to believe the full valuation allowance established against its total U.S. deferred tax asset is appropriate as the facts and circumstances necessitating the allowance have not changed. For the six months ended June 30, 2025 and 2024, the Company recorded income expense of \$1.5 million and \$0.4 million, respectively. The increase in the income tax expense is largely due to recording an uncertain tax position for certain tax matters, including penalties and interest.

Liquidity and Capital Resources

	June 30, 2025		December 31, 2024
	(in thousands)		
Cash and cash equivalents	\$	234,578	\$ 267,763
Working capital		259,088	299,737

The Company's cash and cash equivalents decreased to \$234.6 million at June 30, 2025 from \$267.8 million at December 31, 2024. The Company's Canadian subsidiary, DNAG, held \$85.1 million or 36% of the \$234.6 million in cash and cash equivalents.

The Company's working capital decreased to \$259.1 million at June 30, 2025 from \$299.7 million at December 31, 2024.

Analysis of the Company's Cash Flows

Operating Activities

During the six months ended June 30, 2025, net cash used in operating activities was \$30.0 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 \$35.7 million included non-cash charges of stock-based compensation expense of \$5.9 million and depreciation and amortization expense of \$5.3 million, and other net non-cash losses of \$1.0 million mostly consisting of the non-cash adjustment to the contingent consideration liabilities and the loss on equity investment. Cash used by the working capital accounts included a decrease in accrued expenses of \$3.1 million largely consisting of the payment of year-end bonuses in March 2025, an increase in accounts receivable of \$1.6 million largely due to timing of shipments at the end of the quarter, and a decrease in accounts payable of \$1.5 million. Cash provided by working capital accounts included a decrease in inventory of \$1.0 million due to the lower revenues.

Investing Activities

Net cash used in investing activities was \$1.6 million for the six months ended June 30, 2025, associated with 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 \$6.8 million for the six months ended June 30, 2025, which was largely comprised of \$5.0 million of repurchase of common stock and \$1.7 million used for the repurchase of common stock to satisfy withholding taxes related to the vesting of restricted shares awarded to the Company's employees.

Resources

The Company expects existing cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements over the next twelve months. The Company's cash requirements, however, may vary materially from those now planned due to many factors, including, but not limited to, the 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 June 30, 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 six months ended June 30, 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 June 30, 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 June 30, 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 June 30, 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.

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 factor:

Changes in tax laws or in their implementation or interpretation may adversely affect us or our investors.

The rules dealing with the U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service, or IRS, and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application), including with respect to net operating losses and research and development tax credits, could adversely affect us or holders of our common stock. In recent years, many changes have been made and changes are likely to continue to occur in the future. For example, recent legislation that was signed into law on July 4, 2025 made significant changes to U.S. federal tax law.

It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in our or our stockholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof.

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

Period	Total number of shares purchased	Average price paid per share	Total number of shares purchased as part of publicly announced plans or programs	Maximum number (or approximate dollar value) of shares that may yet be repurchased under the plans or programs ⁽¹⁾
April 1, 2025 - April 30, 2025	— ⁽²⁾	\$ —	—	\$ 40,000,000
May 1, 2025 - May 31, 2025	1,217,912 ⁽²⁾	\$ 2.64	1,187,456	\$ 38,000,000
June 1, 2025 - June 30, 2025	874,180 ⁽²⁾	\$ 2.93	633,300	\$ 35,000,000
	<u>2,092,092</u>		<u>1,820,756</u>	

- (1) 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 management through various methods in compliance with applicable state and federal securities laws.
- (2) Includes shares retired to satisfy minimum tax withholdings, in connection with the vesting of restricted and performance shares, pursuant to the OraSure Technologies, Inc. Stock Award Plan.

Item 3. DEFAULTS UPON SENIOR SECURITIES

None

Item 4. MINE SAFETY DISCLOSURES

Not applicable

Item 5. OTHER INFORMATION

Amended and Restated Bylaws

On August 5, 2025, our Board approved and adopted the Company’s Third Amended and Restated Bylaws (the “Bylaws”), which became effective immediately. The Bylaws supersede and replace in their entirety the Company’s Second Amended and Restated Bylaws in effect immediately prior to effectiveness of the Bylaws.

The Bylaws, among other things:

- amend the advanced notice provisions of the Bylaws by changing the existing deadline for the submission of notices of director nominations and business proposals submitted by stockholders to provide that submissions must be made between 120 and 90 days before the anniversary date of the previous year’s annual meeting, subject to limited exceptions;
- clarify that stockholder proposals and nominations shall only be considered for annual meetings of stockholders and not special meetings of stockholders; and
- incorporate certain other administrative, technical, clarifying and conforming changes.

As a result of the changes to the advance notice provisions discussed herein and reflected in the Bylaws, any stockholder who wishes to submit a matter (other than a stockholder proposal brought in accordance with SEC Rule 14a-8) for consideration at the 2026 annual meeting of stockholders, including any stockholder proposal or director nomination, must submit the matter to the Company, in writing, to be received by the Secretary of the Company no later than 5:00 p.m. Eastern Time on February 13, 2026 and no earlier than 5:00 p.m. Eastern Time on January 14, 2026. The notice of such matter must contain the information and adhere to the procedures required by the Bylaws. This updated window for submissions amends the deadlines for stockholder proposals and director nominations previously disclosed in the Company’s 2025 proxy statement filed on April 4, 2025 and made available or mailed to stockholders on that date.

The foregoing description does not purport to be complete and is qualified in its entirety by reference to the full text of the Bylaws, a copy of which is attached hereto as Exhibit 3.1 and is incorporated herein by reference.

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 June 30, 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

Exhibit Number	Exhibit
3.2*	Third Amended and Restated Bylaws of OraSure Technologies, Inc. as of August 5, 2025.
10.1	Amended and Restated OraSure Technologies, Inc. 2000 Stock Award Plan is incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 14, 2025.
31.1*	Certification of Carrie Eglinton-Manner required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.2*	Certification of Kenneth J. McGrath required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
32.1*+	Certification of Carrie Eglinton-Manner required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*+	Certification of Kenneth J. McGrath required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the Instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page from Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in exhibits 101).

* Filed herewith

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

SIGNATURES

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

ORASURE TECHNOLOGIES, INC.

Date: August 6, 2025

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

Date: August 6, 2025

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

**THIRD AMENDED AND RESTATED BYLAWS
OF
ORASURE TECHNOLOGIES, INC.**

Effective as of August [5], 2025

**ARTICLE I
Name and Location**

SECTION 1. Name.

The name of the Corporation shall be the name set forth in the Certificate of Incorporation.

SECTION 2. Principal Office.

The principal office of the Corporation is located at 220 East First Street, Bethlehem, Pennsylvania 18015-1360.

SECTION 3. Additional Offices.

Other offices for the transaction of business of the Corporation may be located at such place or places as the Board of Directors may from time to time determine.

**ARTICLE II
Capital Stock**

SECTION 1. Shares of Stock.

The shares of the capital stock of the Corporation shall be represented by a certificate, unless and until the Board of Directors of the Corporation adopts a resolution permitting shares to be uncertificated. Notwithstanding the adoption of any such resolution providing for uncertificated shares, every holder of capital stock of the Corporation theretofore represented by certificates shall be entitled to continue to hold such certificates until surrender to the Corporation, and, upon written request to the transfer agent or registrar of the Corporation, every holder of uncertificated shares shall be entitled to receive and hold a certificate for shares of capital stock of the Corporation signed by, or in the name of, the Corporation, by (a) the Chairman of the Board of Directors, the Chief Executive Officer, the President or any Vice President of the Corporation, and (b) the Treasurer or an Assistant Treasurer or the Secretary or an Assistant Secretary of the Corporation, certifying the number of shares owned by such stockholder in the Corporation and sealed with the corporate seal.

SECTION 2. Stock Transfers.

Stock of the Corporation shall be transferable in the manner prescribed by applicable law and in these Bylaws. Transfers of stock shall be made on the books of the Corporation, and (a) in the case of certificated shares of stock, only by the person named in the certificate or by such person's attorney lawfully constituted in writing and upon the surrender of the certificate therefor, properly endorsed for transfer and payment of all necessary transfer taxes; or (b) in the case of uncertificated shares of stock, upon receipt of proper transfer instructions from the registered holder of the shares or by such person's attorney lawfully constituted in writing, and upon payment of all necessary transfer taxes and compliance with appropriate procedures for transferring shares in uncertificated form; provided, however, that such surrender and endorsement, payment of taxes or compliance shall not be required in any case in which the officers of the Corporation shall determine to waive such requirement. With respect to certificated shares of stock, every certificate exchanged, returned or surrendered to the Corporation shall be marked "Cancelled," with the date of cancellation, by the Secretary or Assistant Secretary of the Corporation or the transfer agent thereof. No transfer

of stock shall be valid as against the Corporation for any purpose until it shall have been entered in the stock records of the Corporation by an entry showing from and to whom transferred.

SECTION 3. Lost or Destroyed Stock Certificates.

A new certificate of stock may be issued in the place of any certificate theretofore issued, alleged to have been lost or destroyed, and the Corporation may, in its discretion, require the owner of the lost or destroyed certificate, or its legal representative, to give a bond sufficient to indemnify the Corporation against any claim that may be made against it on account of the alleged loss of any certificate; provided, however, that if such shares have ceased to be certificated, a new certificate shall be issued only upon written request by the owner to the transfer agent or registrar of the Corporation.

SECTION 4. Preemptive Rights Denied.

No holder of shares of any class of the Corporation, or holder of any securities or obligations convertible into shares of any class of the Corporation, shall have any preemptive right whatsoever to subscribe for, purchase or otherwise acquire shares of the Corporation of any class, whether now or hereafter authorized; provided, however, that nothing in this Section 4 shall prohibit the Corporation from granting, contractually or otherwise, to any such holder, the right to purchase additional securities of the Corporation.

ARTICLE III Stockholders' Meetings

SECTION 1. Annual Meeting.

The annual meeting of the stockholders of the Corporation shall be held, either within or without the State of Delaware, on such date and at such time as may from time to time be determined by the Board of Directors. At such meeting the stockholders shall elect directors in the manner provided in the Certificate of Incorporation of the Corporation. The stockholders may transact such other business at such annual meetings as may properly come before the meeting.

SECTION 2. Special Meeting.

A special meeting of the holders of any one or more classes of the capital stock of the Corporation entitled to vote as a class or classes with respect to any matter, as required by law or as provided by the Certificate of Incorporation, may be called at any time and place, either within or without the state of Delaware, only by the Chairman of the Board, the Chief Executive Officer, the President or the Board of Directors. Only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders of the Corporation. The Board of Directors may postpone or reschedule any previously scheduled special meeting of stockholders. Nominations of persons for election to the Board of Directors and stockholder proposals of other business shall not be brought before a special meeting of stockholders to be considered by the stockholders unless such special meeting is held in lieu of an annual meeting of stockholders, in which case such special meeting in lieu thereof shall be deemed an annual meeting for purposes of these Bylaws and the provisions of Section 4 of ARTICLE III of these Bylaws shall govern such special meeting.

SECTION 3. Notice.

Notice of the time and place of all annual meetings and of the time, place and purpose of all special meetings shall be mailed by the Secretary to each stockholder at his or her last known post office address as it appears on the records of the Corporation at least ten (10) days before the date set for such meeting.

SECTION 4. Nomination of Directors.

Nomination of persons for election to the Board of Directors of the Corporation at a meeting of the stockholders may be made by or at the direction of the Board of Directors or may be made at a meeting of stockholders by any stockholder of the Corporation who is a stockholder of record at the time of giving of notice provided for in this Section 4 and at the time of the meeting is entitled to vote for the election of Directors at the meeting and complies with the notice procedures set forth in this Section 4 of ARTICLE III. Such nomination, other than those made by or at the direction of the Board of Directors, shall be made pursuant to timely notice in writing to the Secretary of the Corporation. To be timely, a stockholder's notice shall be delivered to or mailed and received at the principal executive offices of the Corporation not later than 5:00 p.m. Eastern time on the ninetieth (90th) day nor earlier than 5:00 p.m. Eastern Time on the one hundred twentieth (120th) day prior to the one-year anniversary of the preceding year's annual meeting; provided, however, that in the event the annual meeting is first convened more than thirty (30) days before or more than sixty (60) days after such anniversary date, or if no annual meeting was held in the preceding year, notice by the stockholder to be timely must be received by the Secretary of the Corporation not later than 5:00 p.m. Eastern time on the later of the ninetieth (90th) day prior to the scheduled date of such meeting or the tenth (10th) day following the day on which public announcement of the date of such meeting is first made. In no event shall any adjournment or postponement of an annual meeting or the announcement thereof commence a new time period for the giving of a stockholder's notice as described above.

Such stockholder's notice to the Secretary shall set forth: (a) as to each person whom the stockholder proposes to nominate for election or re-election as a Director, (i) the name, age, business address and residence address of the person, (ii) the principal occupation or employment of the person, (iii) the class and number of shares of capital stock of the Corporation which are beneficially owned or owned of record by the person, and (iv) any other information relating to the person that is required to be disclosed in solicitations for proxies for election of Directors pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended (the "Exchange Act") (including such person's written consent to being named in the proxy statement as a nominee and to serving as a Director, if elected); and (b) as to the stockholder giving the notice and the beneficial owner, if any, on whose behalf the nomination is made: (i) the name and address of the stockholder, as they appear in the Corporation's books and records, and of such beneficial owner; (ii) the class and number of shares of capital stock of the Corporation which are held of record or beneficially owned by such stockholder and such beneficial owner and any other direct or indirect pecuniary or economic interest in any capital stock of the Corporation of such stockholder and such beneficial owner, including without limitation, any derivative instrument, swap, option, warrant, short interest, hedge, profit sharing arrangement or borrowed or loaned shares; (iii) a description of any arrangements or understandings between such stockholder and each proposed nominee and any other person (including their names) pursuant to which the nomination(s) are to be made by such stockholder and such beneficial owner or with respect to actions to be proposed or taken by such nominee if elected as a Director; (iv) a representation that such stockholder intends to appear in person or by proxy at the meeting to nominate the persons named in its notice; (v) a statement whether either such stockholder and/or the other Proposing Person(s) (as defined below), if any, intends to (a) deliver a proxy statement and form of proxy to holders of, in the case of a proposal, at least the percentage of the voting power of all of the shares of capital stock of the Corporation required under applicable law to carry the proposal or, in the case of a nomination or nominations, at least 67 percent of the voting power of all of the shares of capital stock of the Corporation entitled to vote on the election of directors or (b) otherwise solicit proxies in support of director nominees other than the Corporation's director nominees in accordance with Rule 14a-19 promulgated under the Exchange Act. Notwithstanding the foregoing, if a Proposing Person or Nominating Person no longer plans to solicit proxies in accordance with its representation pursuant to this Section 4 of ARTICLE III, such Proposing Person or Nominating Person shall inform the Corporation of this change by delivering a written notice to the Secretary at the principal executive offices of the Corporation no later than two (2) business days after making the determination not to proceed with a solicitation of proxies. The term "Nominating Person" shall mean (a) the stockholder providing the notice of nomination proposed to be made at the meeting, (b) the beneficial owner or beneficial owners, if different, on whose behalf the notice of the nomination proposed to be made at the meeting is made, and (c) any other participant in such solicitation. The term "Proposing Person" shall mean (a) the stockholder providing the notice of business proposed to be brought before an annual meeting, (b) the beneficial owner or beneficial owners, if different, on whose behalf the notice of the business proposed to be brought before the annual meeting is made, and (c) any other participant in such solicitation and (vi) any other information relating to such stockholder and such beneficial owner that would be required to be disclosed in a proxy statement or other filings required to be made in connection with solicitations of proxies for election of Directors, or may otherwise be

required, in each case pursuant to Section 14 of the Exchange Act and the rules and regulations promulgated thereunder. The Corporation may require any proposed nominee to furnish such other information as may reasonably be required by the Corporation to determine the eligibility of such proposed nominee to serve as a Director of the Corporation. No person shall be eligible for election as a Director of the Corporation at a meeting of the stockholders unless such person has been nominated in accordance with the procedures set forth herein. If the facts warrant, the Chairman of the meeting shall determine and declare to the meeting that a nomination does not satisfy the requirements set forth in the preceding sentence and the defective nomination shall be disregarded, notwithstanding that proxies in respect of such nomination may have been received by the Corporation. If the facts warrant, the Chairman of the meeting shall determine and declare to the meeting that a nomination fails to comply with any applicable requirements of the Exchange Act, including, but not limited to, Rule 14a-19 promulgated thereunder, such stockholder's proposed nomination shall be deemed to have not been made in compliance with these Bylaws and shall be disregarded. The requirements of this Section 4 of ARTICLE III shall apply to any nomination of a person for election as a Director, whether such nominee is to be included in the Corporation's proxy statement pursuant to Rule 14a-8 (or any successor provision) of the Exchange Act or presented to stockholders by means of an independently financed proxy solicitation. Further notwithstanding the foregoing provisions of these Bylaws, unless otherwise required by law, if any Nominating Person (A) provides notice pursuant to Rule 14a-19(b) promulgated under the Exchange Act, (B) subsequently fails to comply with the requirements of Rule 14a-19(a)(2) or Rule 14a-19(a)(3) promulgated under the Exchange Act, including the provision to the Corporation of notices required thereunder with timely notice, and (C) no other Nominating Person has provided notice pursuant to, and in compliance with, Rule 14a-19 under the Exchange Act that it intends to solicit proxies in support of the election of such proposed nominee in accordance with Rule 14a-19(b) under the Exchange Act, then such proposed nominee shall be disqualified from nomination, the Corporation shall disregard the nomination of such proposed nominee, and no vote on the election of such proposed nominee shall occur. Upon request by the Corporation, if any Nominating Person provides notice pursuant to Rule 14a-19(b) promulgated under the Exchange Act, such Nominating Person shall deliver to the Corporation, no later than five (5) business days prior to the applicable meeting date, reasonable evidence that it has met the requirements of Rule 14a-19(a)(3) promulgated under the Exchange Act. Nothing in this Section 4 shall be deemed to affect any right of a stockholder to request inclusion of a proposal in, nor the right of the Corporation to omit a proposal from, the Corporation's proxy statement pursuant to Rule 14a-8 (or any successor provision) under the Exchange Act. Nothing in this Section 4 shall be construed to affect the requirements for proxy statements of the Corporation under Regulation 14A of the Exchange Act.

SECTION 5. Presentation of Business at Stockholders' Meetings.

At any meeting of the stockholders, only such business shall be conducted as shall have been properly brought before the meeting. To be properly brought before a meeting, business must be: (a) specified in the notice of meeting (or any supplement thereto) given by or at the direction of the Board of Directors, (b) otherwise properly brought before the meeting by or at the direction of the Board of Directors, or (c) otherwise properly brought before the meeting by a stockholder who is a stockholder of record at the time of giving the notice provided for in this Section 5 and at the time of the meeting is entitled to vote at such meeting and complies with the notice procedures set forth in this Section 5 of ARTICLE III. For business to be properly brought before a meeting by such a stockholder, the stockholder must have given timely notice thereof in writing to the Secretary of the Corporation. To be timely, a stockholder's notice shall be delivered to or mailed and received at the principal executive offices of the Corporation not later than 5:00 p.m. Eastern time on the ninetieth (90th) day nor earlier than 5:00 p.m. Eastern Time on the one hundred twentieth (120th) day prior to the one-year anniversary of the preceding year's annual meeting; provided, however, that in the event the annual meeting is first convened more than thirty (30) days before or more than sixty (60) days after such anniversary date, or if no annual meeting was held in the preceding year, notice by the stockholder to be timely must be received by the Secretary of the Corporation not later than 5:00 p.m. Eastern time on the later of the ninetieth (90th) day prior to the scheduled date of such annual meeting or the tenth (10th) day following the day on which public announcement of the date of such meeting is first made. In no event shall any adjournment or postponement of a meeting or the announcement thereof commence a new time period for the giving of a stockholder's notice as described above. Such stockholder's notice to the Secretary shall set forth: (a) as to each matter the stockholder proposes to bring before the meeting, a brief description of the business desired to be brought before the meeting and the reasons for conducting such business at the meeting, and (b) as to the stockholder giving the notice and the beneficial owner, if any, on whose behalf notice of the proposed business is made: (i) the name

and address of the stockholder, as they appear in the Corporation's books and records, and of such beneficial owner; (ii) any material interest of such stockholder and such beneficial holder in such business; (iii) the class and number of shares of capital stock of the Corporation which are held of record or beneficially owned by the stockholder and such beneficial owner and any other direct or indirect pecuniary or economic interest in any capital stock of the Corporation of such stockholder and such beneficial owner, including without limitation, any derivative instrument, swap, option, warrant, short interest, hedge, profit sharing arrangement or borrowed or loaned shares; (iv) a representation that such stockholder intends to appear in person or by proxy at the meeting to propose the business described in its notice; and (v) any other information relating to such business matter that would be required to be disclosed in a proxy statement or other filings required to be made in connection with solicitations of proxies pursuant to Section 14 of the Exchange Act and the rules and regulations promulgated thereunder. Notwithstanding the foregoing provisions of this Section 5 of ARTICLE III, a stockholder shall also comply with all applicable requirements of state law and of the Exchange Act and the rules and regulations thereunder with respect to the matters set forth in this Section 5. Notwithstanding anything in these Bylaws to the contrary, no business shall be conducted at a meeting of the stockholders unless proposed in accordance with the procedures set forth herein. The Chairman of the meeting shall, if the facts warrant, determine and declare to the meeting that business was not properly brought before the meeting in accordance with the foregoing procedure and such business shall not be transacted, notwithstanding that proxies in respect of such business may have been received by the Corporation. The requirements of this Section 5 of ARTICLE III shall apply to any business to be brought before a meeting by a stockholder (other than the nomination of a person for election as a Director, which is governed by Section 4 of ARTICLE III) whether such business is to be included in the Corporation's proxy statement pursuant to Rule 14a-8 (or any successor provision) of the Exchange Act or presented to stockholders by means of an independently financed proxy solicitation. Nothing in this Section 5 shall be deemed to affect any right of a stockholder to request inclusion of a proposal in, nor the right of the Corporation to omit a proposal from, the Corporation's proxy statement pursuant to Rule 14a-8 (or any successor provision) under the Exchange Act. Nothing in these Bylaws shall require the Corporation to include in any notice, proxy statement or other mailing to stockholders any information regarding proposals made by stockholders except as otherwise required by law. To the extent this Section 5 shall be deemed by the Board of Directors or the Securities and Exchange Commission, or finally adjudged by a court of competent jurisdiction, to be inconsistent with the right of stockholders to request inclusion of a proposal in the Corporation's proxy statement pursuant to Rule 14a-8 promulgated under the Exchange Act, such rule shall prevail.

SECTION 6. Presiding Officials.

The Chairman of the Board of Directors, or in his or her absence or inability to act, the Chief Executive Officer, or in his or her absence or inability to act, the President, or in his or her absence or inability to act, any Vice President, shall preside at all stockholders' meetings.

SECTION 7. Voting.

Except as otherwise provided in the Certificate of Incorporation of the Corporation, at each meeting of the stockholders, each stockholder shall be entitled to cast one vote for each share of voting stock standing of record on the books of the Corporation, in his or her name, and may cast such vote either in person or by proxy. All proxies shall be in writing and filed with the Secretary of the meeting. Any stockholder directly or indirectly soliciting proxies from other stockholders must use a proxy card color other than white, which shall be reserved for the exclusive use by the Board of Directors.

SECTION 8. Quorum; Adjournment.

At any meeting held for the purpose of electing directors, the presence in person or by proxy of the holders of at least a majority of the then outstanding voting shares of the Corporation shall be required and be sufficient to constitute a quorum for the election of directors. At a meeting held for any purpose other than the election of directors, shares representing a majority of the votes entitled to be cast on such matter, present in person or represented by proxy, shall constitute a quorum. In the absence of the required quorum at any meeting of stockholders, a majority of such holders present in person or by proxy shall have the power to adjourn the meeting,

from time to time, without notice (except as required by law) other than an announcement at the meeting, until a quorum shall be present.

SECTION 9. Annual Statement of Business.

At each of the annual stockholders' meetings, one of the executive officers of the Corporation shall submit a statement of the business done during the preceding year, together with a report of the general financial condition of the Corporation.

ARTICLE IV Directors

SECTION 1. Powers of the Board.

The business and property of the Corporation shall be managed by a Board of Directors consisting of such number of Directors as is determined from time to time in accordance with the provisions of the Certificate of Incorporation of the Corporation. The Board of Directors may elect one of their number to act as Chairman of the Board.

SECTION 2. Qualification and Election of Directors.

Each Director upon his or her election shall qualify by filing his or her written acceptance with the Secretary or an Assistant Secretary and by fulfilling any prerequisite to qualification that may be set forth in the Certificate of Incorporation of the Corporation.

At each annual meeting of stockholders, the class of Directors whose term is expiring shall be elected. In an uncontested election of Directors, provided a quorum is present, a nominee for Director shall be elected to the Board of Directors if the votes validly cast "for" such nominee's election exceed the votes validly cast "against" such nominee's election in such election (with "abstentions" and "broker nonvotes" not counted as a vote cast either for or against such nominee's election). In a contested election of Directors, provided a quorum is present, each Director will be elected by the affirmative vote of a plurality of the shares present in person or represented by proxy at any such meeting and entitled to vote on the election of Directors. An election of Directors will be considered "contested" if, as of the record date for the applicable meeting of stockholders, there are more nominees for election than positions on the Board of Directors to be filled by election at such meeting. All other elections of Directors will be considered "uncontested."

In any uncontested election of Directors, any Director nominee who does not receive the vote of the majority of shares present in person or represented by proxy at the meeting, shall, within ten (10) days following the certification of the election results, tender his or her resignation, and the Board of Directors shall decide, through a process managed by the Board committee responsible for Director nominations, whether to accept or reject the resignation, or whether other action should be taken.

SECTION 3. Annual Meetings.

The annual meeting of the Board of Directors shall be held immediately after the adjournment of each annual meeting of the stockholders and in the event a quorum is not present, said meeting shall be held within ten (10) days after adjournment upon proper notice by the Chairman of the Board of Directors, the Chief Executive Officer, the President or a Vice President.

SECTION 4. Special Meetings.

Special meetings of the Board of Directors may be called at any time or place by the Chairman of the Board, the Chief Executive Officer, or by the President, and in the absence or inability of all of them to act, by any Vice

President, and may also be called by any two members of the Board of Directors. By unanimous consent of the Directors, special meetings of the Board of Directors may be held without notice, at any time and place.

SECTION 5. Notice; Telephonic Attendance; Unanimous Consent.

Notice of all regular and special meetings of the Board of Directors or the Executive Committee or any committee established pursuant to this ARTICLE IV (an "Other Committee") shall be sent to each Director or member of such committee, as the case may be, by the Secretary or any Assistant Secretary, by a means reasonably calculated to be received at least seven (7) days prior to the time fixed for such meeting, or notice of special meetings of the Board of Directors or the Executive Committee or any Other Committee may be given by telephone, telegraph, telefax or telex to each Director or member of such committee, as the case may be, at least twenty-four (24) hours prior to the time fixed for such meeting, or on such shorter notice as the person or persons calling the meeting may reasonably deem necessary or appropriate in the circumstances. To the extent provided in the notice of the meeting or as otherwise determined by the Chairman of the Board or the Board of Directors, Directors may participate in any regular or special meeting by means of conference telephone, videoconference or similar communications equipment which allows all persons participating in such meeting to hear each other, and participation in such meeting by means of such a device shall constitute presence in person at such meeting. Attendance of a director at any meeting shall constitute a waiver of notice of such meeting except where a director attends a meeting for the express purpose of objecting to the transaction of any business because the meeting is not lawfully called or convened.

If all the directors shall severally or collectively consent in writing to any action to be taken by the directors, such consents shall have the same force and effect as a unanimous vote of the directors at a meeting duly held. The Secretary shall file such consents with the minutes of the meetings of the Board of Directors.

SECTION 6. Quorum; Adjournment.

Except as otherwise provided in the Certificate of Incorporation of the Corporation, a quorum for the transaction of business at any meeting of the directors shall consist of a majority of the members of the Board of Directors, but the directors present, although less than a quorum, shall have the power to adjourn the meeting from time to time or to some future date.

SECTION 7. Election of Officers.

The directors shall elect the officers of the Corporation and fix their salaries and other compensation. Such election shall be made at the Directors' meeting following each annual stockholders' meeting.

SECTION 8. Advisers to the Board of Directors.

The Board of Directors from time to time, as they may deem proper, shall have authority to appoint a general manager, counsel or attorneys and other employees for such length of time and upon such terms and conditions and at such salaries and other compensation as they may deem necessary and/or advisable.

SECTION 9. Compensation; Reimbursement of Expenses.

The members of the Board of Directors shall receive compensation for their services in such amount as may be reasonable and proper and consistent with the time and service rendered. The members of the Board of Directors shall receive the reasonable expenses necessarily incurred in the attendance of meetings and in the transaction of business for the Corporation.

SECTION 10. Indemnification; Insurance.

(a) Indemnification.

(1) Actions Other than Those by or in the Right of the Corporation. To the extent permitted by Delaware law from time to time in effect and subject to the provisions of paragraph (c) of this Section 10, the Corporation shall indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the Corporation) by reason of the fact that such person is or was a director, officer, employee or agent of the Corporation, or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the Corporation (or such other corporation or organization), and, with respect to any criminal action or proceeding, had no reasonable cause to believe such person's conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction, or upon a plea of nolo contendere or its equivalent shall not, of itself, create a presumption that the person did not act in good faith and in a manner which such person reasonably believed to be in or not opposed to the best interests of the Corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that such person's conduct was unlawful.

(2) Action by or in the Right of the Corporation. To the extent permitted by Delaware law from time to time in effect and subject to the provisions of paragraph (c) of this Section 10, the Corporation shall indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the Corporation to procure a judgment in its favor by reason of the fact that such person is or was a director, officer, employee or agent of the Corporation or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the Corporation (or such other corporation or organization) and except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the Corporation (or such other corporation or organization) unless and only to the extent that the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which such court shall deem proper.

(3) Successful Defense of Action. Notwithstanding, and without limitation of, any other provision of this Section 10, to the extent that a director, officer, employee or agent of the Corporation has been successful on the merits or otherwise in defense of any action, suit or proceeding referred to in sub-paragraph (1) or (2) of this paragraph (a), or in defense of any claim, issue or matter therein, such director, officer, employee or agent shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection therewith.

(4) Determination Required. Any indemnification under sub-paragraph (1) or (2) of this paragraph (a) (unless ordered by a court) shall be made by the Corporation only as authorized in the specific case upon a determination that indemnification of the director, officer, employee or agent is proper in the circumstances because such director, officer, employee or agent has met the applicable standard of conduct set forth in said sub-paragraph. Such determination shall be made: (i) by the Board of Directors by a majority vote of a quorum consisting of directors who were not parties to the particular action, suit or proceeding, or (ii) if such a quorum is not obtainable, or, even if obtainable, a quorum of disinterested directors so directs, by independent legal counsel in a written opinion, or (iii) by the stockholders.

(b) Insurance. The Corporation may, when authorized by the Board of Directors, purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the Corporation, or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against such person and incurred by such person in any such capacity, or arising out of such person's status as such, whether or not the Corporation would have the power to indemnify him against such liability under the provisions of this Section 10. The risks insured under any insurance

policies purchased and maintained on behalf of any person as aforesaid or on behalf of the Corporation shall not be limited in any way by the terms of this Section 10 and to the extent compatible with the provisions of such policies, the risks insured shall extend to the fullest extent permitted by law, common or statutory.

(c) **Advancement of Expenses; Nonexclusivity; Duration.** Expenses (including attorneys' fees) incurred by an officer or director in defending any civil, criminal, administrative or investigative action, suit or proceeding shall be paid by the Corporation in advance of the final disposition of such action, suit or proceeding upon receipt of an undertaking by or on behalf of such officer or director to repay such amount if it shall ultimately be determined that such person is not entitled to be indemnified by the Corporation as authorized in this Section 10. Such expenses (including attorneys' fees) incurred by other employees and agents may be so paid by the Corporation upon such terms and conditions, if any, as the Board of Directors deems appropriate. The indemnifications, advancement of expenses and rights provided by, or granted pursuant to, this Section 10 shall not be deemed exclusive of any other indemnifications, advancement of expenses, rights or limitations of liability to which any person seeking indemnification or advancement of expenses may be entitled under any Bylaw, agreement, vote of stockholders or disinterested directors, or otherwise, either as to action in such person's official capacity or as to action in another capacity while holding office, and they shall continue although such person has ceased to be a director, officer, employee or agent and shall inure to the benefit of such person's heirs, executors and administrators. The authorization to purchase and maintain insurance set forth in paragraph (b) shall likewise not be deemed exclusive.

SECTION 11. Committees.

(a) The Board of Directors may, by resolution or resolutions adopted by a majority of the whole Board of Directors, designate one or more committees, each of which shall consist of two or more directors of the Corporation. Each such committee, to the extent provided in such resolution or resolutions or in a Charter adopted by the Board of Directors, shall have and may exercise all of the authority of the Board of Directors in the management of the

Corporation and may authorize the seal of the Corporation to be affixed to all papers which may require it; provided, however, that the designation of each such committee and the delegation thereto of authority shall not operate to relieve the Board, or any member thereof, of any responsibility imposed upon it or such member by law.

(b) The Board of Directors, by resolution adopted by a majority of the whole Board of Directors, may designate one or more additional directors as alternate members of any committee to replace any absent or disqualified member at any meeting of that committee, and at any time may change the membership of any committee or amend or rescind the resolution designating the committee or any Charter adopted for such committee. In the absence or disqualification of a member or alternate member of a committee, the member or members thereof present at any meeting and not disqualified from voting, whether or not the member or members constitute a quorum, may unanimously appoint another director to act at the meeting in the place of any such absent or disqualified member, provided that the director so appointed meets any qualifications stated in these Bylaws, the Charter (if any) approved by the Board of Directors for the committee or the resolutions designating the committee or any amendment thereto.

(c) Notwithstanding any other provision of these Bylaws, no committee of the Board of Directors shall have the power or authority of the Board of Directors with respect to (i) amending the Certificate of Incorporation, (ii) approving or recommending to stockholders any type or form of "business combination" (as defined in Section 203 of the General Corporation Law of Delaware as in effect on January 1, 1996), (iii) approving or recommending to stockholders an agreement of merger or consolidation or the sale, lease or exchange of all or substantially all of the Corporation's property or assets, (iv) approving or recommending to the stockholders a dissolution of the Corporation or a revocation of a dissolution, (v) amending these Bylaws, (vi) declaring a dividend or making any other distribution to the stockholders, or (vii) authorizing the issuance of stock otherwise than pursuant to the grant or exercise of a stock option under employee stock options of the Corporation.

(d) Each such committee shall keep regular minutes of its proceedings, which minutes shall be recorded in the minute book of the Corporation. The Secretary or an Assistant Secretary of the Corporation may act as Secretary for each such committee if the committee so requests.

(e) Unless otherwise provided in these Bylaws, or in the resolutions designating any committee or the Charter (if any) approved by the Board of Directors for the committee, any committee may fix its rules or procedures, fix the time and place of its meetings and specify what notice of meetings, if any, shall be given.

ARTICLE V Officers

SECTION 1. Designations.

The officers of this Corporation shall be a Chairman of the Board of Directors, a Chief Executive Officer, a President, as many Vice Presidents as the Board of Directors may from time to time deem advisable and one or more of which may be designated Executive Vice President or Senior Vice President, a Secretary, a Treasurer, and such Assistant Secretaries and Assistant Treasurers as the Board of Directors may from time to time deem advisable, and such other officers as the Board of Directors may from time to time deem advisable and designate. The Chairman of the Board of Directors shall be a member of and be elected by the Board of Directors. All other officers shall be elected by the Board of Directors. All officers shall hold office until their respective successors are elected and shall have qualified. Any two offices may be held by one person except the office of President and Vice President.

SECTION 2. Chairman of the Board.

The Chairman of the Board of Directors shall preside at all meetings of the Directors and stockholders at which he or she is present and shall have such other duties, power and authority as may be prescribed by the Board of Directors from time to time or elsewhere in these Bylaws.

SECTION 3. Chief Executive Officer.

The Chief Executive Officer shall have such general executive powers and duties as are usually vested in the office of the chief executive officer and shall perform such other duties as are authorized by the Board of Directors. Unless the Board of Directors otherwise provides, the Chief Executive Officer, or any person designated in writing by the Chief Executive Officer, shall have full power and authority on behalf of the Corporation to: (i) attend and to vote or take action at any meeting of the holders of securities of corporations in which the Corporation may hold securities, and at such meetings shall possess and may exercise any and all rights and powers incident to being a holder of such securities, and (ii) execute and deliver waivers of notice and proxies for and in the name of this Corporation with respect to securities of any such corporation held by this Corporation.

SECTION 4. President.

The President shall have such general executive powers and duties of supervision and management as are usually vested in such office and shall perform such other duties as are authorized by the Board of Directors or the Chief Executive Officer. The Chairman of the Board, the Chief Executive Officer, or the President shall sign contracts, certificates and other instruments of the Corporation as authorized by the Board of Directors.

SECTION 5. Vice Presidents.

A Vice President shall have the right and power to perform all duties and exercise all authority of the President, in case of the absence of the President or upon vacancy in the office of President or delegation by the Board of Directors, until the Board of Directors otherwise provides, and shall have all power and authority usually enjoyed by a person holding the office of Vice President.

SECTION 6. Secretary and Assistant Secretaries.

The Secretary shall issue notices of all directors' and stockholders' meetings, and shall attend and keep the minutes of the same; shall have charge of all corporate books, records and papers; shall be custodian of the corporate seal;

shall attest with his or her signature, which may be a facsimile signature if authorized by the Board of Directors, and impress with the corporate seal, all stock certificates and written contracts of the Corporation; and shall perform all other duties as are incident to his or her office. Any Assistant Secretary, in the absence or inability of the Secretary, shall perform all duties of the Secretary and such other duties as may be required.

SECTION 7. Treasurer and Assistant Treasurers.

The Treasurer shall have custody of all money and securities of the Corporation and shall give bond in such sum and with such sureties as the directors may specify, conditioned upon the faithful performance of the duties of his or her office. He or she shall keep regular books of account and shall submit them, together with all of his or her records and other papers, to the directors for their examination and approval annually; and quarterly or as and when directed by the Board of Directors, he or she shall submit to each director a statement of the condition of the business and accounts of the Corporation; and shall perform all such other duties as are incident to his or her office. An Assistant Treasurer, in the absence or inability of the Treasurer, shall perform all the duties of the Treasurer and such other duties as may be required.

SECTION 8. Bonding.

Any officer or employee of the Corporation shall give such bond for the faithful performance of his or her duties in such sum, as and when the Board of Directors may direct.

**ARTICLE VI
Dividends**

SECTION 1. Dividends shall be paid out of the net income or earned surplus of the Corporation, determined after making proper provision for required sinking fund deposits for debt obligations and proper provisions for working capital and such reserves as may be required by good and generally accepted accounting practice, when declared from time to time by resolution of the Board of Directors. No such dividends shall be declared or paid which will impair the capital of the Corporation.

**ARTICLE VII
Amendments**

SECTION 1. Except as otherwise provided in the Certificate of Incorporation of the Corporation, these Bylaws may be amended, altered or repealed by the affirmative vote of a majority of the Board of Directors, subject to the power of stockholders to amend, alter or repeal the Bylaws, or as otherwise may from time to time be authorized by the laws of the State of Delaware.

**ARTICLE VIII
Corporate Seal**

SECTION 1. The corporate seal of this Corporation shall have inscribed thereon the name of the Corporation and its state of incorporation.

* * *

Certification

I, Carrie Eglinton Manner, certify that:

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

Date: August 6, 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: August 6, 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 June 30, 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

August 6, 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 June 30, 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

August 6, 2025