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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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	**36-4370966**
(State or Other Jurisdiction of Incorporation or Organization)	**(IRS Employer Identification No.)**
220 East First Street, Bethlehem, Pennsylvania	**18015**
(Address of Principal Executive Offices)	**(Zip code)**

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

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

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

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

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

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

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

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

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

As of October 31, 2025, the registrant had 71,733,530 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;
- 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

PART II. OTHER INFORMATION

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Item 1. FINANCIAL STATEMENTS (UNAUDITED)

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

	September 30, 2025	December 31, 2024
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 216,478	$ 267,763
Accounts receivable, net of allowance for doubtful accounts of $166 and $773	24,300	23,816
Inventories	33,401	34,197
Prepaid expenses	4,709	3,956
Other current assets	4,123	3,488
Total current assets	283,011	333,220
Noncurrent Assets:		
Property, plant and equipment, net of accumulated depreciation of $73,118 and $65,918	40,795	45,105
Operating right-of-use assets, net	12,240	13,442
Finance right-of-use assets, net	164	145
Intangible assets, net of accumulated amortization of $26,802 and $32,413	17,202	17,435
Goodwill	41,313	40,330
Investment in equity method investee	26,600	28,300
Deferred tax asset	211	156
Other noncurrent assets	1,562	1,526
Total noncurrent assets	140,087	146,439
TOTAL ASSETS	**$ 423,098**	**$ 479,659**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 6,360	$ 8,173
Deferred revenue	1,879	2,961
Accrued expenses and other current liabilities	12,669	20,179
Finance lease liability	63	41
Operating lease liability	2,045	2,129
Acquisition-related contingent consideration obligation	17,232	—
Total current liabilities	40,248	33,483
Noncurrent Liabilities:		
Finance lease liability	117	113
Operating lease liability	11,240	12,321
Acquisition-related contingent consideration obligation	7,264	22,910
Other noncurrent liabilities	2,249	494
Total noncurrent liabilities	20,870	35,838
TOTAL LIABILITIES	61,118	69,321
Commitments and contingencies (Note 12)		
STOCKHOLDERS' EQUITY		
Preferred stock, par value $0.000001, 25,000 shares authorized, none issued	—	—
Common stock, par value $0.000001, 120,000 shares authorized, 72,265 and 74,598 shares issued and outstanding	—	—
Additional paid-in capital	535,029	538,129
Accumulated other comprehensive loss	(20,173)	(24,360)
Accumulated deficit	(152,876)	(103,431)
Total stockholders' equity	361,980	410,338
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 423,098**	**$ 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 September 30,		For the Nine Months Ended September 30,	
	2025	2024	2025	2024
NET REVENUES:				
Products and services	$ 25,336	$ 39,651	$ 84,180	$ 147,379
Other	1,749	264	4,078	1,003
	27,085	39,915	88,258	148,382
COST OF PRODUCTS AND SERVICES SOLD	15,313	22,845	51,028	82,558
Gross profit	11,772	17,070	37,230	65,824
OPERATING EXPENSES:				
Research and development	10,106	5,623	31,110	19,960
Sales and marketing	6,299	7,615	19,533	23,994
General and administrative	11,081	9,831	37,859	33,310
Loss on impairments	—	—	—	4,392
Change in the estimated fair value of acquisition-related contingent consideration	376	—	1,587	—
Gain on sale of assets	—	—	(993)	—
	27,862	23,069	89,096	81,656
Operating loss	(16,090)	(5,999)	(51,866)	(15,832)
OTHER INCOME	2,799	2,781	5,712	9,338
Loss before income taxes and equity investment	(13,291)	(3,218)	(46,154)	(6,494)
INCOME TAX EXPENSE	47	678	1,591	1,041
LOSS BEFORE EQUITY INVESTMENT	(13,338)	(3,896)	(47,745)	(7,535)
LOSS ON EQUITY INVESTMENT	(374)	(611)	(1,700)	(1,171)
NET LOSS	$ (13,712)	$ (4,507)	$ (49,445)	$ (8,706)
LOSS PER SHARE:				
BASIC	$ (0.19)	$ (0.06)	$ (0.67)	$ (0.12)
DILUTED	$ (0.19)	$ (0.06)	$ (0.67)	$ (0.12)
SHARES USED IN COMPUTING LOSS PER SHARE:				
BASIC	73,004	74,583	74,131	74,330
DILUTED	73,004	74,583	74,131	74,330

See accompanying notes to the consolidated financial statements.

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2025	2024	2025	2024
NET LOSS	(13,712)	(4,507)	(49,445)	(8,706)
OTHER COMPREHENSIVE (LOSS) INCOME				
Currency translation adjustments	(2,802)	1,431	4,187	(2,259)
COMPREHENSIVE LOSS	$ (16,514)	$ (3,076)	$ (45,258)	$ (10,965)

See accompanying notes to the consolidated financial statements.

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

	For the Nine Months Ended September 30,	
	2025	**2024**
OPERATING ACTIVITIES:		
Net loss	$ (49,445)	$ (8,706)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities		
Stock-based compensation	8,687	9,178
Depreciation and amortization	7,789	8,380
Loss on impairments	—	4,392
Other non-cash amortization	(221)	(569)
Provision for credit losses	(176)	521
Unrealized foreign currency loss (gain)	294	(154)
Interest expense on finance leases	6	20
Loss on equity investment	1,700	1,171
Deferred income taxes	(86)	165
Gain on sale of fixed assets	(993)	(121)
Change in the estimated fair value of acquisition-related contingent consideration	1,587	—
Changes in assets and liabilities:		
Accounts receivable	(16)	12,658
Inventories	894	8,659
Prepaid expenses and other assets	(1,915)	2,622
Accounts payable	(1,733)	(3,431)
Deferred revenue	(1,085)	66
Accrued expenses and other liabilities	(5,314)	(7,586)
Net cash (used in) provided by operating activities	(40,027)	27,265
INVESTING ACTIVITIES:		
Purchases of short-term investments	—	(53,244)
Purchase of equity method investee	—	(30,000)
Proceeds from maturities and redemptions of short-term investments	—	53,052
Proceeds from sale of assets	888	—
Purchases of property and equipment	(3,275)	(3,341)
Net cash used in investing activities	(2,387)	(33,533)
FINANCING ACTIVITIES:		
Cash payments for lease liabilities	(43)	(746)
Proceeds from exercise of stock options	—	214
Repurchase of common stock	(10,001)	—
Payment of taxes related to net share settlement of equity awards	(1,786)	(3,533)
Net cash used in financing activities	(11,830)	(4,065)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	2,959	(1,503)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(51,285)	(11,836)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	267,763	290,407
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 216,478	$ 278,571
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for income taxes	$ 2,582	$ 1,637
Non-cash investing and financing activities		
Accrued property and equipment purchases	$ 372	$ 103

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

(all tabular amounts in thousands)

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 nine months ended September 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 $0.1 million was recorded in the statement of operations for the nine months ended September 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 September 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 September 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.

		September 30,	December 31,
	Level	2025	2024
Guaranteed investment certificates	1	$ 66,857	$ 66,584
Contingent consideration:	3		
Current portion		$ 17,232	$ —
Long-term portion		7,264	22,910
		$ 24,496	$ 22,910

Included in cash and cash equivalents at September 30, 2025 and December 31, 2024 was $66.9 million and $66.6 million, respectively, invested in guaranteed investment certificates.

Included in cash and cash equivalents at September 30, 2025 and December 31, 2024, was $122.4 million and $118.5 million, respectively, invested in government money market funds. These 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 the Company's Board of Directors. The assets of the plan are held in the name of the Company at a third-party financial institution. Separate accounts are maintained for each participant to reflect the amounts deferred by the participant and all earnings and losses on those deferred amounts. The assets of the plan are held in mutual funds and Company stock. The fair value of the plan assets as of September 30, 2025 and December 31, 2024 was $0.6 million and $0.7 million, respectively, and was calculated using the quoted market prices of the assets as of those dates. All investments in the plan are classified as trading securities and measured as Level 1 instruments. The fair value of plan assets is included in both current assets and other noncurrent assets with the same amounts 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 $1.6 million in the fair value of the Company's contingent consideration from date of acquisition to September 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 September 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 $26.6 million as of September 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 September 30, 2025 financial statements, the Company considered whether there were any triggering events that may indicate impairment in the investment in Sapphiros and concluded that no such triggers 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 $0.6 million and $(0.2) million for the three months ended September 30, 2025 and 2024, respectively.

Net foreign exchange gains (losses) resulting from foreign currency transactions for the nine months ended September 30, 2025 and 2024 were $(0.7) million and $0.1 million respectively.

Accumulated Other Comprehensive Loss

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

	Foreign Currency	Total
Balance at December 31, 2024	$ (24,360)	$ (24,360)
Other comprehensive gain	4,187	4,187
Balance at September 30, 2025	$ (20,173)	$ (20,173)

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 are (1) more likely than not of being sustained based on their technical merits, (2) effectively settled through examination, negotiation or litigation, or (3) settled through actual expiration of the relevant tax statures. The assessment of an uncertain tax position requires significant judgment.

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), Measurement of Credit Losses for Accounts Receivable and Contract Assets*. 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.

In July 2025, the FASB issued ASU No. 2025-05, *Financial Instruments—Credit Losses (Topic 326), Scope Application of Profits Interest and Similar Awards*. The purpose of this update was to address challenges encountered when applying the guidance in Topic 326, Financial Instruments—Credit Losses, to current accounts receivable and current contract assets arising from transactions accounted for under Topic 606, Revenue from Contracts with Customers 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 all business entities, the amendments in this ASU are effective for fiscal years beginning after December 15, 2025, and interim periods within those fiscal periods. The amendments are applied prospectively, and early adoption is permitted. Management does not expect an impact on the Company's consolidated financial statements.

In September 2025, the FASB issued ASU No. 2025-06, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40), Targeted Improvements to the Accounting for Internal-Use Software*. The purpose of this update was to modernize the accounting for software costs. For all business entities, the amendments in this ASU are effective for fiscal years beginning after December 15, 2027, and interim periods within those fiscal periods. The amendments can be applied prospectively, a modified transition or retrospectively. Early adoption is permitted as of the beginning of an annual reporting period. Management does not expect an impact on the Company's consolidated financial statements.

2. INVENTORIES:

	September 30, 2025	December 31, 2024
Raw materials	$ 15,039	$ 17,002
Work in process	685	420
Finished goods	17,677	16,775
	$ 33,401	$ 34,197

3. PROPERTY, PLANT, AND EQUIPMENT, NET:

	September 30, 2025	December 31, 2024
Land	$ 1,118	$ 1,118
Buildings and improvements	39,112	36,152
Machinery and equipment	57,337	51,015
Computer equipment and software	12,385	11,502
Furniture and fixtures	1,644	1,621
Construction in progress	2,317	9,615
	113,913	111,023
Accumulated depreciation	(73,118)	(65,918)
	$ 40,795	$ 45,105

4. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES:

	September 30, 2025	December 31, 2024
Payroll and related benefits	$ 7,385	$ 11,147
Professional fees	2,077	2,469
Sales tax payable	1,092	1,339
Other	2,115	5,224
	$ 12,669	$ 20,179

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 statement of operations are as follows:

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

As of September 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*. The charges for termination benefits included in the Company's consolidated statements of operations are as follows:

	For the Nine Months Ended September 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 September 30, 2025 the Company had $0.3 million accrued and had paid $1.4 million related to the reduction in workforce. No additional expenses were incurred during the nine months ended September 30, 2025. The Company expects this reduction in workforce to be completed by October 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. 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:

	For the Three Months Ended September 30, 2024
Cost of products and services sold	$ 7
Research and development	—
Sales and marketing	346
General and administrative	—
	$ 353

As of September 30, 2025 the Company had $0.2 million accrued and had paid $1.0 million related to the reduction in workforce. No additional expense was incurred during the nine months ended September 30, 2025. The Company expects this reduction in workforce to be completed by December 2025.

6. REVENUES:

Revenues by Product Line. The following table represents total net revenues by product line:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2025	2024	2025	2024
HIV	$ 11,141	$ 18,347	$ 38,439	$ 45,379
Sample Management Solutions [1]	10,306	12,806	29,271	36,237
HCV	2,604	3,228	11,063	10,962
Other product and services revenues [2]	1,196	1,196	2,963	2,623
COVID-19 [3]	89	2,155	578	44,222
Risk Assessment Testing [4]	—	1,911	1,866	6,265
Molecular Services	—	9	—	1,692
Net product and services revenues	$ 25,336	$ 39,652	$ 84,180	$ 147,380
Non-product and services revenues [5]	1,749	263	4,078	1,002
Net revenues	$ 27,085	$ 39,915	$ 88,258	$ 148,382

[1] Includes Genomics, Microbiome and Colli-Pee® product revenues.
[2] Includes Syphilis revenues.
[3] Includes COVID-19 Diagnostics and COVID-19 Sample Management Solutions revenues.
[4] Includes substance abuse testing product 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:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2025	2024	2025	2024
United States	$ 19,662	$ 25,353	$ 60,070	$ 115,055
Africa	4,875	11,376	19,023	23,446
Europe	1,300	2,126	5,064	5,892
Other regions	1,248	1,060	4,101	3,989
	$ 27,085	$ 39,915	$ 88,258	$ 148,382

Customer Concentrations. The following table represents customer concentration risk:

	For the Three Months Ended September 30,	For the Nine Months Ended September 30,
	2024	2024
Net Revenues		
Commercial customer [1]	11%	N/A
Commercial customer [1]	10%	N/A
Non-commercial customer	N/A	26%

	September 30,	December 31,
	2025	2024
Accounts Receivable		
Commercial customer	20%	10%

[1] Each commercial customer is different.

There were no customers that accounted for over 10% of the Company's consolidated net revenues during the three and nine months ended September 30, 2025.

Vendor concentrations. The Company currently purchases certain products and critical components of the Company's 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 the Company's 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 the Company's business, as well as the Company's financial condition and results of operations.

Deferred Revenue. The Company records deferred revenue when funds are received prior to the recognition of the associated revenue. Deferred revenue as of September 30, 2025 and December 31, 2024 was comprised of customer prepayments of $1.9 million and $3.0 million, respectively.

The following table represents deferred revenue recognized:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
Deferred Revenue Recognized	**2025**	**2024**	**2025**	**2024**
Accrued at beginning of year	$ 529	$ 171	$ 1,991	$ 1,365

7. INCOME TAXES:

The components of income tax expense are as follows:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2025	2024	2025	2024
Federal income tax expense	$ 3	$ —	$ 168	$ —
State income tax (benefit) expense	(612)	18	1,792	(209)
Foreign income tax expense (benefit)	656	660	(369)	1,250
	$ 47	$ 678	$ 1,591	$ 1,041

During the three months ended September 30, 2025 and 2024, the Company recorded income tax expense of $47.0 thousand and $0.7 million, respectively. The state income tax benefit for the three months ended September 30, 2025 is largely comprised of an adjustment made to the Company's liability for uncertain tax position for certain tax matters, including penalty and interest. During the nine months ended September 30, 2025 and 2024, the Company recorded income tax expense of $1.6 million and $1.0 million, respectively. The state income tax expense for the nine months ended September 30, 2025 is largely due to recording an uncertain tax position for certain tax matters, including penalty and interest. The decline in foreign taxes for the nine months ended September 30, 2025 is due to lower pretax earnings in 2025 as compared to 2024.

Income tax expense reflects taxes due to the taxing authorities and the tax effects of temporary differences between the basis of assets and liabilities recognized for financial reporting and tax purposes, and net operating loss and tax credit carryforwards. The significant components of the Company's total deferred tax asset as of September 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 September 30, 2025 and December 31, 2024.

Uncertain tax positions were approximately $1.9 million and $0.0 million, as of September 30, 2025 and December 31, 2024, respectively. 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 will result in changes to the Company’s income tax expense. The Company has evaluated the impacts of the OBBBA and determined changes in tax law will not 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 anti-dilutive. 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 September 30, 2025 and 2024, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 585 shares and 389 shares, respectively, were excluded from the computation of diluted loss per share.

For the nine months ended September 30, 2025 and 2024, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 605 shares and 999 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 3.3 million shares of its common stock under the Repurchase Program during the nine months ended September 30, 2025.

The reconciliation of the changes in stockholders' equity for the three and nine months ended September 30, 2025 and 2024 is as follows:

	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	73,735	$ —	$ 537,256	$ (17,371)	$ (139,164)	$ 380,721
Vesting of restricted stock and performance stock units	76	—	—	—	—	—
Purchase and retirement of common shares	(21)	—	(61)	—	—	(61)
Stock-based compensation	—	—	2,835	—	—	2,835
Repurchase of common stock	(1,525)	—	(5,001)	—	—	(5,001)
Net loss	—	—	—	—	(13,712)	(13,712)
Currency translation adjustments	—	—	—	(2,802)	—	(2,802)
Balance at September 30, 2025	72,265	$ —	$ 535,029	$ (20,173)	$ (152,876)	$ 361,980

	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
Vesting of restricted stock and performance stock units	44	—	—	—	—	—
Purchase and retirement of common shares	(19)	—	(87)	—	—	(87)
Stock-based compensation	—	—	2,888	—	—	2,888
Net loss	—	—	—	—	(4,507)	(4,507)
Currency translation adjustments	—	—	—	1,431	—	1,431
Balance at September 30, 2024	74,593	$ —	$ 535,402	$ (17,200)	$ (92,637)	$ 425,565

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:

	September 30, 2025	December 31, 2024
United States	$ 37,424	$ 40,286
United Kingdom	10,532	12,849
Canada	4,868	5,468
Other regions	375	89
	$ 53,199	$ 58,692

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2025	2024	2025	2024
Net revenues	$ 27,085	$ 39,915	$ 88,258	$ 148,382
Cost of products and services sold [2]	15,313	22,845	51,028	82,558
Gross profit	11,772	17,070	37,230	65,824
Research and development [2]	10,106	5,623	31,110	19,960
Sales and marketing [2]	6,299	7,615	19,533	23,994
General and administrative [2]	11,081	9,831	37,859	33,310
Loss on impairments	—	—	—	4,392
Change in the estimated fair value of acquisition-related contingent consideration	376	—	1,587	—
Gain on sale of assets	—	—	(993)	—
Operating loss	(16,090)	(5,999)	(51,866)	(15,832)
Other income	154	95	138	335
Interest revenue	2,051	2,885	6,279	8,938
Other segment items [1]	594	(199)	(705)	65
Loss before income taxes	(13,291)	(3,218)	(46,154)	(6,494)
Income tax expense	47	678	1,591	1,041
Loss on equity investment	(374)	(611)	(1,700)	(1,171)
Net loss	$ (13,712)	$ (4,507)	$ (49,445)	$ (8,706)

[1] Includes interest expense and foreign currency gains (losses).
[2] The following tables represent additional significant segment expense categories:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2025	2024	2025	2024
Stock-based Compensation				
Cost of products and services sold	$ 208	$ 195	$ 584	$ 539
Research and development	282	159	764	689
Sales and marketing	213	317	648	887
General and administrative	2,132	2,217	6,691	7,063
	$ 2,835	$ 2,888	$ 8,687	$ 9,178

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2025	2024	2025	2024
Depreciation and Amortization				
Cost of products and services sold	$ 1,054	$ 1,934	$ 3,503	$ 4,988
Research and development	514	248	1,568	734
Sales and marketing	21	48	78	143
General and administrative	865	818	2,640	2,515
	$ 2,454	$ 3,048	$ 7,789	$ 8,380

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 in late 2025 or early 2026 for r. 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	$	28,349

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

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 has completed the fair value of the assets acquired and liabilities assumed.

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.

	For the Three Months Ended September 30,	For the Nine Months Ended September 30,
	2024	2024
Net revenues	$ 40,424	$ 149,462
Net loss	$ (12,472)	$ (36,675)

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, 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.

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 case is currently in the discovery phase and the schedule for any further proceedings is currently pending.

13. SUBSEQUENT EVENTS:

On November 5, 2025, the Company signed a definitive merger agreement (the "Agreement") with BioMedomics, Inc. (“BioMedomics”), pursuant to which BioMedomics will become a wholly-owned subsidiary of the Company. The closing of the foregoing transaction is subject to various customary conditions, and is expected to occur within the fourth quarter of 2025. The upfront purchase price is $4.0 million in cash, adjusted for certain transaction costs, indebtedness, holdback amounts and working capital adjustments. In addition, pursuant to the Agreement, the Company has agreed to pay certain contingent consideration based on achievement of defined revenue targets by December 31, 2031. Under certain circumstances, the original BioMedomics shareholders may opt to forgo a portion of the final revenue milestone, and instead choose either (i) different revenue milestones related to sales of certain products currently in development by BioMedomics (the “BM Pipeline Products”), or (ii) to share in a portion of the proceeds in the event that the Company enters into a disposition of any of the BM Pipeline Products on or prior to December 31, 2030.

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 did not contribute to revenues during the three months ended September 30, 2025. Sales of its risk assessment products contributed $1.9 million to revenues during the three months ended September 30, 2025 and 2024. Sales of its risk assessment products contributed $1.9 million and $6.3 million to revenues during the nine months ended September 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.

Acquisition of BioMedomics, Inc.

On November 5, 2025, the Company signed a definitive merger agreement (the "Agreement") with BioMedomics, Inc. ("BioMedomics"), pursuant to which BioMedomics will become a wholly-owned subsidiary of the Company. The closing of the foregoing transaction is subject to various customary conditions, and is expected to occur within the fourth quarter of 2025. The upfront purchase price is $4.0 million in cash, adjusted for certain transaction costs, indebtedness, holdback amounts and working capital adjustments. In addition, pursuant to the Agreement, the Company has agreed to pay certain contingent consideration based on achievement of defined revenue targets by December 31, 2031. Under certain circumstances, the original BioMedomics shareholders may opt to forgo a portion of the final revenue milestone, and instead choose either (i) different revenue milestones related to sales of certain products currently in development by BioMedomics (the "BM Pipeline Products"), or (ii) to share in a portion of the proceeds in the event that the Company enters into a disposition of any of the BM Pipeline Products on or prior to December 31, 2030.

Results of Operations

All dollar amounts in tables are presented in thousands.

For the three months ended September 30, 2025 compared to September 30, 2024.

CONSOLIDATED NET REVENUES

The table below shows total consolidated net revenues for the three months ended September 30, 2025 and 2024:

	For the Three Months Ended September 30,				
	Dollars			Percentage of Total Net Revenues	
	2025	2024	% Change	2025	2024
Diagnostics [1]	$ 14,499	$ 22,023	(34)%	54 %	55 %
Sample Management Solutions [2]	10,306	12,806	(20)	38	32
Other products and services [4]	442	748	(41)	2	2
COVID-19 Diagnostics	89	2,155	(96)	—	5
Risk Assessment Testing [3]	—	1,911	(100)	—	5
Molecular Services	—	9	(100)	—	—
Net product and services revenues	25,336	39,652	(36)	94	99
Non-product and services revenues [5]	1,749	263	565	6	1
Net revenues	$ 27,085	$ 39,915	(32)%	100 %	100 %

[1] Includes HIV, HCV, Syphilis, and SureQuick® product revenues.
[2] Includes Genomics, Microbiome, and Colli-Pee® product revenues.
[3] Includes COVID-19 Sample Management Solutions product revenues.
[4] Includes substance abuse testing product revenues.
[5] Includes funded research and development contracts, royalty income and grant revenues.

Product and Services Revenues

Consolidated net revenues decreased 32% to $27.1 million for the three months ended September 30, 2025 from $39.9 million for the three months ended September 30, 2024.

Sales of the Company's Diagnostics products decreased 34% to $14.5 million for the three months ended September 30, 2025 from $22.0 million for the three months ended September 30, 2024. This decrease in revenues is largely due to lower international HIV revenues driven by reduced funding and customer ordering patterns. Sales of domestic HIV also declined driven by reduced funding and due to a decrease in orders under the Together Take Me Home program.

Sample Management Solutions revenues decreased 20% to $10.3 million for the three months ended September 30, 2025 from $12.8 million for the three months ended September 30, 2024. Sales of the Company's genomics products are being impacted by a large customer's bankruptcy proceedings.

Risk Assessment revenue decreased 100% to nil for the three months ended September 30, 2025 from $1.9 million for the three months ended September 30, 2024. The Company discontinued this line of business at the end of 2024 and business wound down in early 2025.

COVID-19 Diagnostics revenues decreased 96% to $0.09 million for the three months ended September 30, 2025 compared to $2.2 million for the three months ended September 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.

Non-Product and Services Revenues

Non-product and services revenues increased 565% to $1.7 million for the three months ended September 30, 2025 from $0.3 million for the three months ended September 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 as well as an increase in funded R&D under other BARDA contracts.

CONSOLIDATED OPERATING RESULTS

Consolidated gross profit margin increased to 43.5% for the three months ended September 30, 2025 compared to 42.8% for the three months ended September 30, 2024. The largest drivers of the margin increase were an improved product mix of higher margin product sales and higher non-product revenues which contribute 100% to gross margin. Offsetting these increases in gross margin was lower manufacturing absorption as a result of lower sales volume and higher scrap expense in the quarter.

Consolidated operating loss for the three months ended September 30, 2025 was $16.1 million compared to a $6.0 million operating loss reported for the three months ended September 30, 2024. The higher operating loss reported in the third quarter of 2025 was largely a result of lower revenues coupled with an increased spend on clinical trials.

Research and development expenses increased 80% to $10.1 million for the three months ended September 30, 2025 from $5.6 million for the three months ended September 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 operational expense layered in from the acquired Sherlock companies.

Sales and marketing expenses decreased 17% to $6.3 million for the three months ended September 30, 2025 from $7.6 million for the three months ended September 30, 2024 due to lower employee costs as a result of reduced headcount from reduction in force initiatives taken in 2024.

General and administrative expenses increased 13% to $11.1 million for the three months ended September 30, 2025 from $9.8 million for the three months ended September 30, 2024 largely due an increase in legal fees and additional general and administrative costs incurred from the newly acquired Sherlock companies.

During the three months ended September 30, 2025, the Company recorded a non-cash adjustment of $0.4 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 was no comparable amount in the third quarter of 2024.

All of the above contributed to the Company's operating loss of $16.1 million for the three months ended September 30, 2025, which included non-cash charges of $2.8 million for stock-based compensation, $2.5 million for depreciation and amortization, and $0.4 million for the change in the estimated fair value of acquisition-related contingent consideration. The Company's operating loss of $6.0 million for the three months ended September 30, 2024 included non-cash charges of $2.9 million for stock-based compensation, and $3.0 million for depreciation and amortization.

CONSOLIDATED INCOME TAXES

The Company continues to believe the full valuation allowance established against its total U.S. deferred tax asset is appropriate as the facts and circumstances necessitating the allowance have not changed. For the three months ended September 30, 2025 and 2024, the Company recorded income tax expense of $47.0 thousand and $0.7 million, respectively. The decrease in the income tax expense is largely due to lower pre-tax earnings in both state and foreign jurisdictions.

Results of Operations

For the nine months ended September 30, 2025 compared to September 30, 2024.

CONSOLIDATED NET REVENUES

The table below shows an outline of total consolidated net revenues for the nine months ended September 30, 2025 and 2024:

	For the Nine Months Ended September 30,				
	Dollars			Percentage of Total Net Revenues	
	2025	2024	% Change	2025	2024
Diagnostics [1]	$ 51,410	$ 57,162	(10)%	58 %	39 %
Sample Management Solutions [2]	29,271	36,237	(19)	33	24
Risk Assessment Testing [3]	1,866	6,265	(70)	2	4
Other products and services [4]	1,059	1,838	(42)	1	1
COVID-19 Diagnostics	574	44,186	(99)	1	30
Molecular Services	—	1,692	(100)	—	1
Net product and services revenues	84,180	147,380	(43)	95	99
Non-product and services revenues [5]	4,078	1,002	307	5	1
Net revenues	$ 88,258	$ 148,382	(41)%	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 41% to $88.3 million for the nine months ended September 30, 2025 from $148.4 million for the nine months ended September 30, 2024.

Sales of the Company's Diagnostics products decreased 10% to $51.4 million for the nine months ended September 30, 2025 from $57.2 million for the nine months ended September 30, 2024. This decrease in revenues is largely due to lower international HIV revenues primarily driven by a decrease in funding and customer ordering patterns in Africa and Asia. Lower sales of the Company's HIV domestic product due to a decrease in overall funding impacting HIV programs also contributed to the decline in diagnostic revenues. Offsetting these decreases in revenues is an increase in Syphilis revenue resulting from the launch in the second quarter of 2024.

Sample Management Solutions revenues decreased by 19% to $29.3 million for the nine months ended September 30, 2025 compared to $36.2 million for the nine months ended September 30, 2024. Sales of the Company's Sample Management Solutions are being impacted by a large customer's bankruptcy.

COVID-19 Diagnostics revenues decreased 99% to $0.6 million for the nine months ended September 30, 2025 from $44.2 million for the nine months ended September 30, 2024 due to decreased sales of the Company's InteliSwab® tests through its U.S. government procurement contracts. The Company experienced a significant decline in COVID-19 revenues during 2024 due to the fulfillment of these contracts and lower overall demand for COVID-19 testing, and expects further declines in 2025.

Risk Assessment testing revenues decreased 70% to $1.9 million for the nine months ended September 30, 2025 from $6.3 million for the nine months ended September 30, 2024. The Company discontinued this line of business at the end of 2024 and the business wound down in early 2025.

Molecular Services revenues, which were largely derived from the Company's microbiome molecular sequencing services, were nil for the nine months ended September 30, 2025 compared to $1.7 million for the nine months ended September 30, 2024. The decrease in services revenues was due to the decision to exit this line of business.

Non-Product and Services Revenues

Non-product and services revenues increased 307% to $4.1 million for the nine months ended September 30, 2025 from $1.0 million for the nine months ended September 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 as well as an increase in funded R&D under other BARDA contracts.

CONSOLIDATED OPERATING RESULTS

Consolidated gross profit margin decreased to 42.2% for the nine months ended September 30, 2025 from 44.4% for the nine months ended September 30, 2024. The largest driver of the margin decline was a negative product mix driven by lower InteliSwab® sales that generate higher gross margins and lower genomics sales that also generate higher gross 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.

Consolidated operating loss for the nine months ended September 30, 2025 was $51.9 million, compared to a $15.8 million operating loss reported for the nine months ended September 30, 2024. Results for the nine months ended September 30, 2025 were negatively impacted by the decrease in revenues, lower gross margins earned on the revenues and by higher operating expenses. Results for the nine months ended September 30, 2025 included change in the estimated fair value of acquisition-related contingent consideration of $1.6 million offset by gain on sale of assets of $1.0 million. Results for the nine months ended September 30, 2024 included impairment charges of $4.4 million.

Research and development expenses increased 56% to $31.1 million for the nine months ended September 30, 2025 from $20.0 million for the nine months ended September 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 operational expense layered in from the acquired Sherlock companies.

Sales and marketing expenses decreased 19% to $19.5 million for the nine months ended September 30, 2025 from $24.0 million for the nine months ended September 30, 2024 primarily due to decreased employee costs associated with a reduction in headcount, and lower advertising and bad debt expense.

General and administrative expenses increased 14% to $37.9 million for the nine months ended September 30, 2025 from $33.3 million for the nine months ended September 30, 2024 largely due to higher legal fees relating to the NowDx litigation (discussed further in Note 12, Commitments and Contingencies, to the consolidated financial statements included herein) and costs associated with the Sherlock acquisition. Also contributing to the higher expenses were increased severance, accounting fees, and operating expenses associated with the Company's acquisition of Sherlock in December 2024.

All of the above contributed to the Company's operating loss of $51.9 million for the nine months ended September 30, 2025, which included non-cash charges of $8.7 million for stock-based compensation, $7.8 million for depreciation and amortization, and $1.6 million for change in the estimated fair value of acquisition-related contingent consideration. The Company's operating loss of $15.8 million for the nine months ended September 30, 2024 included a non-cash charge of $9.2 million for stock-based compensation, $8.4 million for depreciation and amortization, and impairment charges of $4.4 million.

CONSOLIDATED OTHER INCOME

Other income for the nine months ended September 30, 2025 was $5.7 million compared to $9.3 million for the nine months ended September 30, 2024. The decrease in other income is primarily due to lower interest income and foreign currency losses in 2025 versus foreign currency gains in 2024.

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. Although the Company has achieved U.S. cumulative pre-tax earnings based on a rolling three year window the Company has not achieved a level of sustained profitability that would, in its judgment, support the release of the valuation allowance. For the nine months ended September 30, 2025 and 2024, the Company recorded income tax expense of $1.6 million and $1.0 million, respectively. The increase in income tax expense is largely due to recording an uncertain tax position for certain US tax matters, including penalties and interest in 2025 offset by lower pre-tax earnings in foreign jurisdictions in 2025 as compared to 2024.

Liquidity and Capital Resources

	September 30, 2025	December 31, 2024
	(in thousands)	
Cash and cash equivalents	$ 216,478	$ 267,763
Working capital	242,763	299,737

The Company's cash and cash equivalents decreased to $216.5 million at September 30, 2025 from $267.8 million at December 31, 2024. $84.7 million, or 39%, of the Company's $216.5 million in cash, cash equivalents and available-for-sale securities is held by DNAG, the Company's Canadian subsidiary.

The Company's working capital decreased to $242.8 million at September 30, 2025 from $299.7 million at December 31, 2024. Working capital is primarily a function of sales, purchase volumes, inventory requirements, and vendor payment terms.

Analysis of the Company's Cash Flows

Operating Activities

During the nine months ended September 30, 2025, net cash used in operating activities was $40.0 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 $49.4 million included non-cash charges of stock-based compensation expense of $8.7 million and depreciation and amortization expense of $7.8 million, a loss on equity investment of $1.7 million, change in estimated fair value of acquisition-related contingent consideration of $1.6 million and other non-cash charges aggregating to $1.2 million.

Cash used by the Company's working capital accounts included a decrease in accrued expenses and other liabilities of $5.3 million largely consisting of the payment of year-end bonuses in March 2025, an increase in prepaid expenses and other assets of $1.9 million as the Company is prepaying for clinical trials, a decrease of $1.7 million in accounts payable, and a decrease in deferred revenue of $1.1 million as work on grant projects is completed and earned. Offsetting these uses of cash is a decrease in inventory of $0.9 million as the Company experienced a decline in sales.

Investing Activities

Net cash used in investing activities was $2.4 million for the nine months ended September 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 $11.8 million for the nine months ended September 30, 2025, which was largely comprised of $10.0 million to repurchase common stock and $1.8 million used for the repurchase of common stock to satisfy withholding taxes related to the vesting of restricted stock awarded to the Company's employees.

Resources

The Company's contractual obligations are included in Note 12 of its consolidated financial statements. 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.

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 nine months ended September 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 September 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 September 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 September 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 case is currently in the discovery phase and the schedule for any further proceedings is currently pending.

Item 1A. RISK FACTORS

There have been no material changes to the risk factors disclosed in Item 1A, entitled “Risk Factors,” in the Company's Annual Report on Form 10-K for the year ended December 31, 2024 filed with the SEC on March 7, 2025 and the Company’s Quarterly Reports on Form 10-Q for the quarter ended March 31, 2025 and June 30, 2025 filed with the SEC on May 7, 2025 and on August 6, 2025, respectively, other than as set forth below.

Supplementing the following risk factor:

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

Recently, beginning on October 1, 2025, the U.S. government shut down, during which time certain regulatory agencies, such as the FDA and the SEC, have furloughed critical employees and stopped critical activities. Additionally, on October 10, 2025, the U.S. government implemented substantial layoffs and workforce reductions in connection with the ongoing federal government shutdown, which has resulted in the suspension or delay of various government-funded programs. While we continue to monitor developments, there is no assurance that affected government employees or contractors will be reinstated and that government-funded programs will resume. Without appropriation of additional funding to federal agencies, our business operations related to our product development for the U.S. market could be impacted. Inadequate funding for the FDA, the SEC and other government agencies, including from government shut downs, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. Any such reduction in personnel may result in longer review times by the FDA, the SEC and other agencies.

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

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

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]
July 1, 2025 - July 31, 2025	620,831 [2]	$ 3.21	613,514	$ 33,000,000
August 1, 2025 - August 31, 2025	347,684 [2]	$ 3.10	335,160	$ 32,000,000
September 1, 2025 - September 30, 2025	576,822 [2]	$ 3.29	575,750	$ 30,000,000
	1,545,337		1,524,424	

(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

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 September 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 (incorporated by reference to Exhibit 3.2 of the Company's Quarterly Report on Form 10-Q filed on August 6, 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.

/s/ Kenneth J. McGrath

Date: November 5, 2025

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

/s/Michele M. Anthony

Date: November 5, 2025

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

Exhibit 31.1

Certification

I, Carrie Eglinton Manner, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 5, 2025

/s/ Carrie Eglinton Manner

Carrie Eglinton Manner

President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification

I, Kenneth J. McGrath, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 5, 2025

/s/ Kenneth J. McGrath

Kenneth J. McGrath

Chief Financial Officer

(Principal Financial Officer)

Exhibit 32.1

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

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

November 5, 2025

Exhibit 32.2

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

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

November 5, 2025