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

FORM 10-Q/A

(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, 2026.

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 November 2, 2026, the registrant had 69,047,266 shares of common stock, $0.000001 par value per share, outstanding.

EXPLANATORY NOTE

OraSure Technologies, Inc. (the "Company") is filing this Amendment No. 1 on Form 10-Q/A (this "Amendment") to amend its Quarterly Report on Form 10-Q for the quarter ended September 30, 2026, filed with the Securities and Exchange Commission on November 9, 2026 (the "Original Report").

The sole purpose of this Amendment is to correct an inadvertent error in the XBRL Interactive Data Tables Exhibits that were initially filed with the Original Report. Such exhibits to the Original Report erroneously included references to a prospective transaction by the Company, which was included due to an administrative error. This Amendment removes those references. The correction does not affect the financial statements or narrative disclosures contained in the Original Report.

Except as described above, this Amendment does not amend, update or modify any disclosure in the Original Report.

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 develop, commercialize, market and sell, its products and services, whether through its internal direct sales force, distributors or third parties;
- The Company's ability to obtain and comply with necessary regulatory approvals for new products or new indications or applications for existing products, including timing and associated costs;
- 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;
- Changes in relationships with strategic partners or other parties, including disputes or disagreements and reliance on such parties 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;
- The Company's ability to achieve its financial and strategic objectives, including increasing its revenues and gross margins, and its 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;
- Changes in market acceptance of the Company's 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 availability of raw materials and the Company's reliance on sole supply sources for critical products and components;
- The impact of contracting with the U.S. government on the Company's business;
- The Company's estimates regarding revenues, expenses, cash flows, capital requirements and needs for additional financing, and the availability and cost of financing;
- The ability to utilize net operating loss carryforwards or other deferred tax assets;

- Volatility of the Company's stock price;
- Uncertainty relating to patent protection, potential patent infringement claims, the availability of licenses to patents or other technology;
- Costs of litigation relating to intellectual property, product liability and other types of litigation;
- The impact of changes in international funding sources and testing algorithms on international sales;
- Adverse movements in foreign currency exchange rates and interest rates;
- The Company's ability to attract and retain qualified personnel;
- Changes in international, federal or state laws and regulations; and
- The impact of geopolitical and economic conditions on the Company's business.

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, 2025, filed with the Securities and Exchange Commission (the “SEC”) on March 9, 2026, 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.

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Item 1. FINANCIAL STATEMENTS

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

	September 30, 2026	December 31, 2025
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 148,238	$ 199,278
Accounts receivable, net of allowance for doubtful accounts of $523 and $188	30,422	22,203
Inventories	30,420	31,060
Prepaid expenses	3,020	5,221
Income tax receivable	1,395	1,733
Other current assets	1,800	2,413
Total current assets	215,295	261,908
Noncurrent Assets:		
Property, plant and equipment, net of accumulated depreciation	36,511	39,179
Operating right-of-use assets, net	10,757	11,996
Finance right-of-use assets, net	159	146
Intangible assets, net of accumulated amortization of $26,732 and $27,180	18,758	19,046
Goodwill	42,741	43,363
Investment in equity method investee	23,755	25,956
Deferred tax asset	136	271
Other noncurrent assets	1,354	1,303
Total noncurrent assets	134,171	141,260
TOTAL ASSETS	**$ 349,466**	**$ 403,168**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 7,773	$ 6,521
Deferred revenue	743	1,518
Accrued expenses and other current liabilities	14,481	11,149
Finance lease liability	85	63
Operating lease liability	2,022	2,164
Acquisition-related contingent consideration obligation	—	18,380
Total current liabilities	25,104	39,795
Noncurrent Liabilities:		
Finance lease liability	100	100
Operating lease liability	9,440	10,870
Acquisition-related contingent consideration obligation	5,233	9,333
Other noncurrent liabilities	2,456	2,243
Total noncurrent liabilities	17,229	22,546
TOTAL LIABILITIES	42,333	62,341
Commitments and contingencies (Note 12)		
STOCKHOLDERS' EQUITY		
Preferred stock, par value $0.000001, 25,000 shares authorized, none issued	—	—
Common stock, par value $0.000001, 120,000 shares authorized, 69,036 and 70,391 shares issued and outstanding	—	—
Additional paid-in capital	530,230	531,393
Accumulated other comprehensive loss	(21,713)	(18,404)
Accumulated deficit	(201,384)	(172,162)
Total stockholders' equity	307,133	340,827
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 349,466**	**$ 403,168**

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,	
	2026	2025	2026	2025
NET REVENUES:				
Products and services	$ 30,092	$ 25,336	$ 86,192	$ 84,180
Other	815	1,749	3,279	4,078
	30,907	27,085	89,471	88,258
COST OF PRODUCTS AND SERVICES SOLD	16,938	15,313	50,381	51,028
Gross profit	13,969	11,772	39,090	37,230
OPERATING EXPENSES:				
Research and development	7,629	10,106	30,720	31,110
Sales and marketing	6,557	6,299	19,931	19,533
General and administrative	11,992	11,081	40,977	37,859
Change in the estimated fair value of acquisition-related contingent consideration	—	376	(22,480)	1,587
Loss (gain) on sale of assets	746	—	726	(993)
	26,924	27,862	69,874	89,096
Operating loss	(12,955)	(16,090)	(30,784)	(51,866)
OTHER INCOME	1,169	2,799	4,094	5,712
Loss before income taxes and equity investment	(11,786)	(13,291)	(26,690)	(46,154)
INCOME TAX EXPENSE	708	47	331	1,591
LOSS BEFORE EQUITY INVESTMENT	(12,494)	(13,338)	(27,021)	(47,745)
LOSS ON EQUITY INVESTMENT	(600)	(374)	(2,201)	(1,700)
NET LOSS	$ (13,094)	$ (13,712)	$ (29,222)	$ (49,445)
LOSS PER SHARE				
BASIC	$ (0.19)	$ (0.19)	$ (0.42)	$ (0.67)
DILUTED	$ (0.19)	$ (0.19)	$ (0.42)	$ (0.67)
SHARES USED IN COMPUTING LOSS PER SHARE:				
BASIC	69,001	73,004	69,224	74,131
DILUTED	69,001	73,004	69,224	74,131

See accompanying notes to the consolidated financial statements.

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2026	2025	2026	2025
NET LOSS	$ (13,094)	$ (13,712)	$ (29,222)	$ (49,445)
OTHER COMPREHENSIVE (LOSS) INCOME				
Currency translation adjustments	184	(2,802)	(3,309)	4,187
COMPREHENSIVE LOSS	$ (12,910)	$ (16,514)	$ (32,531)	$ (45,258)

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,	
	2026	**2025**
OPERATING ACTIVITIES:		
Net loss	$ (29,222)	$ (49,445)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation	7,333	8,687
Depreciation and amortization	6,911	7,789
Other non-cash amortization	(259)	(221)
Provision for credit losses	367	(176)
Unrealized foreign currency loss	206	294
Interest expense on finance leases	9	6
Loss on equity investment	2,201	1,700
Deferred income taxes	186	(86)
Gain (loss) on sale of fixed assets	726	(993)
Change in the estimated fair value of acquisition-related contingent consideration	(22,480)	1,587
Changes in assets and liabilities:		
Accounts receivable	(8,653)	(16)
Inventories	546	894
Prepaid expenses and other assets	2,973	(1,915)
Accounts payable	1,586	(1,733)
Deferred revenue	(772)	(1,085)
Accrued expenses and other liabilities	3,654	(5,314)
Net cash used in operating activities	(34,688)	(40,027)
INVESTING ACTIVITIES:		
Proceeds from sale of assets	20	888
Purchases of property and equipment	(5,015)	(3,275)
Net cash used in investing activities	(4,995)	(2,387)
FINANCING ACTIVITIES:		
Cash payments for lease liabilities	(68)	(43)
Proceeds from exercise of stock options	47	—
Repurchase of common stock	(7,000)	(10,001)
Payment of taxes related to net share settlement of equity awards	(1,543)	(1,786)
Net cash used in financing activities	(8,564)	(11,830)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	(2,793)	2,959
NET DECREASE IN CASH AND CASH EQUIVALENTS	(51,040)	(51,285)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	199,278	267,763
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 148,238	$ 216,478
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
(Refund received) cash paid for income taxes	$ (43)	$ 2,582
Non-cash investing and financing activities		
Accrued property and equipment purchases	$ 160	$ 372

See accompanying notes to the consolidated financial statements.

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”), Sherlock Biosciences, Inc. and its wholly-owned subsidiary Sense Biodetection Limited (collectively, "Sherlock"), and BioMedomics, Inc. ("BioMedomics"). Novosanis NV ("Novosanis") was a subsidiary of OraSure until it was legally dissolved in June 2025. 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, 2025. Results of operations for the three and nine months ended September 30, 2026 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, 2025 that have had a material impact on the consolidated financial statements and related notes except as discussed herein.

Cash Equivalents & Short-Term Investments

The Company considers all its investments in debt securities to be available-for-sale securities. These securities consist of guaranteed investment certificates purchased with maturities greater than ninety days and are considered short-term investments. 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 maintains cash balances in the United States in excess of the federally insured limits. The Company periodically evaluates financial institutions and believes the risk of loss to be remote due to this evaluation.

Fair Value of Financial Instruments

As of September 30, 2026 and December 31, 2025, 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. The following table provides a summary of the recognized assets and liabilities that are measured at fair value on a recurring basis:

		September 30,	December 31,
	Level	2026	2025
Guaranteed investment certificates	1	$ 12,808	$ 13,114
Trading securities	1	479	543
Contingent consideration:	3		
Current portion		$ —	$ 18,380
Long-term portion		5,233	9,333
		$ 5,233	$ 27,713

Included in cash and cash equivalents at September 30, 2026 and December 31, 2025 was $12.8 million and $13.1 million, respectively, invested in guaranteed investment certificates.

Included in cash and cash equivalents at September 30, 2026 and December 31, 2025, was $50.1 million and $68.4 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. The Company paused the plan in January 2026 and is no longer allowing new participants to enter the plan. 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, 2026 and December 31, 2025 was $0.5 million, and was calculated using the quoted market prices of the assets as of those dates. All investments in the plan are classified as trading securities and measured as Level 1 instruments. The fair value of plan assets is included in both current assets and other noncurrent assets with the same amounts included in accrued expenses and other noncurrent liabilities in the accompanying consolidated balance sheets.

Contingent Consideration

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 three different tranches: milestone payments, royalty payments, and earnout payments. The significant quantitative unobservable inputs for the milestone payments are the discount rate and probability of achieving regulatory approval milestones. In December 2025, the Company submitted a premarket notification, or 510(k), to the U.S. Food and Drug Administration (the "FDA") for clearance of its rapid molecular self-test for chlamydia trachomatis and Neisseria gonorrhoeae ("CT/NG") on the Sherlock platform. Following constructive interactions with the FDA, the Company is updating its submission plan for the CT/NG test on the Sherlock platform to incorporate feedback received from the agency. As part of this process, in July 2026, the Company elected to withdraw its current submission and plans to pursue a future submission. Due to this withdrawal, the Company has concluded that it will not obtain FDA clearance by December 31, 2026 as outlined in the terms of the merger agreement. Accordingly, the Company will not be obligated to pay the milestone contingent payments and the milestone contingent consideration liability was reduced to zero. Furthermore, as a result of the delay in the commercialization of the CT/NG product, the royalty based contingent consideration liability was reduced to reflect the delay in recognizing revenue from the sale of the CT/NG product and increase in discount rate associated with the cash flows. During the three and nine months ended September 30, 2026, to reflect these changes in these liabilities, a decrease in the estimated fair value of acquisition-related contingent consideration of $0 and $22.5 million, respectively, was recorded on the Company's consolidated statement of operations.

The fair value methodology for royalty payments is based on a discounted cash flow model. The significant quantitative unobservable inputs include internally developed future expected cash flows, a discount rate and the 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 and development intangible asset.

The fair value methodology for earnout payments is based on a Monte Carlo model. Significant quantitative unobservable inputs are future expected cash flows, discount rate and volatility rate.

There has been a net decrease of $17.9 million in the fair value of the Company's contingent consideration from date of acquisition to September 30, 2026 primarily due to the release of the milestone liability and a reduction in royalty liability as described above.

	Fair Value
Balance at December 31, 2025	$ 27,713
Additions	—
Change in fair value	(22,480)
Balance at September 30, 2026	$ 5,233

The fair value analysis as of September 30, 2026, utilized a 20.4% discount rate.

Indefinite-Lived Intangible Asset

Indefinite-lived intangible assets are not amortized but rather tested annually for impairment or more frequently if the Company believes that indicators of impairment exist. Current generally accepted accounting principles permit the Company to make a qualitative evaluation about the likelihood of indefinite-lived intangible asset impairment. If the Company concludes that it is more likely than not that the carrying value of an indefinite-lived intangible asset is greater than its fair value, then the Company would be required to perform a quantitative analysis. The Company would recognize an impairment charge for the amount by which the carrying amount exceeds the fair value.

In December 2025, the Company submitted a 510(k) to the FDA for clearance of its rapid molecular self-test for CT/NG. Following constructive interactions with the FDA, the Company is updating its submission plan for the CT/NG test on the Sherlock platform to incorporate feedback received from the agency. As part of this process, in July 2026, the Company elected to withdraw its current submission and plans to pursue a future submission. This withdrawal was considered an indicator of impairment, which necessitated review of the facts and circumstances underlying the value of the in-process research and development ("IPR&D") technology intangible asset as of June 30, 2026. The Company performed a quantitative indefinite-lived intangible asset impairment test on the IPR&D technology which concluded that the carrying value of the Company's IPR&D technology was below its fair value indicating there was no impairment as of June 30,

2026. The carrying value was 6% below its fair value. There were no triggering events identified for the three months ended September 30, 2026.

As of September 30, 2026, the IPR&D technology intangible asset was $17.0 million. The impairment analysis used an income approach. 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 revenue and cash flows assumes CT/NG receives regulatory authorization and market competition of future products is low. The revenues assume market growth will accelerate each year. If there are delays to attaining regulatory approval or successfully launching CT/NG, this could have a negative outcome on the indefinite-lived intangible asset impairment analysis.

The below table illustrates the discount rate sensitivity to the fair value of the IPR&D technology intangible asset when performing the impairment analysis as of June 30, 2026. In the IPR&D technology intangible asset impairment analysis as of June 30, 2026, the impairment analysis utilized a 40% discount rate.

		Discount Rate		
38.0%	39.0%	40.0%	41.0%	42.0%
$22,000	$20,000	$18,000	$17,000	$15,000

Equity Method Investee

In January 2024, the Company led 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, 2026, 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 value of the investment in Sapphiros of $23.8 million as of September 30, 2026 is included in the investment in equity method investee line of the Company's balance sheet. 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, 2026 financial statements, the Company evaluated the investment in Sapphiros for impairment and concluded there was no such impairment. The Company's investment in Sapphiros was valued at $26.0 million as of December 31, 2025.

Related Party

The Company loaned Sapphiros $0.3 million during the year ended December 31, 2025. The loan plus interest is due in December 2026. During the year ended December 31, 2025, the Company entered into an agreement with Sapphiros to assist in the development of certain products for Sapphiros. A total of $1.9 thousand and $0.2 million of products and services revenue was recognized from this agreement for the three and nine months ended September 30, 2026. No equivalent amounts were recognized for the three and nine months ended September 30, 2025.

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. The Company assesses 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 statutes. The assessment of an uncertain tax position requires significant judgment.

Foreign Currency Transactions

Net foreign exchange gains resulting from foreign currency transactions that are included in other income in the Company's consolidated statements of operations were $33.0 thousand and $0.6 million for the three months ended September 30, 2026 and 2025, respectively.

Net foreign exchange gains (losses) resulting from foreign currency transactions for the nine months ended September 30, 2026 and 2025 were $0.1 million and $(0.7) million respectively.

Accumulated Other Comprehensive Loss

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

	Foreign Currency	Total
Balance at December 31, 2025	$ (18,404)	$ (18,404)
Other comprehensive loss	(3,309)	(3,309)
Balance at September 30, 2026	$ (21,713)	$ (21,713)

Recent Accounting Pronouncements

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 July 2025, the FASB issued ASU No. 2025-05, *Financial Instruments—Credit Losses (Topic 326), Measurement of Credit Losses for Accounts Receivable and Contract Assets*. 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*. 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 a material 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 a material impact on the Company's consolidated financial statements.

In December 2025, the FASB issued ASU No. 2025-10, *Government Grants (Topic 832), Accounting for Government Grants Received by Business Entities*. The purpose of this update was to improve US GAAP by establishing authoritative guidance on the accounting for government grants received by business entities. For public business entities, the amendments in this ASU are effective for annual reporting periods beginning after December 15, 2028, and interim reporting periods within those annual reporting periods. Early adoption is permitted in both interim and annual reporting periods in which financial statements have not yet been issued or made available for issuance. The amendments can be applied under a modified prospective approach, a modified retrospective approach, or a retrospective approach. Management is evaluating the impact on the Company's consolidated financial statements.

In December 2025, the FASB issued ASU No. 2025-11, *Interim Reporting (Topic 270), Narrow-Scope Improvements*. The purpose of this update was to improve the navigability of the required interim disclosures and clarifying when that guidance is applicable. The update also provides additional guidance on what disclosures should be provided in interim periods and adds a principal that requires entities to disclose events since the end of the last annual reporting period that have a material impact on the entity. For public business entities, the amendments in this ASU are effective for interim reporting periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted. The amendments in this update can be applied either prospectively 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.

2. INVENTORIES:

	September 30, 2026	December 31, 2025
Raw materials	$ 15,950	$ 14,831
Work in process	831	56
Semi-finished goods	2,939	1,965
Finished goods	10,700	14,208
	$ 30,420	$ 31,060

3. PROPERTY, PLANT, AND EQUIPMENT, NET:

	September 30, 2026	December 31, 2025
Land	$ 1,118	$ 1,118
Buildings and improvements	38,333	39,071
Machinery and equipment	44,236	46,202
Computer equipment and software	11,888	11,101
Furniture and fixtures	1,566	1,632
Construction in progress	6,019	2,931
	103,160	102,055
Accumulated depreciation	(66,649)	(62,876)
	$ 36,511	$ 39,179

4. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES:

	September 30, 2026	December 31, 2025
Payroll and related benefits	$ 8,944	$ 5,255
Professional fees	2,958	1,938
Sales tax payable	1,092	1,152
Other	1,487	2,804
	$ 14,481	$ 11,149

5. TERMINATION BENEFITS:

Q2 2024 Reduction in Workforce

During the second quarter of 2024, the Company executed a 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.

As of March 31, 2026 the Company had paid the full $1.7 million related to the reduction in workforce. This reduction in workforce was completed by March 31, 2026 and no additional charges were incurred during nine months ended September 30, 2026.

Q3 2024 Reduction in Workforce

During the third quarter of 2024, the Company executed a reduction in workforce 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.

As of September 30, 2026, the Company had $2.7 thousand accrued and had paid $1.2 million related to this reduction in workforce. No additional charges were incurred during the nine months ended September 30, 2026. The Company expects this reduction in workforce to be completed by October 2026.

Q1 2026 Reduction in Workforce

During the first quarter of 2026, the Company executed a reduction in workforce to better align the Company's cost structure. The charges for termination benefits included in the Company's consolidated statements of operations are as follows:

	For the Nine Months Ended September 30, 2026
Cost of products and services sold	$ 65
Research and development	264
Sales and marketing	260
General and administrative	680
	$ 1,269

As of September 30, 2026, the Company had $0.1 million accrued and had paid $1.1 million related to the reduction in workforce. No additional charges were incurred during the nine months ended September 30, 2026. The Company expects this reduction in workforce to be completed by February 2027.

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,	
	2026	2025	2026	2025
HIV	$ 12,116	$ 11,141	$ 39,305	$ 38,439
Sample Management Solutions [1]	12,498	10,306	31,431	29,271
HCV	3,221	2,604	9,277	11,063
Other products and services revenues [2]	2,235	1,196	6,138	2,963
COVID-19 [3]	22	89	41	578
Risk Assessment Testing [4]	—	—	—	1,866
Net product and services revenues	30,092	25,336	86,192	84,180
Non-product and services revenues [5]	815	1,749	3,279	4,078
Net revenues	$ 30,907	$ 27,085	$ 89,471	$ 88,258

[1] Includes Genomics, Microbiome and Colli-Pee® product revenues.
[2] Includes Syphilis, Ebola, and Sickle SCAN® product revenues and single order fulfillment.
[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,	
	2026	2025	2026	2025
United States	$ 20,532	$ 19,662	$ 59,439	$ 60,070
Africa	6,399	4,875	19,959	19,023
Europe	2,223	1,300	5,415	5,064
Other regions	1,753	1,248	4,658	4,101
	$ 30,907	$ 27,085	$ 89,471	$ 88,258

Customer Concentrations. The following table represents customer concentration risk:

	For the Three Months Ended September 30,	
Net Revenues	2026	2025
Commercial customer[1]	10 %	N/A

	September 30,	December 31,
Accounts Receivable	2026	2025
Commercial customer [1]	20 %	15 %
Commercial customer [1]	11 %	N/A

[1] Each commercial customer is a different international distributor.

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, 2026 and December 31, 2025 was comprised of customer prepayments of $0.7 million and $1.2 million, respectively. Deferred revenue as of December 31, 2025 was also comprised of $0.4 million of unearned grant income. The Company had no unearned grant income in deferred revenue as of September 30, 2026.

The following table represents deferred revenue recognized:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
Deferred Revenue Recognized	2026	2025	2026	2025
Accrued at beginning of year	$ 39	$ 529	$ 1,148	$ 1,991

7. INCOME TAXES:

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2026	2025	2026	2025
Federal income tax expense	$ 3	$ 3	$ 8	$ 168
State income tax expense	18	(612)	74	1,792
Foreign income tax expense (benefit)	687	656	249	(369)
	$ 708	$ 47	$ 331	$ 1,591

During the three months ended September 30, 2026 and 2025, the Company recorded income tax expense of $0.7 million and $47.0 thousand, respectively. During the nine months ended September 30, 2026 and 2025, the Company recorded income tax expense of $0.3 million and $1.6 million, respectively. The higher federal and state income tax expense in 2025 is largely due to recording an uncertain tax position for certain tax matters, including penalties and interest. During the three and nine months ended September 30, 2026, the Company had an effective tax rate of (6.0)% and (1.2)%, respectively. During the three and nine months ended September 30, 2025, the Company had an effective tax rate of (0.4)% and (3.4)%, respectively. The change in the tax in the quarterly periods is largely due to a reduction in the uncertain tax position made in Q3 2025 that did not reoccur in the third quarter of 2026. The increase in the Company's tax rate for the year-to-date period is primarily due to the recording of the uncertain tax positions in 2025 and an estimated increase in foreign pre-tax income in 2026.

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.

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, 2026 and December 31, 2025.

Uncertain tax positions were approximately $2.0 million as of September 30, 2026 and December 31, 2025. The Company’s uncertain tax positions relate 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 the Company's contingencies related to positions on prior years’ tax filings.

8. EARNINGS (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, 2026 and 2025, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 1,729 and 585 shares were excluded from the computation of diluted loss per share.

For the nine months ended September 30, 2026 and 2025, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 1,179 shares and 605 shares, respectively, were excluded from the computation of diluted loss per share.

9. STOCKHOLDERS' EQUITY:

In March 2025, the Company's Board of Directors authorized a stock repurchase program (the "Repurchase Program") effective March 21, 2025, whereby the Company may purchase up to $40.0 million in shares of its common stock over a period of up to two years. The amount and timing of share repurchases under the Repurchase Program may be carried out at the discretion of the Company's management through various methods in compliance with applicable state and federal securities laws. The Company did not repurchase shares of its common stock under the Repurchase Program during the three months ended September 30, 2026, and the Company repurchased 1.5 million shares during the three months ended September 30, 2025. The Company repurchased 2.4 million and 3.3 million shares of its common stock under the Repurchase Program during the nine months ended September 30, 2026 and 2025, respectively.

The reconciliation of the changes in stockholders' equity for the three and nine months ended September 30, 2026 and 2025 is as follows:

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balance at December 31, 2025	70,391	$ —	$ 531,393	$ (18,404)	$ (172,162)	$ 340,827
Vesting of restricted stock and performance stock units	1,190	—	—	—	—	—
Purchase and retirement of common shares in satisfaction of minimum tax withholdings for vested restricted stock and performance stock units	(416)	—	(1,261)	—	—	(1,261)
Stock-based compensation	—	—	2,768	—	—	2,768
Shares repurchased and retired in connection with share repurchase program	(1,768)	—	(5,000)	—	—	(5,000)
Net loss	—	—	—	—	(22,377)	(22,377)
Currency translation adjustments	—	—	—	(1,633)	—	(1,633)
Balance at March 31, 2026	69,397	$ —	$ 527,900	$ (20,037)	$ (194,539)	$ 313,324
Vesting of restricted stock and performance stock units	291	—	—	—	—	—
Purchase and retirement of common shares in satisfaction of minimum tax withholdings for vested restricted stock and performance stock units	(73)	—	(223)	—	—	(223)
Stock-based compensation	—	—	2,287	—	—	2,287
Shares repurchased and retired in connection with share repurchase program	(647)	—	(2,000)	—	—	(2,000)
Net income	—	—	—	—	6,249	6,249
Currency translation adjustments	—	—	—	(1,860)	—	(1,860)
Balance at June 30, 2026	68,968	$ —	$ 527,964	$ (21,897)	$ (188,290)	$ 317,777
Common stock issued upon exercise of options	14	—	47	—	—	47
Vesting of restricted stock and performance stock units	69	—	—	—	—	—
Purchase and retirement of common shares in satisfaction of minimum tax withholdings for vested restricted stock and performance stock units	(15)	—	(59)	—	—	(59)
Stock-based compensation	—	—	2,278	—	—	2,278
Shares repurchased and retired in connection with share repurchase program	—	—	—	—	—	—
Net loss	—	—	—	—	(13,094)	(13,094)
Currency translation adjustments	—	—	—	184	—	184
Balance at September 30, 2026	69,036	$ —	$ 530,230	$ (21,713)	$ (201,384)	$ 307,133

	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 in satisfaction of minimum tax withholdings for vested restricted stock and performance stock units	(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 in satisfaction of minimum tax withholdings for vested restricted stock and performance stock units	(271)	—	(784)	—	—	(784)
Stock-based compensation	—	—	3,165	—	—	3,165
Shares repurchased and retired in connection with share repurchase program	(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 in satisfaction of minimum tax withholdings for vested restricted stock and performance stock units	(21)	—	(61)	—	—	(61)
Stock-based compensation	—	—	2,835	—	—	2,835
Shares repurchased and retired in connection with share repurchase program	(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

10. BUSINESS SEGMENT INFORMATION:

The Company is organized on the basis of products and services into a single reportable segment. All products and services reside under the same reporting hierarchy. 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, 2026	December 31, 2025
United States	$ 35,278	$ 36,254
United Kingdom	8,110	10,061
Canada	3,756	4,642
Other regions	283	364
	$ 47,427	$ 51,321

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2026	2025	2026	2025
Net revenues	$ 30,907	$ 27,085	$ 89,471	$ 88,258
Cost of products and services sold [1]	16,938	15,313	50,381	51,028
Gross profit	13,969	11,772	39,090	37,230
Research and development [1]	7,629	10,106	30,720	31,110
Sales and marketing [1]	6,557	6,299	19,931	19,533
General and administrative [1]	11,992	11,081	40,977	37,859
Change in the estimated fair value of acquisition-related contingent consideration	—	376	(22,480)	1,587
Loss (gain) on sale of assets	746	—	726	(993)
Operating loss	(12,955)	(16,090)	(30,784)	(51,866)
Other income	86	154	490	138
Interest revenue	1,053	2,051	3,478	6,279
Other segment items [2]	30	594	126	(705)
Loss before income taxes and equity investment	(11,786)	(13,291)	(26,690)	(46,154)
Income tax expense	708	47	331	1,591
Loss on equity investment	(600)	(374)	(2,201)	(1,700)
Net loss	$ (13,094)	$ (13,712)	$ (29,222)	$ (49,445)

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2026	2025	2026	2025
Stock-based Compensation				
Cost of products and services sold	$ 169	$ 208	$ 550	$ 584
Research and development	353	282	990	764
Sales and marketing	277	213	696	648
General and administrative	1,479	2,132	5,097	6,691
	$ 2,278	$ 2,835	$ 7,333	$ 8,687

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2026	2025	2026	2025
Depreciation & Amortization				
Cost of products and services sold	$ 845	$ 1,054	$ 2,813	$ 3,503
Research and development	350	514	1,048	1,568
Sales and marketing	2	21	4	78
General and administrative	1,002	865	3,046	2,640
	$ 2,199	$ 2,454	$ 6,911	$ 7,789

11. BUSINESS COMBINATIONS:

BioMedomics

On November 12, 2025, the Company acquired all of the outstanding stock of BioMedomics, pursuant to the terms of an acquisition agreement (the "Acquisition Agreement"). The Company began operating this entity as of the November 12, 2025 closing date.

The primary reason for the acquisition of BioMedomics was to expand the Company's diagnostic portfolio by adding Sickle SCAN®, a rapid, point-of-need test for sickle cell disease that is sold outside of the United States.

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

Cash paid to BioMedomics	$	2,865
Transaction expenses		403
Debt paid off		330
Earnout contingent consideration		233
Expense fund		40
Initial aggregate purchase price	$	3,871

Pursuant to the Acquisition Agreement, the Company agreed to pay up to $5.0 million of contingent consideration based on the achievement of sales thresholds before December 31, 2031. The acquisition-date fair value of the earnout contingent consideration was $0.2 million. The range of outcome for the earnout contingent consideration is zero to $5.0 million.

During the year ended December 31, 2025, the Company incurred a total of $0.5 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, 2025.

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

Assets Acquired		
Other current and non current assets	$	10
Inventory		284
Operating right-of-use assets		120
Developed technology intangible asset		1,900
Goodwill		1,775
Total assets acquired		4,089
Liabilities Assumed		
Accounts payable		34
Current liabilities		17
Deferred revenue		72
Operating lease liability		120
Total liabilities assumed		243
Net Assets Acquired		3,846
Estimated fair value of contingent consideration		(233)
Net Cash Paid (net of cash acquired of $25)	$	3,613

The purchase price was allocated to the tangible assets and identifiable intangible asset acquired and liabilities assumed based on their acquisition-date estimated fair values. The identifiable intangible asset was developed technology. The developed technology was all assigned a ten year useful life.

The Company, with the assistance of an independent valuation specialist, assessed the fair value of the intangible asset and contingent consideration of BioMedomics. The fair values recorded as of November 12, 2025 are based on significant inputs that are not observable in the market and thus represent a fair value measurement categorized within Level 3 of the fair value hierarchy.

The fair value of the acquired developed technology was determined using the multi-period excess earnings method, which required judgment in estimating appropriate cash flows, discount rate, survival factor, and remaining useful life.

The fair value of the earnout contingent consideration was determined using the Monte Carlo simulation model, which required judgment in estimating expected revenue, volatility, expected discount rate and risk-free interest 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 the Company expects to achieve as a result of the acquisition. The Company believes the goodwill related to the acquisition was a result of BioMedomics providing a product that will enable the Company to leverage the product with existing and new customers. The goodwill is not deductible for income tax purposes.

The Company continues to evaluate the fair value of assets acquired and liabilities assumed. Additional information, which existed as of the acquisition date, but was at that time unknown to the Company, may become known during the remainder of the measurement period. Changes to amounts recorded as a result of the final determination may result in a corresponding adjustment to these assets and liabilities, including goodwill. The determination of the estimated fair values of all assets acquired was completed as of June 30, 2026.

Revenues from BioMedomics consist of sales from the Sickle SCAN® test. Effective as of November 12, 2025, the financial results of BioMedomics are included in the consolidated financial results of the Company. BioMedomics contributed $0.1 million and $1.1 thousand of revenue and net income, respectively, to the consolidated statement of operations for the year ended December 31, 2025.

Unaudited Pro Forma Financial Information

The unaudited pro forma results presented below include the results of the BioMedomics acquisition as if it had been consummated as of January 1, 2025. The unaudited pro forma results include amortization of the acquired intangible asset, stock compensation, and lease expense 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, 2025.

	For the Three Months Ended September 30,	For the Nine Months Ended September 30,
	2025	2025
Net revenues	$ 27,303	$ 88,998
Net loss	$ (13,838)	$ (49,609)

12. CONTINGENCIES:

Collaborations

Sherlock has active third-party license agreements entered into in order to advance and obtain technologies and services related to the business. Under these licenses, the Company is required to make up to $3.3 million of cash payments upon the achievement of certain scientific and commercial milestones as well as low single digit royalty payments on product sales. The Company has the right to terminate the licenses.

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. On February 11, 2026, the Court issued an order scheduling trial for January 17, 2027. On October 27, 2026, the parties resolved the litigation in a manner which resulted in a positive outcome for the Company. The Court, upon the parties' agreement, replaced the February 27, 2025, preliminary injunction with a permanent injunction protecting the Company's proprietary information and trade secrets at issue in the case, and dismissed all claims in the case with prejudice.

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, 2025, filed with the Securities and Exchange Commission on March 9, 2026. 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, 2025 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, sale and distribution of simple, easy to use diagnostic products and specimen collection devices using its proprietary technologies. The Company's diagnostic products include tests for diseases including HIV, Hepatitis C, Syphilis, Sickle Cell 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 and HCV products, as a self-test to individuals in a number of other countries, including, for the HIV products, as an oral swab in-home test for HIV-1 and HIV-2 in Europe, and for the HCV products, as an OTC test.

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, and companion animal market segments. 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. In June 2026, the Company received FDA 510(k) clearance for its Colli-Pee™•Dx Urine Collection Kit, a prescription device for the at-home self-collection of first-void urine for use with FDA-cleared sexually transmitted infection (STI) molecular assays with which the device has been validated. The device has been validated for use with Roche's cobas® CT/NG and cobas® TV/MG assays.

Risk Assessment Testing

During 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 and as such the Company had no sales of its risk assessment products during the three and nine months ended September 30, 2026. There were no sales of the Company's risk assessment products during the three months ended September 30, 2025 and $1.9 million of sales for the nine months ended September 30, 2025. During the first quarter of 2025, the Company sold certain assets that made up the risk assessment product line including certain intellectual property, contracts, permits, and equipment.

Results of Operations (all dollar amounts in tables are presented in thousands)

For the three months ended September 30, 2026 compared to September 30, 2025.

CONSOLIDATED NET REVENUES

The table below shows total consolidated net revenues for the three months ended September 30, 2026 and 2025:

	For the Three Months Ended September 30, 2026				
	Dollars			Percentage of Total Net Revenues	
	2026	2025	% Change	2026	2025
Diagnostics [1]	$ 16,801	$ 14,499	16 %	54 %	54 %
Sample Management Solutions [2]	12,498	10,306	21 %	40 %	38 %
Other products and services	771	442	74 %	2 %	2 %
COVID-19 Diagnostics	22	89	(75)%	— %	— %
Net product and services revenues	30,092	25,336	19 %	96 %	94 %
Non-product and services revenues [3]	815	1,749	(53)%	4 %	6 %
Net revenues	$ 30,907	$ 27,085	14 %	100 %	100 %

[1] Includes HIV, HCV, Syphilis, Sickle SCAN® and SureQuick® product revenues.
[2] Includes Genomics, Microbiome, and Colli-Pee® product revenues.
[3] Includes funded research and development contracts, royalty income and grant revenues.

Product and Services Revenues

Consolidated net revenues increased 14% to $30.9 million for the three months ended September 30, 2026, from $27.1 million for the three months ended September 30, 2025.

Sales of the Company's Diagnostics products increased 16% to $16.8 million for the three months ended September 30, 2026, from $14.5 million for the three months ended September 30, 2025. This increase was primarily driven by higher international HIV revenues associated with stabilization in our African markets and timing of customer orders. The company also experienced an increase in domestic and international HCV revenue and revenue in the quarter also included Sickle SCAN® revenues, a new revenue stream acquired through the BioMedomics, Inc. acquisition completed in November 2025.

Sample Management Solutions revenues increased 21% to $12.5 million for the three months ended September 30, 2026, from $10.3 million for the three months ended September 30, 2025. This increase in revenue was driven by key commercial customer growth and timing of specific commercial orders.

Non-Product and Services Revenues

Non-product and services revenues decreased 53% to $0.8 million for the three months ended September 30, 2026, from $1.7 million for the three months ended September 30, 2025, primarily due to the completion of various funded R&D contracts.

CONSOLIDATED OPERATING RESULTS

Consolidated gross profit margin increased to 45.2% for the three months ended September 30, 2026, compared to 43.5% for the three months ended September 30, 2025. The drivers of the margin increase are attributable to better absorption of fixed overhead costs due to operational efficiencies, partially offset by higher scrap and lower non-product revenues which contribute 100% to gross margin.

Consolidated operating loss for the three months ended September 30, 2026 was $13.0 million compared to an operating loss of $16.1 million for the three months ended September 30, 2025.

Research and development expenses decreased 25% to $7.6 million for the three months ended September 30, 2026, from $10.1 million for the three months ended September 30, 2025, primarily due to lower costs associated with the development of Company's CT/NG application on its molecular self-test device.

Sales and marketing expenses increased 4% to $6.6 million for the three months ended September 30, 2026 from $6.3 million for the three months ended September 30, 2025.

General and administrative expenses increased 8% to $12.0 million for the three months ended September 30, 2026 from $11.1 million for the three months ended September 30, 2025 largely due to higher legal fees.

All of the above contributed to the Company's operating loss of $13.0 million for the three months ended September 30, 2026, which included non-cash charges of $2.3 million for stock-based compensation and $2.2 million for depreciation and amortization. The Company's operating loss of $16.1 million for the three months ended September 30, 2025, 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.

OTHER INCOME

Other income for the three months ended September 30, 2026 was $1.2 million compared to $2.8 million for the three months ended September 30, 2025. The decrease in other income is due to lower interest income and lower foreign currency gains.

CONSOLIDATED INCOME TAXES

The Company continues to believe the full valuation allowance established against its total U.S. and U.K. deferred tax asset is appropriate as the facts and circumstances necessitating the allowance have not changed. For the three months ended September 30, 2026 and 2025, the Company recorded income tax expense of $0.7 million and $47.0 thousand, respectively. During the three months ended September 30, 2026 and 2025, the Company had an effective tax rate of (6.0)% and (0.4)%, respectively. The decrease in the Company's tax rate was primarily due to the recording of a reduction in an uncertain tax position made in the third quarter of 2025 that did not reoccur in the third quarter of 2026.

Results of Operations

For the nine months ended September 30, 2026 compared to September 30, 2025.

CONSOLIDATED NET REVENUES

The table below shows an outline of total consolidated net revenues for the nine months ended September 30, 2026 and 2025:

	For the Nine Months Ended September 30,				
	Dollars			Percentage of Total Net Revenues	
	2026	2025	% Change	2026	2025
Diagnostics [1]	$ 53,018	$ 51,410	3 %	59 %	58 %
Sample Management Solutions [2]	31,431	29,271	7 %	35 %	33 %
Other products and services	1,702	1,059	61 %	2 %	1 %
COVID-19 Diagnostics	41	574	(93)%	— %	1 %
Risk Assessment Testing [3]	—	1,866	(100)%	— %	2 %
Net product and services revenues	86,192	84,180	2 %	96 %	95 %
Non-product and services revenues [4]	3,279	4,078	(20)%	4 %	5 %
Net revenues	$ 89,471	$ 88,258	1 %	100 %	100 %

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

Product and Services Revenues

Consolidated net revenues increased 1% to $89.5 million for the nine months ended September 30, 2026, from $88.3 million for the nine months ended September 30, 2025.

Sales of the Company's Diagnostics products increased 3% to $53.0 million for the nine months ended September 30, 2026 from $51.4 million for the nine months ended September 30, 2025. This increase is primarily attributable to higher HIV international revenues associated with the Company's near shoring efforts in Africa, stabilization of African markets, and due to the timing of customer orders. The increase in revenues is also driven by higher syphilis sales associated with new customers in the women's health market and the inclusion of Sickle SCAN® revenues, a new revenue stream acquired through the BioMedomics, Inc. acquisition completed in November 2025. These increases in revenues were offset by lower international HCV revenues driven by reduced reimbursement subsidies in the Asian market and a large order shipped into Africa in the second quarter of 2025 that did not recur. Domestic HIV revenues also declined due to lower purchases under the Together Take Me Home program.

Sample Management Solutions revenues increased 7% to $31.4 million for the nine months ended September 30, 2026, from $29.3 million for the nine months ended September 30, 2025. This increase in revenue was largely driven by key commercial customer growth and timing of specific commercial orders.

COVID-19 Diagnostics revenues decreased 93% to $41.0 thousand for the nine months ended September 30, 2026, from $574.0 thousand for the nine months ended September 30, 2025 due to lower overall demand for COVID-19 testing.

Risk Assessment testing revenues was zero for nine months ended September 30, 2026, compared to $1.9 million for the nine months ended September 30, 2025. The Company discontinued this line of business at the end of 2024 and the business wound down in early 2025.

Non-Product and Services Revenues

Non-product and services revenues decreased 20% to $3.3 million for the nine months ended September 30, 2026, from $4.1 million for the nine months ended September 30, 2025, primarily due to the completion of certain funded R&D contracts and due to the timing of the related spend associated with the contracts.

CONSOLIDATED OPERATING RESULTS

Consolidated gross profit margin increased to 43.7% for the nine months ended September 30, 2026, from 42.2% for the nine months ended September 30, 2025. The largest driver of the margin improvement is better absorption of fixed overhead costs due to operational efficiencies partially offset by higher scrap expense.

Consolidated operating loss for the nine months ended September 30, 2026 was $30.8 million, compared to a $51.9 million operating loss reported for the nine months ended September 30, 2025. Results for the nine months ended September 30, 2026 benefited from a $22.5 million change in the estimated fair value of acquisition-related contingent consideration but were negatively impacted by higher operating expenses.

Research and development expenses decreased 1% to $30.7 million for the nine months ended September 30, 2026, from $31.1 million for the nine months ended September 30, 2025 largely due to lower spend incurred for clinical trials for the CT/NG and Colli-Pee® devices as the clinical trials were completed in second quarter of 2026.

Sales and marketing expenses increased 2% to $19.9 million for the nine months ended September 30, 2026 from $19.5 million for the nine months ended September 30, 2025.

General and administrative expenses increased 8% to $41.0 million for the nine months ended September 30, 2026, from $37.9 million for the nine months ended September 30, 2025, largely due to higher professional, consulting, and legal fees associated with litigation, and stockholder activism costs.

All of the above contributed to the Company's operating loss of $30.8 million for the nine months ended September 30, 2026, which included non-cash income of $22.5 million reflected in the change in the estimated fair value of acquisition-related contingent consideration, and non-cash charges of $7.3 million for stock-based compensation, and $6.9 million for depreciation and amortization. The Company's operating loss of $51.9 million for the nine months ended September 30, 2025 included a non-cash charge of $8.7 million for stock-based compensation, $7.8 million for depreciation and amortization, and $1.6 million for the change in the estimated fair value of acquisition-related contingent consideration.

CONSOLIDATED OTHER INCOME

Other income decreased to $4.1 million for the nine months ended September 30, 2026 from $5.7 million for the nine months ended September 30, 2025. The decrease in other income is due to lower interest income offset by higher foreign currency gains.

CONSOLIDATED INCOME TAXES

The Company continues to believe the full valuation allowance established against its total U.S. deferred tax asset is appropriate as the facts and circumstances necessitating the allowance have not changed. The Company has not achieved U.S. cumulative pre-tax earnings based on a rolling three-year window as 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, 2026 and 2025, the Company recorded income tax expense of $0.3 million and $1.6 million, respectively, reflecting effective tax rates of (1.2)% and (3.4)%, respectively. The increase in the Company's tax rate was primarily due to the recording of an uncertain tax position in 2025 and a estimated increase in foreign pre-tax income in 2026.

Liquidity and Capital Resources

	September 30, 2026	December 31, 2025
	(in thousands)	
Cash and cash equivalents	$ 148,238	$ 199,278
Working capital	190,191	222,113

The Company's cash and cash equivalents decreased to $148.2 million at September 30, 2026, from $199.3 million at December 31, 2025. The Company has $82.1 million, or 55%, of its $148.2 million of cash and cash equivalents held by DNAG, the Company's Canadian subsidiary.

The Company's working capital decreased to $190.2 million at September 30, 2026, from $222.1 million at December 31, 2025. 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, 2026, net cash used in operating activities was $34.7 million. Cash flows from operations can be significantly impacted by factors such as timing of receipts from customers, inventory purchases, and payments to vendors. The Company's net loss of $29.2 million included a $22.5 million non-cash benefit from the change in the estimated fair value of acquisition-related contingent consideration, partially off set by stock-based compensation expense of $7.3 million, depreciation and amortization expense of $6.9 million, a loss on equity investment of $2.2 million, and other non-cash charges aggregating to $1.2 million.

Cash used by the Company's working capital accounts included an increase in accounts receivable of $8.7 million due to timing of shipments and invoicing and a decrease in deferred revenue of $0.6 million as work on grant projects is completed and earned. These uses of cash were partially offset by an increase in accrued expenses and other liabilities of $3.7 million largely associated with an increase in the company's profit sharing accrual as it builds toward a payout in early 2027, a decrease in prepaid expenses and other assets of $3.0 million resulting from the timing of payment for the Company's insurance renewals, an increase of $1.6 million in accounts payable largely associated with the timing of spend on inventory purchases, and an overall decrease in inventory balances of $0.5 million.

Investing Activities

Net cash used in investing activities was $5.0 million for the nine months ended September 30, 2026, for purchases of property and equipment.

Financing Activities

Net cash used in financing activities was $8.6 million for the nine months ended September 30, 2026, which was largely comprised of $7.0 million to repurchase common stock pursuant to the Company's stock repurchase plan and $1.5 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, 2025 filed with the SEC on March 9, 2026. No material changes have been made to such critical accounting policies during the nine months ended September 30, 2026.

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, 2025.

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, 2026. 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, 2026, 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, 2026, 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. On February 11, 2026, the Court issued an order scheduling trial for January 17, 2027. On October 27, 2026, the parties resolved the litigation in a manner which resulted in a positive outcome for the Company. The Court, upon the parties' agreement, replaced the February 27, 2025, preliminary injunction with a permanent injunction protecting the Company's proprietary information and trade secrets at issue in the case, and dismissed all claims in the case with prejudice.

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, 2025 filed with the SEC on March 9, 2026.

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, 2026 - July 31, 2026	—	$ —	—	$ 17,960,005
August 1, 2026 - August 31, 2026	9,245 [2]	$ 4.13	—	$ 17,960,005
September 1, 2026 - September 30, 2026	6,188 [2]	$ 3.42	—	$ 17,960,005
	15,433		—	

[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] Represents shares retired to satisfy 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, 2026, none of the Company's 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
3.1	Certificate of Amendment to Certificate of Incorporation dated June 3, 2026 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K as filed on June 3, 2026).
10.1ˆ	Amended and Restated OraSure Technologies, Inc. 2000 Stock Award Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K as filed on June 3, 2026).
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

ˆ Management contract or compensatory plan or arrangement.

† Pursuant to Item 601(a)(5) of Regulation S-K, certain exhibits have been omitted and will be furnished supplementally to the Securities and Exchange Commission upon request.

+ 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 12, 2026

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

/s/Michele M. Anthony

Date: November 12, 2026

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/A 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 12, 2026

/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/A 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 12, 2026

/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/A for the quarter ended September 30, 2026 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 12, 2026

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/A for the quarter ended September 30, 2026 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 12, 2026