

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

FORM 8-K

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

Date of Report (Date of earliest event reported): November 6, 2024

OraSure Technologies, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-16537
(Commission
File Number)

36-4370966
(I.R.S. Employer
Identification No.)

220 East First Street
Bethlehem, Pennsylvania
(Address of Principal Executive Offices)

18015-1360
(Zip Code)

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

N/A
(Former Name or Former Address, if changed since Last Report)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the Registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by a check mark whether the Registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

Item 2.02 – Results of Operations and Financial Condition.

On November 6, 2024, OraSure Technologies, Inc. (the “Company”) issued a press release announcing its consolidated financial results for the quarter ended September 30, 2024 and certain other matters. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

Item 7.01 – Regulation FD Disclosure.

On November 6, 2024, the Company held a webcast conference call with analysts and investors, during which members of the Company’s management team, including Carrie Eglinton Manner, the Company’s President and Chief Executive Officer, and Kenneth J. McGrath, the Company’s Chief Financial Officer, discussed the Company’s consolidated financial results for the quarter ended September 30, 2024, and described certain business developments.

The information in these Items and attached Exhibit shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section, nor shall such information and Exhibit be deemed incorporated by reference in any filing under the Securities Act of 1933, except as shall be expressly set forth by specific reference in such a filing. The fact that the information and Exhibit are being furnished should not be deemed an admission as to the materiality of any information contained therein. The Company undertakes no duty or obligation to publicly update or revise the information contained in this Current Report or attached Exhibit.

Item 9.01 – Financial Statements and Exhibits.**(d) Exhibits**

Exhibit Number	Description
99.1	Press Release, dated November 6, 2024, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter ended September 30, 2024 and certain other matters.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ORASURE TECHNOLOGIES, INC.

Date: November 6, 2024

By: /s/ Carrie Eglinton Manner
Carrie Eglinton Manner
President and Chief Executive Officer



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OraSure Reports Q3 '24 Revenue of \$39.9 Million

Q3 GAAP EPS of \$(0.06); Q3 Non-GAAP EPS of \$(0.01)

OraQuick® HCV Self-test receives initial orders following receipt of WHO pre-qualification status

Expanding Sample Management applications into blood proteomics

Exiting Risk Assessment testing business to focus on markets with attractive growth opportunities

BETHLEHEM, PA, November 6, 2024 (GLOBE NEWSWIRE) – OraSure Technologies, Inc. (NASDAQ: OSUR), a leader in point-of-care and home diagnostic tests and sample management solutions, today announced its financial results for the three months ended September 30, 2024.

“Our Q3 results were consistent with our expectations, and we continue to make progress on our strategic transformation. Core revenue improved sequentially in the third quarter and our key end markets are showing signs of gradual recovery. Our sustained focus on operational efficiency is delivering consistent productivity gains, and we generated positive cash flow from operations for the core business in Q3,” said OraSure President and CEO Carrie Eglinton Manner.

She added, “We are winding down our Risk Assessment testing business to focus on opportunities that align with our strengths in Diagnostics and Sample Management and elevate profitable growth in our core. As we position OraSure for a return to growth, our strong balance sheet provides flexibility as we invest in our innovation roadmap, including internal development, partnerships, and potential acquisition opportunities that leverage our existing capabilities.”

Financial Highlights

	For the Three Months Ended September 30,			For the Nine Months Ended September 30,		
	2024	2023	% Change	2024	2023	% Change
Core Business ⁽¹⁾	\$ 37,751	\$ 38,154	(1) %	\$ 102,468	\$ 109,909	(7) %
Molecular Services	9	834	(99)	1,692	3,567	(53)
COVID-19	2,155	50,199	(96)	44,222	216,115	(80)
Total Net Revenues	\$ 39,915	\$ 89,187	(55) %	\$ 148,382	\$ 329,591	(55) %

⁽¹⁾ Includes Diagnostics, Molecular Sample Management Solutions, other products and services revenues, and non-product and services revenues.

	For the Three Months Ended September 30,			For the Nine Months Ended September 30,		
	2024	2023	% Change	2024	2023	% Change
Net revenues	\$ 39,915	\$ 89,187	(55)%	\$ 148,382	\$ 329,591	(55)%
Gross profit	17,070	44,340	(62)	65,824	136,526	(52)
Gross margin	42.8 %	49.7 %		44.4 %	41.4 %	
Non-GAAP gross profit	17,272	44,609	(61)	67,490	137,998	(51)
Non-GAAP gross margin	43.3 %	50.0 %		45.5 %	41.9 %	
Operating income (loss)	(5,999)	10,894	NM	(15,832)	28,786	NM
Operating margin	(15.0)%	12.2 %		(10.7)%	8.7 %	
Non-GAAP operating income (loss)	(2,698)	20,568	NM	323	51,198	(99)
Non-GAAP operating margin	(6.8)%	23.1 %		0.2 %	15.5 %	
Net income (loss)	(4,507)	11,159	NM	(8,706)	33,582	NM
Non-GAAP net income (loss)	(688)	20,034	NM	8,173	52,790	(85)
Diluted GAAP EPS	\$ (0.06)	\$ 0.15	NM	\$ (0.12)	\$ 0.45	NM
Diluted Non-GAAP EPS	\$ (0.01)	\$ 0.27	NM	\$ 0.11	\$ 0.71	(85)

NM – not meaningful

- Total net revenues for the third quarter of 2024 decreased 55% to \$39.9 million from \$89.2 million in the third quarter of 2023.
- Core revenues (all revenues excluding COVID-19 and Molecular Services revenues) of \$37.8 million in the third quarter decreased 1% year-over-year. Diagnostics revenues in the third quarter increased 13% year-over-year to \$22.0 million and Molecular Sample Management revenues decreased 16% to \$12.8 million. The year-over-year decline in Core revenues was impacted by a decrease in revenues from the Risk Assessment testing business that we are exiting.
- COVID-19 revenues of \$2.2 million in the third quarter decreased 96% year-over-year primarily due to the completion of our largest government contract earlier in 2024.
- GAAP gross margin percentage was 42.8% in the third quarter of 2024 compared to 49.7% in the third quarter of 2023. Non-GAAP gross margin percentage in the third quarter of 2024 was 43.3% compared to 50.0% in the third quarter of 2023¹. On a year-over-year basis, gross margin was impacted by the decline in COVID-19 revenues and the higher mix of International revenues.
- GAAP operating loss in the third quarter of 2024 was \$6.0 million compared to operating income of \$10.9 million in the third quarter of 2023. Non-GAAP operating loss was \$2.7 million in the third quarter of 2024 compared to non-GAAP operating income of \$20.6 million in the third quarter of 2023.
- Cash and cash equivalents were \$279 million as of September 30, 2024. Cash flow from operations in the third quarter of 2024 was \$12.7 million.

¹ For additional information on non-GAAP financial measures and a reconciliation of the GAAP financial results to non-GAAP financial results, see the schedules below. A description of the adjustments made to the GAAP financial measures is included at the end of the schedules.

Recent Business Developments

- Received initial international orders for our OraQuick® HCV Self-test following receipt of WHO pre-qualification status in July. The OraQuick® HCV Self-test is the first Hepatitis C self-test to earn this designation, and we are actively working with the global health community to bring this test to populations in need.
- Expanding our sample management portfolio with the planned launch of a new solution targeting the blood proteomics market in the second half of 2025. Blood proteomics is a large and rapidly growing market, and there is a need for collection devices that effectively stabilize blood proteins in an easy-to-use format.
- Initiated steps to exit our Risk Assessment testing business by the end of 2024 to focus on markets that offer attractive growth opportunities. Risk Assessment testing products generated revenues of \$1.9 million during the third quarter and \$6.3 million during the first nine months of 2024, which was a decline from \$2.6 million during the third quarter of 2023 and \$7.5 million during the first nine months of 2023.
- Generated \$12.7 million of operating cash flow in the third quarter, driven by positive cash flow generation in our Core business and collections of accounts receivable related to InteliSwab®.

Financial Guidance

The Company is guiding to Q4 2024 revenues of \$36 to \$38 million. The Company anticipates Core revenues in Q4 2024 of \$35 to \$37 million, which includes \$1 to \$2 million of Risk Assessment testing revenues. The Company anticipates COVID-19 revenues in Q4 2024 of approximately \$1 million.

Conference Call

The Company will host a conference call and audio webcast to discuss the Company's third quarter 2024 results and certain business developments, beginning today at 5 p.m. Eastern Time. On the call will be Carrie Eglinton Manner, President and Chief Executive Officer, and Ken McGrath, Chief Financial Officer. The call will include prepared remarks by management and a question and answer session.

A webcast of the conference call will be available on the investor relations page of OraSure's website at <https://orasure.gcs-web.com/events-and-presentations>. Please click on the webcast link and follow the prompts for registration and access at least 10 minutes prior to the call. The webcast will be archived on OraSure's website shortly after the call has ended and will be available for approximately 90 days. If a participant will be listen-only, they are encouraged to listen via the webcast.

For participants interested in asking a question during the conference call, please follow the link below to pre-register. After registering, you will be provided with your access details via email. It is recommended to dial in at least 15 minutes prior to the call start time.

<https://register.vevent.com/register/Blbe76f335a1d54f62abf8377abec292b4>

OraSure intends to use the Investor Relations Section of its website as a means of disclosing material non-public information (MNPI) and for complying with its disclosure obligations under Regulation FD. Accordingly, investors should monitor OraSure's website in addition to following its press releases, SEC filings, public conference calls, presentations, and webcasts.

Financial Data (Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Results of Operations				
Net revenues	\$ 39,915	\$ 89,187	\$ 148,382	\$ 329,591
Cost of products and services sold	22,845	44,847	82,558	193,065
Gross profit	17,070	44,340	65,824	136,526
Operating expenses:				
Research and development	5,623	8,516	19,960	26,737
Sales and marketing	7,615	8,736	23,994	29,413
General and administrative	9,831	10,051	33,310	44,186
Loss on impairments	—	6,183	4,392	7,503
Change in the estimated fair value of acquisition-related contingent consideration	—	(40)	—	(99)
Total operating expenses	23,069	33,446	81,656	107,740
Operating income (loss)	(5,999)	10,894	(15,832)	28,786
Other income	2,781	2,612	9,338	6,752
Income (loss) before income taxes	(3,218)	13,506	(6,494)	35,538
Income tax expense	678	2,347	1,041	1,956
Loss on equity investment	(611)	—	(1,171)	—
Net income (loss)	\$ (4,507)	\$ 11,159	\$ (8,706)	\$ 33,582
Income (loss) per share:				
Basic	\$ (0.06)	\$ 0.15	\$ (0.12)	\$ 0.46
Diluted	\$ (0.06)	\$ 0.15	\$ (0.12)	\$ 0.45
Weighted average shares outstanding:				
Basic	74,583	73,453	74,330	73,298
Diluted	74,583	74,349	74,330	74,197

	For the Three Months Ended September 30,			For the Nine Months Ended September 30,				
	2024	2023	% Change	2024	2023	% Change		
Consolidated Net Revenues								
COVID-19 Diagnostics	\$ 2,155	\$ 50,145	(96)%	\$ 44,186	\$ 215,876	(80)%		
Diagnostics	22,023	19,551	13	57,162	56,475	1		
Molecular Sample Management Solutions	12,806	15,238	(16)	36,237	41,230	(12)		
Risk Assessment Testing	1,911	2,554	(25)	6,265	7,540	(17)		
Other products and services	748	638	17	1,802	1,739	4		
Molecular Services	9	834	(99)	1,692	3,567	(53)		
COVID-19 Molecular Products	—	54	(100)	36	239	(85)		
Net product and services revenues	39,652	39,652	89,014	(55)	147,380	147,380	326,666	(55)
Non-product and services revenues	263	173	52	1,002	2,925	(66)		
Net revenues	\$ 39,915	\$ 89,187	(55)%	\$ 148,382	\$ 329,591	(55)%		

Condensed Consolidated Balance Sheets (Unaudited)

	September 30, 2024	December 31, 2023
<u>Assets</u>		
Cash and cash equivalents	\$ 278,571	\$ 290,407
Accounts receivable, net	26,954	40,171
Inventories	38,870	47,614
Other current assets	5,756	8,267
Property, plant and equipment, net	38,143	45,420
Intangible assets, net	665	1,206
Goodwill	35,287	35,696
Investment in equity method investee	28,829	—
Other noncurrent assets	11,010	14,064
Total assets	\$ 464,085	\$ 482,845
<u>Liabilities and Stockholders' Equity</u>		
Accounts payable	\$ 9,581	\$ 13,151
Deferred revenue	1,619	1,559
Other current liabilities	16,584	24,826
Other noncurrent liabilities	10,736	12,638
Stockholders' equity	425,565	430,671
Total liabilities and stockholders' equity	\$ 464,085	\$ 482,845

Additional Financial Data (Unaudited)

	For the Nine Months Ended September 30,	
	2024	2023
Capital expenditures	\$ 3,341	\$ 9,018
Proceeds from funding under government contract ⁽¹⁾	—	24,290
Depreciation and amortization	8,380	17,372
Stock-based compensation	9,178	7,602
Cash provided by operating activities	\$ 27,265	\$ 100,217

⁽¹⁾ Proceeds represent reimbursement for capital expenditures, engineering consulting costs, and guaranteed profit to cover project management costs.

Consolidated Statement of Cash Flows (Unaudited)

	For the Nine Months Ended September 30,	
	2024	2023
OPERATING ACTIVITIES:		
Net (loss) income	\$ (8,706)	\$ 33,582
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Stock-based compensation	9,178	7,602
Depreciation and amortization	8,380	17,372
Loss on impairments	4,392	7,503
Other non-cash amortization	(569)	3
Provision for credit losses	521	(75)
Unrealized foreign currency gain	(154)	(66)
Interest expense on finance leases	20	42
Loss on equity investment	1,171	—
Deferred income taxes	165	(490)
Loss on sale of fixed assets	(121)	—
Change in the estimated fair value of acquisition-related contingent consideration	—	(99)
Payment of acquisition-related contingent consideration	—	(19)
Changes in assets and liabilities:		
Accounts receivable	12,658	17,468
Inventories	8,659	36,425
Prepaid expenses and other assets	2,622	10,530
Accounts payable	(3,431)	(25,122)
Deferred revenue	66	(449)
Accrued expenses and other liabilities	(7,586)	(3,990)
Net cash provided by operating activities	27,265	100,217
INVESTING ACTIVITIES:		
Purchases of short-term investments	(53,244)	(74,652)
Investment in equity method investee	(30,000)	—
Proceeds from maturities and redemptions of short-term investments	53,052	94,980
Purchases of property and equipment	(3,341)	(4,517)
Purchase of property and equipment under government contracts	—	(4,501)
Proceeds from funding under government contract ⁽¹⁾	—	24,290
Net cash (used in) provided by investing activities	(33,533)	35,600
FINANCING ACTIVITIES:		
Cash payments for lease liabilities	(746)	(835)
Proceeds from exercise of stock options	214	76
Payment of acquisition-related contingent consideration	—	(46)
Repurchase of common stock	(3,533)	(1,863)
Net cash used in financing activities	(4,065)	(2,668)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	(1,503)	404
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(11,836)	133,553
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	290,407	83,980
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 278,571	\$ 217,533

About OraSure Technologies

OraSure Technologies, Inc. (“OraSure”) transforms health through actionable insight and powers the shift that connects people to healthcare wherever they are. OraSure improves access, quality, and value of healthcare with innovation in effortless tests and sample management solutions. OraSure, together with its wholly-owned subsidiary, DNA Genotek Inc., is a leader in the development, manufacture, and distribution of rapid diagnostic tests and sample collection and stabilization devices designed to discover and detect critical medical conditions. OraSure’s portfolio of products is sold globally to clinical laboratories, hospitals, physician’s offices, clinics, public health and community-based organizations, research institutions, government agencies, pharmaceutical companies, and direct to consumers. For more information on OraSure Technologies, please visit www.orasure.com

About IntelliSwab®

OraSure has received Emergency Use Authorizations (EUA) from the FDA for its IntelliSwab® COVID-19 rapid tests. The U.S. Food and Drug Administration (“FDA”) has authorized the IntelliSwab® COVID-19 Rapid Test for Over-the-Counter (OTC) use without a prescription. The FDA has also authorized the IntelliSwab® COVID-19 Rapid Test Pro for professional use in point of care (POC) CLIA-waived settings, and the IntelliSwab® COVID-19 Rapid Test Rx for Prescription Home Use. These remarkably simple COVID-19 lateral flow tests use samples self-collected from the lower nostrils. The IntelliSwab® test’s unique design incorporates a built-in swab fully integrated into the test stick. After users swab their lower nostrils, the test stick is swirled in a pre-measured buffer solution, and the result appears right on the test stick within 30 minutes, with no instruments, batteries, smartphone or laboratory analysis needed to see the result. With less than one minute of “hands-on time,” it is as simple as “Swab, Swirl, and See.”

This product has not been FDA cleared or approved, but it has been authorized by the FDA under an EUA. The emergency use of this product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. This product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb- 3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Development of the IntelliSwab® COVID-19 Rapid Test has been funded in whole or in part with federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority, under contract numbers 75A50120C00061 and 75A50121C00078, utilizing Health Care Enhancement Act (HCEA) funding. The DoD’s Defense Assisted Acquisition (DA2) Cell led the manufacturing expansion effort for the IntelliSwab® COVID-19 rapid test in coordination with the Department of the Air Force’s Acquisition COVID-19 Task Force (DAF ACT). The manufacturing effort was funded through the American Rescue Plan Act (ARPA) to enable and support domestic industrial base expansion for critical medical resources.

Forward Looking Statements

This press release contains certain forward-looking statements, including with respect to products, product development and manufacturing activities, regulatory submissions and authorizations, revenue growth and guidance, expected revenue from government orders, cost savings, cash flow, increasing margins and other

matters. 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: our ability to satisfy customer demand; ability to reduce our spending rate, capitalize on manufacturing efficiencies and drive profitable growth; ability to achieve the anticipated cost savings as a result of our business restructuring, including from insourcing third party manufacturing and exiting microbiome services; ability to market and sell products, whether through our internal, direct sales force or third parties; impact of significant customer concentration in the genomics business; failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our products; ability to manufacture or have manufactured products in accordance with applicable specifications, performance standards and quality requirements; ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; ability to comply with applicable regulatory requirements; ability to effectively resolve warning letters, audit observations and other findings or comments from the FDA or other regulators; the impact of the novel coronavirus ("COVID-19") pandemic or other public health crises on the Company's business, supply chain, labor force, ability to successfully develop new products, validate the expanded use of existing collector products, receive necessary regulatory approvals and authorizations and commercialize such products for COVID-19 testing, and demand for our COVID-19 testing products; changes in relationships, including disputes or disagreements, with strategic partners or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements; impact of replacing distributors; inventory levels at distributors and other customers; ability of the Company to achieve its financial and strategic objectives and continue to increase its revenues, including the ability to expand international sales and the ability to continue to reduce costs; impact of competitors, competing products and technology changes; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products; market acceptance of oral fluid or urine testing, collection or other products; market acceptance and uptake of microbiome informatics, microbial genetics technology and related analytics services; changes in market acceptance of products based on product performance or other factors, including changes in testing guidelines, algorithms or other recommendations by the Centers for Disease Control and Prevention or other agencies; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical products and components; availability of related products produced by third parties or products required for use of our products; impact of contracting with the U.S. government; impact of negative economic conditions; ability to achieve and maintain sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of the Company's stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to attract and retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; cybersecurity breaches or other attacks involving our systems or those of our third-party contractors and IT service providers, suppliers and customers; the impact of terrorist attacks, civil unrest, hostilities and war ; and general political, business and economic conditions, including inflationary pressures and banking stability. These and other factors that could affect our results are discussed more fully in our SEC filings, including our registration statements, Annual Report on Form 10-K for the year ended December 31, 2023, Quarterly Reports on Form 10-Q, and other filings with the SEC. 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 press release and OraSure Technologies undertakes no duty to update these statements.

Statement Regarding Use of Non-GAAP Financial Measures

In this press release, the Company's financial results and financial guidance are provided in accordance with accounting principles generally accepted in the United States (GAAP) and using certain non-GAAP financial measures, including non-GAAP gross margin, non-GAAP gross profit, non-GAAP net income (loss), non-GAAP operating income (loss), and non-GAAP earnings (loss) per share. Management believes that presentation of operating results using these non-GAAP financial measures provides useful supplemental information to investors and facilitates the analysis of the Company's core operating results and comparison of operating results across reporting periods, while excluding certain expenses that may not be indicative of the Company's recurring core business operating results. In addition, management believes these non-GAAP financial measures are useful to investors both because they (1) allow for greater transparency with respect to key metrics used by management in its financial and operational decision-making and (2) are used by OraSure's institutional investors and the analysis community to help them analyze the health of OraSure's business. Management also uses non-GAAP financial measures to establish budgets and to manage the Company's business. A reconciliation of the GAAP financial results to non-GAAP financial results is included in the schedules below and a description of the adjustments made to the GAAP financial measures is included at the end of the schedules.

The Company encourages investors to carefully consider its results under GAAP, as well as its supplemental non-GAAP information and the reconciliation between these presentations, to more fully understand its business. Non-GAAP financial results are reported in addition to, and not as a substitute for, or superior to, financial measures calculated in accordance with GAAP. Further, non-GAAP financial measures, even if similarly titled, may not be calculated in the same manner by all companies, and therefore should not be compared.

OraSure Technologies GAAP to Non-GAAP Reconciliation (\$ in 000's)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue	\$ 39,915	\$ 89,187	\$ 148,382	\$ 329,591
GAAP Cost of products and services sold	22,845	44,847	82,558	193,065
<i>GAAP Gross Margin</i>	42.8 %	49.7 %	44.4 %	41.4 %
Stock compensation	195	137	539	426
Amortization of acquisition-related intangible assets	—	132	—	396
Reduction in workforce severance	7	—	1,127	369
Transformation related expenses	—	—	—	281
Non-GAAP Cost of Goods Sold	22,643	44,578	80,892	191,593
<i>Non-GAAP Gross Margin</i>	43.3 %	50.0 %	45.5 %	41.9 %
GAAP Operating Income (Loss)	(5,999)	10,894	(15,832)	28,786
Stock compensation	2,889	2,590	9,178	7,602
Amortization of acquisition-related intangible assets	59	467	176	1,399
Reduction in workforce severance	353	—	2,409	3,264
Loss on impairment	—	6,183	4,392	7,503
Transformation related expenses	—	26	—	707
Government grant accounting	—	448	—	2,036
Change in fair value of acquisition-related contingent consideration	—	(40)	—	(99)
Non-GAAP Operating Income (Loss)	(2,698)	20,568	323	51,198
GAAP Net Income (Loss)	(4,507)	11,159	\$ (8,706)	33,582
Stock compensation	2,889	2,590	9,178	7,602
Amortization of acquisition-related intangible assets	59	467	176	1,399
Reduction in workforce severance	353	—	2,409	3,264
Loss on impairment	—	6,183	4,392	7,503
Transformation related expenses	—	26	—	707
Change in fair value of acquisition-related contingent consideration	—	(40)	—	(99)
Loss on equity investment	611	—	1,171	—
Tax effect of Non-GAAP adjustments	(93)	(351)	(447)	(1,168)
Non-GAAP Net Income (Loss)	\$ (688)	\$ 20,034	\$ 8,173	\$ 52,790
GAAP Earnings (Loss) Per Share:	\$ (0.06)	\$ 0.15	\$ (0.12)	\$ 0.45
Non-GAAP Earnings (Loss) Per Share:	\$ (0.01)	\$ 0.27	\$ 0.11	\$ 0.71
Diluted Shares Outstanding	74,583	74,349	74,330	74,197
Diluted Shares Outstanding Used For Computing Non-GAAP Earnings (Loss) Per Share	74,583	74,349	75,328	74,197

The following is a description of the adjustments made to GAAP financial measures:

- Stock Compensation: non-cash equity-based compensation provided to OraSure employees and directors
- Amortization of acquisition-related intangible assets: represents recurring amortization charges resulting from the acquisition of intangible assets associated with our business combinations
- Reduction in workforce severance: termination benefits associated with the Company's workforce reduction associated with certain business events
- Loss on impairment: charges related to the write down of Company's intangibles, PP&E, or leased assets
- Transformation related expenses: transitory costs such as consulting and professional fees related to transformation initiatives
- Government contract accounting: As required under International Accounting Standard Board IAS 20, *Accounting for Government Contracts and Disclosure of Government Assistance*, our operating expenses associated with the Department of Defense expansion contract are reflected in operating expenses with offsetting reimbursement reflected in other income
- Change in fair value of acquisition-related contingent consideration: changes in the fair value of contingent consideration liability associated with estimate changes in reaching contingent consideration metrics
- Loss on equity investment: we have excluded our proportionate share of our equity method investee's net loss as we do not have direct control over the investee's operations or resulting revenue and expenses
- Tax impact associated with non-GAAP adjustments – tax expense/(benefit) due to non-GAAP adjustments

A reconciliation of our non-GAAP measures to their most directly comparable GAAP measures can also be found at: <https://orasure.gcs-web.com/gaap-non-gaap-reconciliation>

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