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): February 27, 2024

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

Delaware	001-16537	36-4370966
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

220 East First Street Bethlehem, Pennsylvania	18015-1360
(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

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 February 27, 2024, OraSure Technologies, Inc. (the "Company") issued a press release announcing its consolidated financial results for the full year and quarter ended December 31, 2023 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 February 27, 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 full year and quarter ended December 31, 2023, 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 February 27, 2024, announcing consolidated financial results of OraSure Technologies, Inc. for the full year and quarter ended December 31, 2023 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: February 27, 2024

By: */s/ Carrie Eglinton Manner*

Carrie Eglinton Manner
President and Chief Executive Officer

EXHIBIT 99.1

Investor Contact:
Jason Plagman
VP, Investor Relations
investorinfo@orasure.com

Media Contact:
Amy Koch
Director, Corporate Communications
media@orasure.com

OraSure Reports Q4 '23 Revenue of $75.9 Million

Q4 GAAP EPS of $0.27; Q4 Non-GAAP EPS of $0.22

Grew cash balance to $290.4 million as of December 31, 2023

Enters U.S. Syphilis testing market via strategic distribution agreement with Diagnostics Direct

BETHLEHEM, PA, February 27, 2024 (GLOBE NEWSWIRE) – OraSure Technologies, Inc. (NASDAQ: OSUR), a leader in point-of-care and home diagnostic tests, sample management solutions, and microbiome laboratory and analytical services, today announced its financial results for the three months ended December 31, 2023.

"We made meaningful progress on our transformation journey in 2023. We generated significant positive operating cash flow with margin expansion, driven by our enterprise-wide focus on innovating and operating with disciplined execution. We expect to deliver additional productivity gains across our organization, and we are on track to achieve our target of break-even in cash flow from operations for the core business by the end of 2024," said OraSure President and CEO Carrie Eglinton Manner.

She continued, "We are focused on elevating our core growth as volumes under our COVID-19 contracts taper down in 2024 and expect that the trajectory in our key segments will begin to improve later in the year. We are investing in our innovation roadmap, organically and inorganically. Our recent investment and agreement with Sapphiros expands our product pipeline potential, and we continue to increase the breadth of our portfolio through additional partnerships, like with Diagnostics Direct. Overall, we believe the progress we are making positions OraSure to drive profitable growth and create additional shareholder value."

Financial Highlights

	Three Months Ended December 31,			Years Ended December 31,		
	2023	2022	% Change	2023	2022	% Change
Core Business [1]	$ 34,217	$ 34,084	— %	$ 147,693	$ 144,154	2 %
COVID-19	41,664	88,994	(53)	257,779	243,325	6
Total Net Revenue	$ 75,881	$ 123,078	(38)%	$ 405,472	$ 387,479	5 %

(1) Includes diagnostics, molecular sample management solutions and molecular services, other products and services revenue, and non-product and services revenue.

	Three Months Ended December 31,			Years Ended December 31,		
	2023	2022	% Change	2023	2022	% Change
Net revenues	$ 75,881	$ 123,078	(38)%	$ 405,472	$ 387,479	5 %
Gross profit	35,126	49,828	(30)	171,652	148,438	16
Gross margin	46.3 %	40.5 %		42.3 %	38.3 %	
Non-GAAP gross profit	37,737	50,365	(25)	184,489	155,265	19
Non-GAAP gross margin	49.7 %	40.9 %		45.5 %	40.1 %	
Operating income (loss)	3,898	14,621	(73)	32,684	(22,156)	NM
Operating margin	5.1 %	11.9 %		8.1 %	(5.7)%	
Non-GAAP operating income (loss)	13,624	18,580	(27)	73,576	22,528	227
Non-GAAP operating margin	18.0 %	15.1 %		18.1 %	5.8 %	
Net income (loss)	20,073	15,801	27	53,655	(17,133)	NM
Non-GAAP net income (loss)	16,479	26,282	(37)	77,585	25,789	201
GAAP EPS	$ 0.27	$ 0.22	23	$ 0.72	$ (0.24)	NM
Non-GAAP EPS	$ 0.22	$ 0.36	(39)	$ 1.04	$ 0.36	189

NM – not meaningful

- Total net revenues for the fourth quarter of 2023 decreased 38% to $75.9 million from $123.1 million in the fourth quarter of 2022.
- Core revenue (all revenue excluding COVID-19 revenue) of $34.2 million in the fourth quarter increased 0.4% year-over-year. Core revenue growth was driven by strong HIV sales in the U.S. and international markets, which were partially offset by a decline in non-product revenue.
- COVID-19 revenue of $41.7 million in the fourth quarter decreased 53% year-over-year.
- GAAP gross margin percentage was 46.3% in the fourth quarter of 2023 compared to 40.5% in the fourth quarter of 2022. Non-GAAP gross margins in the fourth quarter of 2023 were 49.7% compared to 40.9% in the fourth quarter of 2022[1]. Gross margins benefited from production efficiencies, cost reduction initiatives, and changes to InteliSwab® packaging that were implemented during the first quarter of 2023.
- GAAP operating income in the fourth quarter of 2023 was $3.9 million compared to $14.6 million in the fourth quarter of 2022. Non-GAAP operating income was $13.6 million in the fourth quarter of 2023 compared to $18.6 million in the fourth quarter of 2022.
- Cash, cash equivalents, and short-term investments increased to $290.4 million as of December 31, 2023. The $65.5 million increase in our cash balance during the fourth quarter of 2023 was primarily driven by our improved operational performance. In addition, during the fourth quarter, we received $24.4 million from the U.S. government related to our manufacturing expansion contract.

Recent Business Highlights

- In January, entered into a strategic distribution relationship and investment in Sapphiros, a next generation consumer diagnostics company. Through this strategic partnership, OraSure expects to be able to offer a more comprehensive range of low-cost diagnostic tests and sample management solutions to our customers globally. OraSure has secured exclusive distribution rights to key products in Sapphiros' development pipeline that align with and enhance OraSure's existing areas of expertise, including self-collected blood samples and diagnostic tests for sexually transmitted infections, respiratory conditions, and other diseases.

[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.

- In February, signed a strategic agreement with Diagnostics Direct to distribute *Syphilis Health Check*, the first CLIA-waived treponemal test, which delivers point of care results in 10 minutes.
- Established new distribution relationships to expand our product offerings in sample management solutions and substance abuse testing.
- Consolidated one of our distribution facilities into our Opus Way facility in order to drive additional operating efficiencies and cost savings.
- Remain on track to achieve operating cash flow break-even for the core business by the end of 2024.

Financial Guidance

The Company is guiding to Q1 2024 revenue of $50 to $54 million, which includes core revenue of $29 to $31 million and InteliSwab® revenue of $21 to $23 million.

Financial Data (Unaudited)

	Three Months Ended December 31,		Years Ended December 31,	
	2023	2022	2023	2022
Results of Operations				
Net revenues	$ 75,881	$ 123,078	$ 405,472	$ 387,479
Cost of products and services sold	40,755	73,250	233,820	239,041
Gross profit	35,126	49,828	171,652	148,438
Operating expenses:				
Research and development	6,991	8,052	33,728	36,237
Sales and marketing	6,906	11,363	36,319	49,238
General and administrative	14,005	15,944	58,191	68,206
Loss on impairment	3,326	—	10,829	17,101
Change in fair value of acquisition-related contingent consideration	—	(152)	(99)	(188)
Total operating expenses	31,228	35,207	138,968	170,594
Operating income (loss)	3,898	14,621	32,684	(22,156)
Other income	16,822	1,014	23,574	6,481
Income (loss) before income taxes	20,720	15,635	56,258	(15,675)
Income tax expense (benefit)	647	(166)	2,603	1,458
Net income (loss)	$ 20,073	$ 15,801	$ 53,655	$ (17,133)
Earnings (loss) per share:				
Basic	$ 0.27	$ 0.22	$ 0.73	$ (0.24)
Diluted	$ 0.27	$ 0.22	$ 0.72	$ (0.24)
Weighted average shares:				
Basic	73,499	72,734	73,348	72,505
Diluted	75,013	73,248	74,389	72,505

	Three Months Ended December 31,			Years Ended December 31,		
	2023	2022	% Change	2023	2022	% Change
COVID-19 Diagnostics	$ 41,617	$ 88,857	(53)%	$ 257,493	$ 233,666	10 %
Diagnostics	17,219	14,422	19	73,694	52,181	41
Molecular Sample Management Solutions	13,044	11,998	9	54,274	63,342	(14)
Other products and services	2,722	3,008	(10)	12,001	11,903	1
Molecular Services	907	2,401	(62)	4,474	7,296	(39)
COVID-19 Molecular Products	47	137	(66)	286	9,659	(97)
Net product and services revenues	75,556	120,823	(37)	402,222 402,222	378,047	6
Non-product and services revenues	325	2,255	(86)	3,250	9,432	(66)
Net revenues	$ 75,881	$ 123,078	(38)%	$ 405,472	$ 387,479	5 %

Condensed Consolidated Balance Sheets (Unaudited)

	December 31, 2023	December 31, 2022
Assets		
Cash and cash equivalents	$ 290,407	$ 83,980
Short-term investments	—	26,867
Accounts receivable, net	40,171	70,797
Inventories	47,614	95,704
Other current assets	8,267	47,842
Property, plant and equipment, net	45,420	59,413
Intangible assets, net	1,206	11,694
Goodwill	35,696	35,104
Other noncurrent assets	14,064	12,779
Total assets	$ 482,845	$ 444,180
Liabilities and Stockholders' Equity		
Accounts payable	$ 13,151	$ 38,020
Deferred revenue	1,559	2,273
Other current liabilities	24,826	28,770
Other non-current liabilities	12,638	10,692
Stockholders' equity	430,671	364,425
Total liabilities and stockholders' equity	$ 482,845	$ 444,180

Additional Financial Data (Unaudited)

	Years Ended December 31,	
	2023	2022
Capital expenditures	$ 10,303	$ 63,909
Proceeds from funding under government contract[(1)]	$ 48,669	$ 60,331
Depreciation and amortization	$ 20,936	$ 15,308
Stock-based compensation	$ 10,729	$ 11,622
Cash provided by (used in) operating activities	$ 141,583	$ (47,202)

(1) Proceeds represent reimbursements for capital expenditures, engineering consulting costs, guaranteed profit to cover project management costs, and the excess of the contract value over the Company's final cash outlay.

Consolidated Statement of Cash Flows (Unaudited)

	Years Ended December 31,	
	2023	2022
OPERATING ACTIVITIES:		
Net income (loss)	$ 53,655	$ (17,133)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Stock-based compensation	10,729	11,622
Depreciation and amortization	20,936	15,308
Loss on impairments	10,829	17,101
Other non-cash amortization	3	228
Provision for credit losses	(462)	(1,032)
Unrealized foreign currency gain	103	(161)
Interest expense on finance leases	51	94
Deferred income taxes	102	(1,651)
Loss on sale of fixed assets	—	729
Change in the estimated fair value of acquisition-related contingent consideration	(99)	(188)
Payment of acquisition-related contingent consideration	(19)	—
Changes in assets and liabilities:		
Accounts receivable	31,116	(25,162)
Inventories	48,228	(43,274)
Prepaid expenses and other assets	(2,499)	(7,091)
Accounts payable	(26,976)	2,634
Deferred revenue	(730)	(596)
Accrued expenses and other liabilities	(3,384)	1,370
Net cash provided by (used in) operating activities	141,583	(47,202)
INVESTING ACTIVITIES:		
Purchases of short-term investments	(74,652)	(22,873)
Proceeds from maturities and redemptions of short-term investments	102,440	47,415
Proceeds from sale of assets	—	121
Purchases of property and equipment	(5,802)	(6,774)
Purchase of property and equipment under government contracts	(4,501)	(57,135)
Proceeds from funding under government contract[(1)]	48,669	60,331
Net cash provided by investing activities	66,154	21,085
FINANCING ACTIVITIES:		
Cash payments for lease liabilities	(1,345)	(1,381)
Proceeds from exercise of stock options	269	15
Payment of acquisition-related contingent consideration	(46)	(208)
Repurchase of common stock	(1,901)	(2,254)
Net cash used in financing activities	(3,023)	(3,828)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	1,713	(2,837)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	206,427	(32,782)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	83,980	116,762
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 290,407	$ 83,980

(1) Proceeds represent reimbursements for capital expenditures, engineering consulting costs, guaranteed profit to cover project management costs, and the excess of the contract value over the Company's final cash outlay.

Conference Call

The Company will host a conference call and audio webcast to discuss the Company's fourth quarter 2023 results and certain business developments, beginning today at 5 p.m. ET. 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.

To participate in the live 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/BI02fb7bbb6778405db15374b4d472fd84

About InteliSwab®

OraSure has received Emergency Use Authorizations (EUA) from the FDA for its InteliSwab® COVID-19 rapid tests. The U.S. Food and Drug Administration ("FDA") has authorized the InteliSwab® COVID-19 Rapid Test for Over-the-Counter (OTC) use without a prescription. The FDA has also authorized the InteliSwab® COVID-19 Rapid Test Pro for professional use in point of care (POC) CLIA-waived settings, and the InteliSwab® 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 InteliSwab® 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 InteliSwab® 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 InteliSwab® 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.

About OraSure Technologies

OraSure Technologies (the "Company") transforms health through actionable insight and powers the shift that connects people to healthcare wherever they are. The Company improves access, quality, and value of healthcare with innovation in effortless tests, sample management solutions, and services. OraSure, together with its wholly-owned subsidiaries, DNA Genotek, Diversigen, and Novosanis, provides its customers with end-to-end solutions that encompass diagnostics, tools, and services. The OraSure family of companies is a leader in the development, manufacture, and distribution of rapid diagnostic tests, sample collection and stabilization devices, and molecular services solutions 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, commercial entities, and direct to consumers. For more information on OraSure Technologies, please visit www.orasure.com

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: Sapphiros' and its related entities'
ability to seek and obtain regulatory approval for products in development; 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; 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 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, such as Sapphiros, or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements; ability to meet increased demand for the Company's products; 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 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; 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, 2022, 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 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)

	Three Months Ended December 31,		Years Ended December 31,	
	2023	2022	2023	2022
Revenue	$ 75,881	$ 123,078	$ 405,472	$ 387,479
GAAP Cost of products and services sold	40,755	73,250	233,820	239,041
GAAP Gross Margin	*46.3 %*	*40.5 %*	*42.3 %*	*38.3 %*
Stock compensation	138	140	564	331
Amortization of acquisition-related intangible assets	—	132	396	528
Reduction in workforce severance	—	—	369	—
Transformation related expenses	—	265	281	1,599
Accelerated depreciation	516	—	7,466	—
Inventory reserve for excess levels	1,957	—	3,761	4,369
Non-GAAP Cost of Goods Sold	38,144	72,713	220,983	232,214
Non-GAAP Gross Margin	*49.7 %*	*40.9 %*	*45.5 %*	*40.1 %*
GAAP Operating Income (Loss)	3,898	14,621	32,684	(22,156)
Stock compensation	3,127	2,349	10,729	9,154
Amortization of acquisition-related intangible assets	150	467	1,549	1,937
Reduction in workforce severance	—	—	3,264	—
Accelerated depreciation	516	—	7,466	—
Inventory reserve for excess levels	1,957	—	3,761	4,369
Loss on impairment	3,326	—	10,829	17,101
Transformation related expenses	—	520	707	6,191
Executive severance expense	—	300	—	3,850
Strategic alternative costs	—	—	—	848
Transaction costs	650	—	650	—
Government grant accounting	—	475	2,036	1,422
Change in fair value of acquisition-related contingent consideration	—	(152)	(99)	(188)
Non-GAAP Operating Income	13,624	18,580	73,576	22,528
GAAP Net Income (Loss)	20,073	15,801	$ 53,655	(17,133)
Stock compensation	3,127	2,349	10,729	9,154
Amortization of acquisition-related intangible assets	150	467	1,549	1,937
Reduction in workforce severance	—	—	3,264	—
Accelerated depreciation	516	—	7,466	—
Inventory reserve for excess levels	1,957	—	3,761	4,369
Loss on impairment	3,326	—	10,829	17,101
Transformation related expenses	—	520	707	6,191
Executive severance expense	—	300	—	3,850
Strategic alternative costs	—	—	—	848
Transaction costs	650	—	650	—
Change in fair value of acquisition-related contingent consideration	—	(152)	(99)	(188)
Additional profit from government contract	(12,802)	—	(12,802)	—
Tax effect of Non-GAAP adjustments	(518)	6,997	(2,124)	(340)
Non-GAAP Net Income (Loss)	$ 16,479	$ 26,282	$ 77,585	$ 25,789
GAAP Earnings (Loss) Per Share:	$ 0.27	$ 0.22	$ 0.72	$ (0.24)

Non-GAAP Earnings (Loss) Per Share:	$ 0.22	$ 0.36	$ 1.04	$ 0.36
Diluted Shares Outstanding	75,013	73,248	74,389	72,505

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 excluding accelerated stock compensation as required under former employees' employment agreements
- 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: one-time termination benefits associated with the Company's workforce reduction
- Inventory reserve for excess levels: reserves recorded for inventory balances that are deemed excess based on current forecasts and expirations dates
- Loss on impairment: charges related to the write down of Company's PP&E, goodwill and intangible assets
- Transaction costs: costs related to mergers and acquisition transactions or strategic investments
- Transformation related expenses: transitory costs such as consulting and professional fees related to transformation initiatives
- Accelerated depreciation: reduction in the useful life of certain assets to fully depreciate those assets which were identified as having no future use beyond the period presented
- Strategic alternative costs: one-time expenses such as legal and banking fees tied to the Company's strategic alternative process
- Executive severance expenses: expenses tied to executive severance agreements including accelerated stock compensation
- 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
- Additional profit from government contracts: income earned under a fixed-firm contract as a result of spending below the original budgeted amount expected under the contract
- 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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