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 7, 2023

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:

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

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. o

Item 2.02 – Results of Operations and Financial Condition.

On November 7, 2023, OraSure Technologies, Inc. (the "Company") issued a press release announcing its consolidated financial results for the quarter ended September 30, 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 November 7, 2023, 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, 2023, and described certain business developments.

The information in these Items and attached Exhibits 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 Exhibits 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 Exhibits.

Item 9.01 – Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release, dated November 7, 2023, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter ended September 30, 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: November 7, 2023

By: */s/ Carrie Eglinton Manner*

Carrie Eglinton Manner

President and Chief Executive Officer

EXHIBIT 99.1

Investor Contact:
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VP, Investor Relations
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Amy Koch
Director, Corporate Communications
media@orasure.com

OraSure Reports Q3 '23 Revenue of $89.2 Million; Core Revenue Grows 7% Year-over-Year

Q3 GAAP EPS of $0.15; Q3 Non-GAAP EPS of $0.27

Grew cash balance to $224.9 million as of September 30, 2023

BETHLEHEM, PA, November 7, 2023 (GLOBE NEWSWIRE) – OraSure Technologies, Inc. (NASDAQ: OSUR), a leader in point-of-care and home diagnostic tests, specimen collection devices, and microbiome laboratory and analytical services, today announced its financial results for the three months ended September 30, 2023.

"We continue to make progress on our transformation journey by 'innovating and operating with disciplined execution and accountability'. During the third quarter, we generated significant positive operating cash flow with margin expansion, driven by our enterprise-wide focus on operational efficiency. Looking ahead, we expect to deliver productivity gains across our organization as part of our focus on strengthening our foundation, and we remain confident that we will 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, and we demonstrated solid progress in the third quarter with 7% core revenue growth on a year-over-year basis. We are investing in our innovation roadmap, organically and inorganically. The addition of four new offerings for international and substance abuse testing segments represents early progress in our portfolio expansion. External partnerships are a key element of our strategy to accelerate profitable growth and create shareholder value."

Financial Highlights

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2023	2022	% Change	2023	2022	% Change
Core Business [1]	$ 38,988	$ 36,543	7 %	$ 113,476	$ 110,070	3 %
COVID-19	50,199	79,920	(37)	216,115	154,331	40
Total Net Revenue	$ 89,187	$ 116,463	(23) %	$ 329,591	$ 264,401	25 %

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2023	2022	% Change	2023	2022	% Change
Net revenues	$ 89,187	$ 116,463	(23)%	$ 329,591	$ 264,401	25 %
Gross profit	44,340	46,514	(5)	136,526	98,610	38
Gross margin	49.7 %	39.9 %		41.4 %	37.3 %	
Non-GAAP gross profit	44,609	46,951	(5)	146,752	104,900	40
Non-GAAP gross margin	50.0 %	40.3 %		44.5 %	39.7 %	
Operating income (loss)	10,894	866	NM	28,786	(36,777)	NM
Operating margin	12.2 %	0.7 %		8.7 %	(13.9)%	
Non-GAAP operating income (loss)	20,568	11,694	76	59,952	3,948	NM
Non-GAAP operating margin	23.1 %	10.0 %		18.2 %	1.5 %	
Net income (loss)	11,159	5,595	99	33,582	(32,934)	NM
Non-GAAP net income (loss)	19,947	10,000	99	61,106	(493)	NM
GAAP EPS	$ 0.15	$ 0.08	88	$ 0.45	$ (0.45)	NM
Non-GAAP EPS	$ 0.27	$ 0.14	93	$ 0.82	$ (0.01)	NM

NM – not meaningful

- Total net revenues for the third quarter of 2023 decreased 23% to $89.2 million from $116.5 million in the third quarter of 2022.
- Core revenue (all revenue excluding COVID-19 revenue) of $39.0 million in the third quarter increased 7% year-over-year. Core revenue growth was driven by strong HIV sales in the U.S. and international markets. Molecular products revenue in the third quarter increased 17% sequentially but decreased 4% on a year-over-year basis, which was in line with our expectations.
- COVID-19 revenue of $50.2 million in the third quarter decreased 37% year-over-year.
- GAAP gross margin percentage was 49.7% in the third quarter of 2023 compared to 39.9% in the third quarter of 2022. Non-GAAP gross margins in the third quarter of 2023 were 50.0% compared to 40.3% in the third quarter of 2022[1]. Gross margins benefited from production efficiencies, cost reduction initiatives, lower manufacturing scrap expense, and changes to InteliSwab® packaging that were implemented during the first quarter of 2023.
- GAAP operating income in the third quarter of 2023 was $10.9 million compared to $0.9 million in the third quarter of 2022. Non-GAAP operating income was $20.6 million in the third quarter of 2023 compared to $11.7 million in the third quarter of 2022.
- Cash, cash equivalents, and short-term investments increased to $224.9 million as of September 30, 2023. The $39.0 million increase in our cash balance during the third quarter of 2023 was primarily driven by our improved operational performance, including lower inventory levels. In addition, during the third quarter we received $6.5 million from the U.S. government related to our manufacturing expansion contract.

Recent Business Highlights

- Received an award for $5.7 million for future orders of InteliSwab® Covid-19 tests from the U.S. Department of Health and Human Services (HHS) through the Administration for Strategic Preparedness and Response (ASPR). The tests are available for free to households across the United States as part of the reopening of COVIDtests.gov.
- Received FDA approval in September for extension of InteliSwab® shelf-life from 18 months to 24 months.

[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.

- Established new distribution agreements to expand our product offerings in international infectious disease diagnostic testing and point-of-care substance abuse testing.
- Successfully completed the final milestones as part of our contract with the Department of Defense related to the installation and testing of new equipment and automation capabilities at our Opus Way facility in Bethlehem, Pennsylvania. With this phase of the expansion completed, we expect to make further progress in consolidating our manufacturing footprint to drive operating efficiencies over the next few years.
- 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 Q4 2023 revenue of $71 to $76 million, which includes core revenue of $33 to $35 million and InteliSwab® revenue of $38 to $41 million. As part of our ongoing focus on enterprise-wide operating efficiency, the Company is on track to exceed the $15 million of annualized cost savings announced in Q1 2023.

Financial Data (Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Results of Operations				
Net revenues	$ 89,187	$ 116,463	$ 329,591	$ 264,401
Cost of products and services sold	44,847	69,949	193,065	165,791
Gross profit	44,340	46,514	136,526	98,610
Operating expenses:				
Research and development	8,516	10,088	26,737	28,185
Sales and marketing	8,736	13,474	29,413	37,875
General and administrative	10,051	15,527	44,186	52,262
Loss on impairment	6,183	6,559	7,503	17,101
Change in fair value of acquisition-related contingent consideration	(40)	—	(99)	(36)
Total operating expenses	33,446	45,648	107,740	135,387
Operating income (loss)	10,894	866	28,786	(36,777)
Other income	2,612	3,586	6,752	5,467
Income (loss) before income taxes	13,506	4,452	35,538	(31,310)
Income tax expense (benefit)	2,347	(1,143)	1,956	1,624
Net income (loss)	$ 11,159	$ 5,595	$ 33,582	$ (32,934)
Earnings (loss) per share:				
Basic	$ 0.15	$ 0.08	$ 0.46	$ (0.45)
Diluted	$ 0.15	$ 0.08	$ 0.45	$ (0.45)
Weighted average shares:				
Basic	73,453	72,616	73,298	72,448
Diluted	74,349	72,785	74,197	72,448

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2023	2022	% Change	2023	2022	% Change
COVID-19 Diagnostics	$ 50,145	$ 79,559	(37)%	$ 215,876	$ 144,809	49 %
Diagnostics	19,551	12,288	59	56,475	37,759	50
Molecular Products	15,238	15,829	(4)	41,230	51,344	(20)
Other products and services	3,192	2,827	13	9,279	8,895	4
Molecular Services	834	1,957	(57)	3,567	4,895	(27)
COVID-19 Molecular Products	54	361	(85)	239	9,522	(97)
Net product and services revenues	89,014	112,821	(21)	326,666 326,666	257,224	27
Non-product and services revenues	173	3,642	(95)	2,925	7,177	(59)
Net revenues	$ 89,187	$ 116,463	(23)%	$ 329,591	$ 264,401	25 %

Condensed Consolidated Balance Sheets (Unaudited)

	September 30, 2023	December 31, 2022
Assets		
Cash and cash equivalents	$ 217,533	$ 83,980
Short-term investments	7,358	26,867
Accounts receivable, net	53,402	70,797
Inventories	59,264	95,704
Other current assets	18,907	47,842
Property, plant and equipment, net	48,027	59,413
Intangible assets, net	3,793	11,694
Goodwill	35,033	35,104
Other noncurrent assets	15,115	12,779
Total assets	$ 458,432	$ 444,180
Liabilities and Stockholders' Equity		
Accounts payable	$ 14,966	$ 38,020
Deferred revenue	1,824	2,273
Other current liabilities	24,157	28,770
Other non-current liabilities	12,600	10,692
Stockholders' equity	404,885	364,425
Total liabilities and stockholders' equity	$ 458,432	$ 444,180

Additional Financial Data (Unaudited)

	Nine Months Ended September 30,	
	2023	2022
Capital expenditures	$ 9,018	$ 66,786
Proceeds from funding under government contract[(1)]	$ 24,290	$ 37,756
Depreciation and amortization	$ 17,372	$ 11,391
Stock-based compensation	$ 7,602	$ 9,100
Cash provided by (used in) operating activities	$ 100,217	$ (29,190)

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

Consolidated Statement of Cash Flows (Unaudited)

	Nine Months Ended September 30,	
	2023	2022
OPERATING ACTIVITIES:		
Net income (loss)	$ 33,582	$ (32,934)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Stock-based compensation	7,602	9,100
Depreciation and amortization	17,372	11,391
Loss on impairments	7,503	17,101
Other non-cash amortization	3	411
Provision for credit losses	(75)	974
Unrealized foreign currency gain	(66)	(396)
Interest expense on finance leases	42	74
Deferred income taxes	(490)	542
Loss on sale of fixed assets	—	729
Change in the estimated fair value of acquisition-related contingent consideration	(99)	(36)
Payment of acquisition-related contingent consideration	(19)	—
Changes in assets and liabilities:		
Accounts receivable	17,468	(19,152)
Inventories	36,425	(26,240)
Prepaid expenses and other assets	10,530	(5,990)
Accounts payable	(25,122)	15,315
Deferred revenue	(449)	(312)
Accrued expenses and other liabilities	(3,990)	233
Net cash provided by (used in) operating activities	100,217	(29,190)
INVESTING ACTIVITIES:		
Purchases of short-term investments	(74,652)	(22,873)
Proceeds from maturities and redemptions of short-term investments	94,980	47,415
Purchases of property and equipment	(4,517)	(28,081)
Purchase of property and equipment under government contracts	(4,501)	(38,705)
Proceeds from funding under government contract[(1)]	24,290	37,756
Net cash provided by (used in) investing activities	35,600	(4,488)
FINANCING ACTIVITIES:		
Cash payments for lease liabilities	(835)	(826)
Proceeds from exercise of stock options	76	15
Payment of acquisition-related contingent consideration	(46)	(208)
Repurchase of common stock	(1,863)	(2,008)
Net cash used in financing activities	(2,668)	(3,027)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	404	(4,852)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	133,553	(41,557)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	83,980	116,762
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 217,533	$ 75,205

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

Conference Call

The Company will host a conference call and audio webcast to discuss the Company's third quarter 2023 results and certain business developments, beginning today at 5:00 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.

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/BIadc801c7a1dd42f1bc673c7fe37f8d2d

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 empowers the global community to improve health and wellness by providing access to accurate, essential information through effortless tests, collection kits and services. OraSure, together with its wholly-owned subsidiaries, DNA Genotek, Diversigen, and Novosanis, provides its customers with end-to-end

solutions that encompass tools, services, and diagnostics. 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, 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; 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 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 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue	$ 89,187	$ 116,463	$ 329,591	$ 264,401
GAAP Cost of products and services sold	44,847	69,949	193,065	165,791
GAAP Gross Margin	*49.7 %*	*39.9 %*	*41.4 %*	*37.3 %*
Stock compensation	137	(114)	426	191
Amortization of acquisition-related intangible assets	132	132	396	396
Reduction in workforce severance	—	—	369	—
Transformation related expenses	—	419	281	1,334
Accelerated depreciation	—	—	6,950	—
Inventory reserve for excess levels	—	—	1,804	4,369
Non-GAAP Cost of Goods Sold	44,578	69,512	182,839	159,501
Non-GAAP Gross Margin	*50.0 %*	*40.3 %*	*44.5 %*	*39.7 %*
GAAP Operating Income (Loss)	10,894	866	28,786	(36,777)
Stock compensation	2,590	2,296	7,602	6,805
Amortization of acquisition-related intangible assets	467	468	1,399	1,470
Reduction in workforce severance	—	—	3,264	—
Accelerated depreciation	—	—	6,950	—
Inventory reserve for excess levels	—	—	1,804	4,369
Loss on impairment	6,183	6,559	7,503	17,101
Transformation related expenses	26	616	707	5,671
Executive severance expense	—	558	—	3,550
Strategic alternative costs	—	—	—	848
Government grant accounting	448	331	2,036	947
Change in fair value of acquisition-related contingent consideration	(40)	—	(99)	(36)
Non-GAAP Operating Income (Loss)	20,568	11,694	59,952	3,948
GAAP Net Income (Loss)	11,159	5,595	$ 33,582	(32,934)
Stock compensation	2,590	2,296	7,602	6,805
Amortization of acquisition-related intangible assets	467	468	1,399	1,470
Reduction in workforce severance	—	—	3,264	—
Accelerated depreciation	—	—	6,950	—
Inventory reserve for excess levels	—	—	1,804	4,369
Loss on impairment	6,183	6,559	7,503	17,101
Transformation related expenses	26	616	707	5,671
Executive severance expense	—	558	—	3,550
Strategic alternative costs	—	—	—	848
Change in fair value of acquisition-related contingent consideration	(40)	—	(99)	(36)
Tax effect of Non-GAAP adjustments	(438)	(6,092)	(1,606)	(7,337)
Non-GAAP Net Income (Loss)	$ 19,947	$ 10,000	$ 61,106	$ (493)
GAAP Earnings (Loss) Per Share:	$ 0.15	$ 0.08	$ 0.45	$ (0.45)
Non-GAAP Earnings (Loss) Per Share:	$ 0.27	$ 0.14	$ 0.82	$ (0.01)
Diluted Shares Outstanding	74,349	72,785	74,197	72,448

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
- 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 due to a manufacturing site closure
- 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
- 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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