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 14, 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:
☐ 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 14, 2023, OraSure Technologies, Inc. (the "Company") issued a press release announcing its consolidated financial results for full year and quarter ended December 31, 2022 and certain other matters. A copy of the press release is attached as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

The information in this Item 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 7.01 – Regulation FD Disclosure.

On February 14, 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 full year and quarter ended December 31, 2022, and described certain business developments.

The information in this Item 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 is 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.

Item 8.01 – Other Events

On February 14, 2023, the Company announced a business restructuring to combine its Molecular Solutions and Diagnostics business units resulting in the elimination of roles impacting approximately 11% of its current non-production workforce. These actions are part of the Company's efforts toward achieving cashflow breakeven for its core business.

Item 9.01 – Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release, dated February 14, 2023, announcing consolidated financial results of OraSure Technologies, Inc. for the full-year and quarter ended December 31, 2022 and certain other matters.
Exhibit 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 14, 2023

By: */s/ Carrie Eglinton Manner*

Carrie Eglinton Manner

President and Chief Executive Officer

OraSure Technologies, Inc.

EXHIBIT 99.1

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OraSure Reports 4Q22 Record Revenue of $123.1 Million Growing 94% Year-Over-Year;
Positions for Longer-Term Growth and Profitability

InteliSwab® revenue of $88.9 million in Q4, up 12% sequentially; wins two new federal government contracts extending the tail on InteliSwab® revenue

Signs a deal with Quest Diagnostics Genomic Sequencing Services for saliva collection kits

Q4 GAAP EPS of $0.21; Non-GAAP EPS of $0.36

Announces restructuring expected to result in operating expense savings of $15 million to be fully implemented by June 2023; targets achieving cash flow breakeven for core business by end of 2024

Cash balance grows to $111 million, up $9 million from prior quarter

Management to Host Analyst/Investor Call and Webcast Today at 5:00 p.m. ET

BETHLEHEM, PA, February 14, 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 December 31, 2022.

“This quarter we have delivered clear progress on our transformation journey to Strengthen our foundation. We identified meaningful expense reductions through restructuring our two business units into a single organization, reducing our non-production workforce by 11%, and lowering manufacturing costs. Importantly, this quarter we further increased our cash balance that will help fund investments for our future,” said OraSure President and CEO Carrie Eglinton Manner.

She continued, “building from our stronger base, our focus this year is to increasingly Elevate core growth across our product lines by expanding our existing business, driving internal innovation, and targeting key strategic partnerships. We believe our actions will drive the Company to achieving cash flow breakeven for the core business by the end of 2024 while we Accelerate profitable growth.”

Financial Highlights

	Three Months Ended December 31,			Year Ended December 31,		
	2022	2021	% Change	2022	2021	% Change
Core Diagnostics	$ 18,400	$ 17,898	3 %	$ 70,007	$ 67,333	4 %
InteliSwab	88,857	14,770	502	233,666	22,707	929
Total Diagnostics	107,257	32,668	228	303,673	90,040	237
Core Molecular Solutions	15,684	22,936	(32)	74,147	89,467	(17)
COVID-19 kits	137	7,964	(98)	9,659	54,167	(82)
Total Molecular Solutions	15,821	30,900	(49)	83,806	143,634	(42)
Total Revenue	$ 123,078	$ 63,568	94 %	$ 387,479	$ 233,674	66 %

	Three Months Ended December 31,			Year ended December 31,		
	2022	2021	% Change	2022	2021	% Change
Net revenues	$ 123,078	$ 63,568	94 %	$ 387,479	$ 233,674	66 %
Gross profit	49,589	27,133	83	147,637	117,600	26
Gross margin	40 %	43 %		38 %	50 %	
Non-GAAP gross profit	50,126	28,685	75	154,464	121,708	27
Non-GAAP gross margin	41 %	45 %		40 %	52 %	
Operating income (loss)	13,435	(9,371)	NM	(22,957)	(10,164)	NM
Operating margin	11 %	-15 %		-6 %	-4 %	
Non-GAAP operating income (loss)	18,340	(1,336)	NM	21,726	5,388	303
Non-GAAP operating income (loss)	15 %	-2 %		6 %	2 %	
Net income (loss)	15,561	(10,393)	NM	(17,935)	(22,998)	-22
Non-GAAP net income (loss)	26,041	(2,490)	NM	24,986	(7,847)	(418)
GAAP EPS	$ 0.21	$ (0.14)	NM	$ (0.25)	$ (0.32)	(23)
Non-GAAP EPS	$ 0.36	$ (0.03)	NM %	$ 0.34	$ (0.11)	(416) %

NM – not meaningful

- Net revenues for the fourth quarter of 2022 were $123.1 million, a 94% increase from the fourth quarter of 2021 and a new record for the Company.
- Total InteliSwab® test revenue of $88.9 million increased 12% sequentially as the Company continued to scale its production capacity and saw increased order volume supporting the Federal government's school testing program.
- Core Diagnostic revenue increased 3% versus the prior year primarily due to strong domestic growth in HIV and HCV product sales. The Company experienced delays of a large number of international diagnostic orders toward the end of the quarter due to timing of product availability which we believe will drive higher sales in the first quarter of 2023. Core Molecular Solutions revenue decreased 32% year-over-year predominantly due to lower order volumes at key customers. The Company believes that some of this decline is associated with customer destocking activity as many organizations focus on cash balances given challenging financial conditions.

- GAAP gross margin percentage was 40.3% in the quarter compared to 42.7% in the fourth quarter of 2021. GAAP gross margins increased 60 basis points on a sequential basis. Non-GAAP gross margins in the quarter were 40.7% compared to 45.1% in the fourth quarter of 2021 and Non-GAAP gross margins increased 70 basis points on a sequential basis. On a year-over-year basis, gross margins were negatively impacted primarily by product mix, but improved sequentially with efficiencies achieved with the Company's InteliSwab® test production.
- GAAP operating income in the fourth quarter was $13.4 million which compares to a ($9.4) million operating loss in the fourth quarter of 2021 and increased $12.6 million on a sequential basis. Non-GAAP operating income was $18.3 million in the quarter compared to a ($1.3) million operating loss in the fourth quarter of 2021 and increased by $7.0 million on a sequential basis. This was driven by higher revenue, improved gross margins, and lower non-GAAP operating expenses which declined by $3.5 million sequentially due to timing and cost control.
- Cash and short-term investments increased $9.2M sequentially to $110.8 million in Q4 2022. Working capital increased significantly in the fourth quarter, which the Company believes will convert to cash as InteliSwab® revenues begin to taper in the future.

Business Restructuring

The Company has shared a business restructuring combining its Molecular Solutions and Diagnostics business units into One OraSure. As part of the restructuring, the Company is announcing role eliminations that will affect 11% of its current non-production workforce. The Company believes that, when coupled with additional cost savings, these changes will lead to annualized operating expense reductions of approximately $15 million to be fully implemented by the end of the second quarter of 2023. With additional system changes and manufacturing site consolidation, the Company targets achieving cash flow breakeven on base business (excluding InteliSwab® revenue) by the end of calendar year 2024. The Company's profitability turnaround enables current cash generation from InteliSwab® to be utilized for innovation and future growth investments.

"To support our long-term goals and growth as an organization, we've made the difficult decision to eliminate a number of roles," said OraSure President and CEO Carrie Eglinton Manner. "The changes we made will streamline levels of leadership, centralize core enterprise functions, and prioritize value creation activities. We believe our new operating structure will unlock significant operating efficiencies, foster stronger collaboration across the organization, and allow us to increase our innovation pipeline for growth."

Recent Business Highlights

- Signed a deal with Quest Diagnostics to serve as the preferred provider of saliva collection kits for Quest's Genomic Sequencing Services Group's test offerings.
- Received FDA approval for a new packaging and labeling configuration for InteliSwab®. The Company expects the new configuration to begin shipping by the end of March 2023. The packaging changes are expected to drive per test cost savings of approximately $0.40 which includes the impact from lower shipping costs based upon the smaller packaging configuration which should reduce total truckloads by approximately 50%.
- Launched four new CE-IVD Collipee urine collection products to support growing interest in non-invasive HPV and STI screening diagnostics and liquid biopsy from first-void urine samples. Included among these launches is a product with a proprietary chemistry for cell-free DNA and extra-cellular vesicles for oncology applications.
- Announced two new federal government contracts for InteliSwab®. The first procurement contract runs through November 2023; and, under the terms of the award, the contract estimate is 18 million

InteliSwab® COVID-19 Rapid Tests, with a maximum award of 36 million tests and a guaranteed minimum award of 3.6 million tests. The second contract was awarded for 3.2 million tests in December of 2022.

- Chosen as one of a group of manufacturers to win a Connecticut tender that allows the Company to compete for a total award of six million potential InteliSwab® tests annually.
- Evaluating new respiratory applications to build upon our COVID-19 success, including internally and externally via strategic partnership.
- Pursuing additional 510(k) clearances for the use of our proprietary collection kits in new applications in women's health and oncology, similar to our recently announced co-clearance with Grifols.
- Announced that its OraQuick HIV® Self-Test, in addition to its InteliSwab® test, is available for purchase directly via Amazon with eligibility for Prime free shipping.
- Noted that the first microbiome based therapeutic received FDA approval which the Company views as a signal of positive catalyst for investment in the microbiome testing services industry.

Financial Guidance

The Company is guiding toward 1Q23 revenue of $125 to $130 million representing 85% to 92% growth relative to the first quarter of last year. Given the continued volatility with the COVID-19 market, OraSure is only providing quarterly financial guidance for fiscal year 2023; however, it is anticipating higher revenue in the first half of the year followed by lower sales in the second half as the Company works down its COVID-19 government contracts.

Financial Data (Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Results of Operations				
Net revenues	$ 123,078	$ 63,568	$ 387,479	$ 233,674
Cost of products and services sold	73,489	36,435	239,842	116,074
Gross profit	49,589	27,133	147,637	117,600
Operating expenses:				
Research and development	8,999	8,900	36,237	34,170
Sales and marketing	11,363	10,915	49,238	44,751
General and administrative	15,944	16,648	68,206	50,328
Loss on impairment	—	—	17,101	—
Change in fair value of acquisition-related contingent consideration	(152)	41	(188)	(1,485)
Total operating expenses	36,154	36,504	170,594	127,764
Operating income (loss)	13,435	(9,371)	(22,957)	(10,164)
Other income	1,960	443	6,480	872
Income (loss) before income taxes	15,395	(8,928)	(16,477)	(9,292)
Income tax expense (benefit)	(166)	1,465	1,458	13,706
Net income (loss)	$ 15,561	$ (10,393)	$ (17,935)	$ (22,998)
Earnings (loss) per share:				
Basic	$ 0.21	$ (0.14)	$ (0.25)	$ (0.32)
Diluted	$ 0.21	$ (0.14)	$ (0.25)	$ (0.32)
Weighted average shares:				
Basic	72,734	72,040	72,505	71,981
Diluted	73,248	72,040	72,505	71,981

	Three Months Ended December 31,			Year Ended December 31,		
	2022	2021	% Change	2022	2021	% Change
DIAGNOSTICS						
Infectious Disease Testing Revenues						
Domestic HIV	$ 4,126	$ 3,773	9 %	$ 16,241	$ 16,641	(2) %
International HIV	7,109	8,626	(18)	22,571	25,503	(11)
Net HIV revenues	11,235	12,399	(9)	38,812	42,144	(8)
Domestic HCV	1,913	1,301	47	8,353	6,881	21
International HCV	1,274	1,100	16	5,016	4,902	2
Net HCV revenues	3,187	2,401	33	13,369	11,783	13
Net OraQuick® revenues	14,422	14,800	(3)	52,181	53,927	(3)
COVID-19	88,857	14,770	502	233,666	22,707	929
Other infectious disease revenues	127	183	(31)	547	718	(24)
Total Infectious Disease	103,406	29,753	248	286,394	77,352	270
Risk Assessment	2,483	2,406	3	10,269	9,678	6
Other non-product revenues	1,368	509	169	7,010	3,010	133
TOTAL DIAGNOSTIC NET REVENUE	107,257	32,668	228	303,673	90,040	237
MOLECULAR SOLUTIONS						
Genomics	$ 9,777	$ 14,017	(30)	$ 54,335	$ 63,350	(14)
Microbiome	1,920	2,050	(6)	7,503	7,944	(6)
COVID-19	137	7,964	(98)	9,659	54,167	(82)
Laboratory services	2,401	3,824	(37)	7,296	11,840	(38)
Other product and services revenues	699	1,334	(48)	2,591	2,566	1
Net product and service revenues	14,934	29,189	(49)	81,384	139,867	(42)
Other non-product and service revenues	887	1,711	(48)	2,422	3,767	(36)
TOTAL MOLECULAR SOLUTIONS NET REVENUE	15,821	30,900	(49)	83,806	143,634	(42)
TOTAL NET REVENUES	$ 123,078	$ 63,568	94 %	$ 387,479	$ 233,674	66 %

Condensed Consolidated Balance Sheets (Unaudited)

	December 31, 2022	December 31, 2021
Assets		
Cash and cash equivalents	$ 83,980	$ 116,762
Short-term investments	26,867	36,279
Accounts receivable, net	70,797	45,323
Inventories	96,232	53,138
Other current assets	47,842	47,804
Property, plant and equipment, net	59,413	73,435
Intangible assets, net	11,694	14,343
Goodwill	35,104	40,279
Long-term investments	—	17,009
Other noncurrent assets	12,779	16,618
Total assets	$ 444,708	$ 460,990
Liabilities and Stockholders' Equity		
Accounts payable	$ 39,349	$ 28,024
Deferred revenue	2,273	2,936
Other current liabilities	28,770	37,104
Other non-current liabilities	10,692	12,393
Stockholders' equity	363,624	380,533
Total liabilities and stockholders' equity	$ 444,708	$ 460,990

Additional Financial Data (Unaudited)	Year Ended December 31,	
	2022	2021
Capital expenditures	$ 4,545	$ 48,117
Depreciation and amortization	$ 15,308	$ 11,658
Stock-based compensation	$ 11,622	$ 7,807
Cash used in operating activities	$ (47,202)	$ 35,382

Conference Call

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's fourth quarter 2022 results and certain business developments, beginning today at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). On the call will be Carrie Eglinton Manner, President and Chief Executive Officer, Ken McGrath, Chief Financial Officer, and Scott Gleason, SVP Investor Relations and Corporate Communications. The call will include prepared remarks by management and a question and answer session.

In order to listen to the conference call, please register to obtain a dial in and pin at the following link:

https://register.vevent.com/register/BIf712ba49243f46c7a741f490d1ea19a4

To listen to the webcast, go to OraSure Technologies' web site, www.orasure.com, and click on the Investor Relations page. Please click on the webcast link and follow the prompts for registration and access 10 minutes prior to the call. A replay of the call will be archived on OraSure Technologies' web site shortly after the call has ended and will be available for 14 days. It is recommended to dial-in 15 to 20 minutes prior to the call start to reduce waiting times. If a participant will be listen-only, they are encouraged to listen via the webcast on OraSure's Investor Relations page.

About InteliSwab®

OraSure has received Emergency Use Authorizations (EUA) from the FDA for its InteliSwab® COVID-19 rapid tests. The 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.

Multiple government agencies, including the U.S. Department of Defense (DoD) and Department of Health and Human Services (HHS) are working to address COVID-19 testing needs. 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 number 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. 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, pharma, 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 activities, regulatory submissions and authorizations, revenue growth, 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 U.S. Food and Drug Administration ("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 ("CDC") 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; the impact of terrorist attacks, civil unrest, hostilities and war ; and general political, business and economic conditions, including inflationary pressures. 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, 2021, 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,		Year Ended December 31,	
	2022	**2021**	**2022**	**2021**
Revenue	$ 123,078	$ 63,568	$ 387,479	$ 233,674
GAAP Cost of Goods Sold	$ 73,489	36,435	239,842	116,074
GAAP Gross Margin	*40%*	*43%*	*38%*	*50%*
Stock compensation	140	162	331	572
Amortization of acquisition-related intangible assets	132	132	528	528
Transformation related expenses	265	-	1,599	-
Inventory reserve for excess levels	-	1,258	4,369	3,008
Non-GAAP Cost of Goods Sold	72,952	34,883	233,015	111,966
Non-GAAP Gross Margin	*40.7%*	*45.1%*	*39.9%*	*52.1%*
GAAP Operating Income (Loss)	13,435	(9,371)	(22,957)	(10,164)
Stock compensation	2,349	2,020	9,154	7,177
Amortization of acquisition-related intangible assets	467	707	1,937	2,843
Inventory reserve for excess levels	-	1,258	4,369	3,008
Loss on impairment	-	-	17,101	-
Transformation related expenses	520	1,200	6,191	1,200
Severance expense	300	2,683	3,850	2,683
Strategic alternative costs	-	126	848	126
Government grant accounting	1,422	-	1,422	-
Change in fair value of acquisition-related contingent consideration	(152)	41	(188)	(1,485)
Non-GAAP Operating Income (Loss)	18,340	(1,336)	21,726	5,388
GAAP Net Income (Loss)	15,561	(10,393)	(17,935)	(22,998)
Stock compensation	2,349	2,020	9,154	7,177
Amortization of acquisition-related intangible assets	467	707	1,937	2,843
Inventory reserve for excess levels	-	1,258	4,369	3,008
Loss on impairment	-	-	17,101	-
Transformation related expenses	520	1,200	6,191	1,200
Severance expense	300	2,683	3,850	2,683
Strategic alternative costs	-	126	848	126
Change in fair value of acquisition-related contingent consideration	(152)	41	(188)	(1,485)
Tax effect of Non-GAAP adjustments	6,997	(132)	(340)	(401)
Non-GAAP Net Income (Loss)	$ 26,041	$ (2,490)	$ 24,986	$ (7,847)
GAAP Earnings (Loss) Per Share:	$ 0.21	$ (0.14)	$ (0.25)	$ (0.32)
Non-GAAP Earnings (Loss) Per Share:	$ 0.36	$ (0.03)	$ 0.34	$ (0.11)
Diluted Shares Outstanding	73,248	72,040	72,505	71,981

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
- 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 assets including PP&E and Goodwill
- Transformation related expenses: transitory costs such as consulting and professional fees related to transformation initiatives
- Strategic alternative costs: one-time expenses such as legal and banking fees tied to the company's strategic alternative process
- 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

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