

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 8, 2022

**OraSure Technologies, Inc.**

(Exact Name of Registrant as Specified in Charter)

Delaware  
(State or Other Jurisdiction  
of Incorporation)

001-16537  
(Commission  
File Number)

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

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

18015-1360  
(Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.000001 par value per share	OSUR	The NASDAQ Stock Market LLC

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

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

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

Emerging growth company

If an emerging growth company, indicate by check mark if the Registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 2.02 – Results of Operations and Financial Condition.**

On November 8, 2022, OraSure Technologies, Inc. (the “Company”) issued a press release announcing its consolidated financial results for the quarter ended September 30, 2022 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 8, 2022, 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, 2022, 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**

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#">Press Release, dated November 8, 2022, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter ended September 30, 2022 and certain other matters.</a>
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: November 8, 2022

By: /s/ Carrie Eglinton Manner

Carrie Eglinton Manner

President and Chief Executive Officer



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**OraSure Reports 3Q22 Record Revenue of \$116.5 Million Growing 116% Year-Over-Year**

*InteliSwab® revenue of \$79.6 million in Q3, up 85% sequentially; Company continues to expand test production capacity*

*Company wins new contracts for COVID-19 testing along with retail wins including availability on Amazon.com*

*Q3 GAAP EPS of \$0.07 and non-GAAP EPS of \$0.13*

*Company generates positive cash flow from operations in quarter ahead of prior guidance;*

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

BETHLEHEM, PA, November 8, 2022 (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, 2022.

“This quarter we made significant progress on our transformation journey. We began to establish the foundations of our future strategy and position the Company for resetting our financial base which is designed to achieve our long-term financial success. We believe we hold a unique position in healthcare as we power the industry with effortless point-of-care diagnostic testing, sample collection, multi-ome services, and innovation. By doing this, we connect healthcare to people and help increase access, affordability, and quality of care,” said OraSure President and CEO Carrie Eglinton Manner.

She continued, “We generated positive cash flow this quarter ahead of our previous guidance which is an important milestone as we look to rebuild our balance sheet through our anticipated significant sales of InteliSwab® tests in coming quarters. To that end, we have recently won additional contracts and expanded retail presence with availability on Amazon.com that will extend our forward visibility for the product. We are strengthening our foundation driving further efficiencies in our core business, which will support future growth investments to bolster our long-term core growth outlook.”

## Financial Highlights

	Three Months Ended			Nine Months Ended		
	September 30,			September 30,		
	2022	2021	% Change	2022	2021	% Change
Core Diagnostics	\$ 18,092	\$ 15,836	14 %	\$ 51,607	\$ 49,430	4 %
InteliSwab	79,559	7,675	937	144,809	7,938	NM
<b>Total Diagnostics</b>	<b>97,651</b>	<b>23,511</b>	<b>315</b>	<b>196,416</b>	<b>57,368</b>	<b>242</b>
Core Molecular Solutions	18,451	24,151	(24)	58,463	66,529	(12)
COVID-19 kits	361	6,255	(94)	9,522	46,209	(79)
<b>Total Molecular Solutions</b>	<b>18,812</b>	<b>30,406</b>	<b>(38)</b>	<b>67,985</b>	<b>112,738</b>	<b>(40)</b>
<b>Total Revenue</b>	<b>\$ 116,463</b>	<b>\$ 53,917</b>	<b>116 %</b>	<b>\$ 264,401</b>	<b>\$ 170,106</b>	<b>55 %</b>

	Three Months Ended			Nine Months Ended		
	September 30,			September 30,		
	2022	2021	% Change	2022	2021	% Change
Net revenues	\$ 116,463	\$ 53,917	116 %	\$ 264,401	\$ 170,106	55 %
Gross profit	46,192	21,468	115	98,048	90,467	8
Gross margin	40%	40%		37%	53%	
Non-GAAP gross profit	46,629	23,626	97	104,338	93,023	12
Non-GAAP gross margin	40%	44%		39%	55%	
Operating income (loss)	875	(13,013)	NM	(36,392)	(793)	NM
Operating margin	1%	-24%		-14%	0%	
Non-GAAP operating income (loss)	11,372	(8,831)	NM	3,386	6,724	(50)
Non-GAAP operating income (loss)	10%	-16%		1%	4%	
Net income (loss)	5,273	(15,015)	NM	(33,496)	(12,605)	166
Non-GAAP net income (loss)	9,678	(11,044)	NM	(1,056)	(5,357)	(80)
GAAP EPS	0.07	(0.21)	NM	(0.46)	(0.18)	164
Non-GAAP EPS	\$ 0.13	\$ (0.15)	NM %	\$ (0.01)	\$ (0.07)	(80) %

NM – not meaningful

- Net revenues for the third quarter of 2022 were \$116.5 million, a 116% increase from the third quarter of 2021 and a new record for the Company.
- Total InteliSwab® test revenue of \$79.6 million increased 85% sequentially as the company scaled its production capacity and saw increased order volume supporting the Federal government's school testing program.
- Core diagnostic revenue increased 14% versus the prior year primarily due to the contribution from non-product revenue strength which complements domestic HIV sales and international HCV sales. Core Molecular Solutions revenue decreased 24% year-over-year predominantly due to lower order volumes at more consumer-oriented accounts.
- GAAP gross margin percentage was 40% in the quarter compared to 40% in the third quarter of 2021. Gross margins were negatively impacted by product mix on a year-over-year basis but positively impacted by significant efficiencies achieved with the Company's InteliSwab® test production.

Non-GAAP gross margins in the quarter were 40% and flat on a sequential basis as product mix headwinds offset continued efficiency and scale benefits achieved with IntelliSwab® tests and the benefit of higher non-product revenue in the quarter.

- GAAP operating income in the third quarter was \$0.9 million which compares to a (\$13.0) million operating loss in the third quarter of 2021. Non-GAAP operating income was \$11.4 million in the quarter, increased by \$12.7 million on a sequential basis.
- Cash flow from operations in the quarter was \$16.3 million in the third quarter compared to (\$19.1) million used in the third quarter of 2021. OraSure generated positive cash flow from operations ahead of previously stated guidance which called for the Company to achieve positive cash flow from operations in the fourth quarter of 2022. The Company ended the quarter with total cash and cash equivalents balance of \$101.6 million, a \$5.8 million increase from \$95.8 million on a sequential basis.

## Recent Business Highlights

- The Company announced that its IntelliSwab® test has been accepted to be sold by Amazon and fulfilled with eligibility for Prime free shipping.
- Announced IntelliSwab® tests will be offered by a new retail distribution partnership the potential for up to 400 stores nationwide.
- Received U.S. FDA clearance for its ORAcollect•Dx saliva collection device for OTC (i.e. direct-to-consumer) use. OraSure received this designation through its partnership with Grifols to support screening for alpha1-antitrypsin deficiency (alpha-1) in individuals who may be at risk for alpha-1. Alpha-1 raises patients' risks for lung disorders and it is estimated that about 3% of COPD patients have alpha-1. Beginning in Q2 2023, Grifols will offer free AlphaID™ At Home Genetic Health Risk Service, supporting alpha-1 screening, that utilize the ORAcollect®•Dx device to help identify individuals at risk.
- Announced a new partnership with Mars Petcare to create the world's largest biobank around microbiome data for cats and dogs. Samples collected as part of the biobank study will be analyzed and Diversigen will sequence the DNA of the microorganisms in the sample. Mars Petcare scientists will then use the data to generate insights about what cat and dog microbiomes look like over time, including on health and disease.
- The first microbiome based therapeutic received the FDA's Vaccines and Related Biological Products Advisory Committee approval. The Company sees this as a signal of positive catalyst for investment in the microbiome testing services industry.
- The Biomedical Advanced Research and Development Authority (BARDA) has awarded the Company an \$8.6 million contract to develop a 2<sup>nd</sup> generation Ebola test on the OraQuick® testing platform. The goal is for the 2nd generation test to have improved sensitivity, increased shelf life, new chemistry and more automation when compared to its de novo U.S. Food and Drug Administration (FDA) 510(k) authorized test.
- OraSure was selected to provide its OraQuick® In-Home HIV tests in support of the Centers for Disease Control and Preventions (CDC) "Together Take Me Home," HIV self-test program. Under the program, the CDC will provide \$41.5 million in total over a five-year period to support community testing with a portion going to test procurement. Emory University will manage the program overall and closely collaborate with a number of partner organizations, including OraSure, to supply tests to vulnerable communities who may not be equitably reached by other existing HIV testing services across the United States.
- Launched the new OMNIgene® GUT RNA/DNA collection kits. This Research Use Only product, based on the OMNIgene® Gut DNA kit, incorporates a newly developed & validated reagent to stabilize microbial DNA and RNA from human fecal samples.

## Financial Guidance

The Company is guiding toward 4Q22 revenue of \$95 to \$100 million representing 49% to 57% growth relative to the fourth quarter of last year. The Company is also guiding to continued positive cash flow from operations in the fourth quarter.

## Financial Data (Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
<b>Results of Operations</b>				
Net revenues	\$ 116,463	\$ 53,917	\$ 264,401	\$ 170,106
Cost of products and services sold	70,271	32,449	166,353	79,639
Gross profit	46,192	21,468	98,048	90,467
Operating expenses:				
Research and development	9,757	8,596	27,238	25,270
Sales and marketing	13,474	13,886	37,875	33,836
General and administrative	15,527	12,499	52,262	33,680
Loss on impairment	6,559	—	17,101	—
Change in fair value of acquisition-related contingent consideration	—	(500)	(36)	(1,526)
Total operating expenses	45,317	34,481	134,440	91,260
Operating income (loss)	875	(13,013)	(36,392)	(793)
Other income	3,255	100	4,520	429
Income (loss) before income taxes	4,130	(12,913)	(31,872)	(364)
Income tax expense (benefit)	(1,143)	2,102	1,624	12,241
Net income (loss)	\$ 5,273	\$ (15,015)	\$ (33,496)	\$ (12,605)
Earnings (loss) per share:				
Basic	\$ 0.07	\$ (0.21)	\$ (0.46)	\$ (0.18)
Diluted	\$ 0.07	\$ (0.21)	\$ (0.46)	\$ (0.18)
Weighted average shares:				
Basic	72,616	72,023	72,448	71,962
Diluted	72,785	72,023	72,448	71,962

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2022	2021	% Change	2022	2021	% Change
<b>DIAGNOSTICS</b>						
<b>Infectious Disease Testing Revenues</b>						
Domestic HIV	\$ 4,609	\$ 3,440	34 %	\$ 12,115	\$ 12,490	(3) %
International HIV	4,445	6,582	(32)	15,462	17,255	(10)
Net HIV revenues	9,054	10,022	(10)	27,577	29,745	(7)
Domestic HCV	1,866	1,827	2	6,440	5,580	15
International HCV	1,368	888	54	3,742	3,802	(2)
Net HCV revenues	3,234	2,715	19	10,182	9,382	9
Net OraQuick® revenues	12,288	12,737	(4)	37,759	39,127	(3)
COVID-19	79,559	7,675	NM	144,809	7,938	NM
Other infectious disease revenues	(40)	195	(121)	420	537	(22)
Total Infectious Disease	91,807	20,607	346	182,988	47,602	284
Risk Assessment	2,595	2,674	(3)	7,786	7,265	7
Other non-product revenues	3,249	230	NM	5,642	2,501	126
<b>TOTAL DIAGNOSTIC NET REVENUE</b>	<b>97,651</b>	<b>23,511</b>	<b>315</b>	<b>196,416</b>	<b>57,368</b>	<b>242</b>
<b>MOLECULAR SOLUTIONS</b>						
Genomics	\$ 13,980	\$ 19,018	(26)	\$ 44,558	\$ 49,333	(10)
Microbiome	1,761	1,693	4	5,583	5,888	(5)
COVID-19	361	6,255	(94)	9,522	46,209	(79)
Laboratory services	1,957	2,406	(19)	4,895	8,017	(39)
Other product and services revenues	360	576	(38)	1,892	1,235	53
Net product and service revenues	18,419	29,948	(38)	66,450	110,682	(40)
Other non-product and service revenues	393	458	(14)	1,535	2,056	(25)
<b>TOTAL MOLECULAR SOLUTIONS NET REVENUE</b>	<b>18,812</b>	<b>30,406</b>	<b>(38)</b>	<b>67,985</b>	<b>112,738</b>	<b>(40)</b>
<b>TOTAL NET REVENUES</b>	<b>\$ 116,463</b>	<b>\$ 53,917</b>	<b>116 %</b>	<b>\$ 264,401</b>	<b>\$ 170,106</b>	<b>55 %</b>
NM – not meaningful						

### Condensed Consolidated Balance Sheets (Unaudited)

	September 30, 2022		December 31, 2021	
<u>Assets</u>				
Cash and cash equivalents	\$	75,205	\$	116,762
Short-term investments		26,432		36,279
Accounts receivable, net		61,306		45,323
Inventories		78,805		53,138
Other current assets		37,984		36,929
Property, plant and equipment, net		85,184		88,164
Intangible assets, net		11,919		14,343
Goodwill		34,476		40,279
Long-term investments		—		17,009
Other noncurrent assets		20,897		12,764
Total assets	\$	432,208	\$	460,990
<u>Liabilities and Stockholders' Equity</u>				
Accounts payable	\$	40,370	\$	28,024
Deferred revenue		2,536		2,936
Other current liabilities		28,791		37,104
Other non-current liabilities		18,621		12,393
Stockholders' equity		341,890		380,533
Total liabilities and stockholders' equity	\$	432,208	\$	460,990



**Additional Financial Data (Unaudited)****Nine Months Ended  
September 30,**

	2022		2021	
Capital expenditures	\$	29,030	\$	27,508
Depreciation and amortization	\$	11,391	\$	8,479
Stock-based compensation	\$	9,100	\$	5,155
Cash used in operating activities	\$	29,190	\$	22,598

**Conference Call**

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's third 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/BI4fc0d4827252407b870a0eab336a7950>

To listen to the webcast, go to OraSure Technologies' web site, [www.orasure.com](http://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 IntelliSwab®**

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

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

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 IntelliSwab® COVID-19 Rapid Test has been funded in whole or in part with federal funds from the HHS; the Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority, under

contract numbers 75A50120C00061 and 75A50121C00078, utilizing Health Care Enhancement Act (HCEA) funding. The DoD's Defense Assisted Acquisition (DA2) Cell led the manufacturing expansion effort for the IntelliSwab® COVID-19 rapid test in coordination with the Department of the Air Force's Acquisition COVID-19 Task Force (DAF ACT). The manufacturing effort was funded through the American Rescue Plan Act (ARPA) to enable and support domestic industrial base expansion for critical medical resources.

## **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](http://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 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue	\$ 116,463	\$ 53,917	\$ 264,401	\$ 170,106
GAAP Cost of Goods Sold	70,271	32,449	166,353	79,639
GAAP Gross Margin	40%	40%	37%	53%
Stock compensation	(114)	276	191	410
Amortization of acquisition-related intangible assets	132	132	396	396
Transformation related expenses	419	-	1,334	-
Inventory reserve for excess levels	-	1,750	4,369	1,750
Non-GAAP Cost of Goods Sold	69,834	30,291	160,063	77,083
Non-GAAP Gross Margin	40%	44%	39%	55%
GAAP Operating Income (Loss)	875	(13,013)	(36,392)	(793)
Stock compensation	2,296	2,219	6,805	5,157
Amortization of acquisition-related intangible assets	468	713	1,470	2,136
Inventory reserve for excess levels	-	1,750	4,369	1,750
Loss on impairment	6,559	-	17,101	-
Transformation related expenses	616	-	5,671	-
Severance expense	558	-	3,550	-
Strategic alternative costs	-	-	848	-
Change in fair value of acquisition-related contingent consideration	-	(500)	(36)	(1,526)
Non-GAAP Operating Income (Loss)	11,372	(8,831)	3,386	6,724
GAAP Net Income (Loss)	5,273	(15,015)	(33,496)	(12,605)
Stock compensation	2,296	2,219	6,805	5,157
Amortization of acquisition-related intangible assets	468	713	1,470	2,136
Inventory reserve for excess levels	-	1,750	4,369	1,750
Loss on impairment	6,559	-	17,101	-
Transformation related expenses	616	-	5,671	-
Severance expense	558	-	3,550	-
Strategic alternative costs	-	-	848	-
Change in fair value of acquisition-related contingent consideration	-	(500)	(36)	(1,526)
Tax effect of Non-GAAP adjustments	(6,092)	(211)	(7,338)	(269)
Non-GAAP Net Income (Loss)	\$ 9,678	\$ (11,044)	\$ (1,056)	\$ (5,357)
GAAP Earnings (Loss) Per Share:	\$ 0.07	\$ (0.21)	\$ (0.46)	\$ (0.18)
Non-GAAP Earnings (Loss) Per Share:	\$ 0.13	\$ (0.15)	\$ (0.01)	\$ (0.07)
Diluted Shares Outstanding	72,785	72,023	72,448	71,962

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.
- Transformation related expenses: transitory costs such as consulting and professional fees related to transformation initiatives.

- Loss on impairment: charges related to the write down of company assets including PP&E and Goodwill
- 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
- 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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