
**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): August 3, 2023

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 August 3, 2023, OraSure Technologies, Inc. (the “Company”) issued a press release announcing its consolidated financial results for the quarter ended June 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 August 3, 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 June 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	<u>Press Release, dated August 3, 2023, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter ended June 30, 2023 and certain other matters.</u>
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: August 3, 2023

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



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

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

OraSure Reports Q2 '23 Revenue of \$85.4 Million; Core Revenue Grows 3% Year-over-Year

InteliSwab® test revenue of \$47.5 million in Q2

Q2 Core revenue of \$37.9 million grew 4% sequentially and 3% year-over-year

Q2 GAAP EPS of \$(0.07); Q2 Non-GAAP EPS of \$0.09

Grew cash balance to \$185.9 million as of June 30, 2023

InteliSwab® orders are expected to generate at least \$70 million of revenue in second half of 2023

On track to achieve operating cash flow breakeven on core business by end of 2024

BETHLEHEM, PA, August 3, 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 June 30, 2023.

“This quarter we continued to deliver clear progress on our transformation journey. Our disciplined execution on our priorities, including InteliSwab® contracts and enterprise-wide operating efficiencies, allowed us to generate positive operating cash flow and build our cash balance to \$186 million as of June 30, 2023. We expect to drive additional productivity enhancements across our organization as part of our multi-year commitment to strengthen our foundation, such as facility consolidation, further leveraging automation, and controlling our non-production costs. As a result, we continue to believe we will achieve our target of breakeven 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 demonstrated solid progress in the second quarter with core revenue growth on both a sequential and a year-over-year basis. We are also investing to support and enhance our leadership position and elevate our growth in our key portfolios. Additionally, we gained visibility to InteliSwab® order trends for the second half of this year. Overall, we believe that the progress we are making positions the Company to further drive profitable growth and deliver shareholder value.”

Financial Highlights

	Three Months Ended June 30,			Six Months Ended June 30,		
	2023	2022	% Change	2023	2022	% Change
Core Business	\$ 37,934	\$ 36,853	3 %	\$ 74,488	\$ 73,527	1 %
COVID-19	47,507	43,378	10	165,916	74,411	123
Total Net Revenue	\$ 85,441	\$ 80,231	6 %	\$ 240,404	\$ 147,938	63 %

	Three Months Ended June 30,			Six months ended June 30,		
	2023	2022	% Change	2023	2022	% Change
Net revenues	\$ 85,441	\$ 80,231	6 %	\$ 240,404	\$ 147,938	63 %
Gross profit	26,371	27,797	(5)	92,186	52,096	77
Gross margin	30.9 %	34.6 %		38.3 %	35.2 %	
Non-GAAP gross profit	35,866	32,422	11	95,193	57,949	64
Non-GAAP gross margin	42.0 %	40.4 %		39.6 %	39.2 %	
Operating income (loss)	(6,429)	(21,471)	70	17,892	(37,643)	NM
Operating margin	(7.5)%	(26.8)%		7.4 %	(25.4)%	
Non-GAAP operating income (loss)	6,726	(1,162)	NM	32,434	(5,451)	NM
Non-GAAP operating margin	7.9 %	(1.4)%		13.5 %	(3.7)%	
Net income (loss)	(4,796)	(18,589)	74	22,423	(38,529)	NM
Non-GAAP net income (loss)	6,604	\$ 169	NM	34,209	(10,493)	NM
GAAP EPS	\$ (0.07)	\$ (0.26)	74	\$ 0.30	\$ (0.53)	NM
Non-GAAP EPS	\$ 0.09	\$ 0.00	NM	\$ 0.46	\$ (0.15)	NM

NM - not meaningful

- Net revenues for the second quarter of 2023 were \$85.4 million, a 6% increase from the second quarter of 2022.
- InteliSwab® test revenue of \$47.5 million in the second quarter grew 10% year-over-year but decreased 60% sequentially as test volumes declined from the record levels experienced in the prior quarter.
- Core revenue (excluding COVID-19 revenues) of \$37.9 million in the second quarter grew 4% sequentially and 3% year-over-year. Core revenue growth was driven by strong HIV sales in the U.S. and international markets. Molecular product revenue in the quarter increased 1% sequentially but declined on a year-over-year basis, which was in line with our expectations.
- GAAP gross margin percentage was 30.9% in the second quarter of 2023 compared to 34.6% in the second quarter of 2022 and compared to 42.5% in the first quarter of 2023. GAAP gross margin in the second quarter of 2023 includes \$7 million of accelerated depreciation expense

related to the wind-down of manufacturing operations in Thailand. Non-GAAP gross margins in the second quarter of 2023 were 42.0% compared to 40.4% in the second quarter of 2022 and compared to 42.8% in the first quarter of 2023¹. Excluding the impact of the accelerated depreciation and other non-GAAP adjustments, on a year-over-year basis, gross margins benefited from certain cost reductions, including a reduction in headcount, IntelliSwab® packaging redesign, and lower freight costs.

- GAAP operating loss in the second quarter of 2023 was \$6.4 million which compares to a \$21.5 million operating loss in the second quarter of 2022. Non-GAAP operating income was \$6.7 million in the second quarter of 2023 compared to a \$1.2 million non-GAAP operating loss in the second quarter of 2022.
- Cash and cash equivalents increased to \$185.9 million as of June 30, 2023. The \$73.5 million increase in our cash balance during the second quarter of 2023 was primarily driven by strong collections of accounts receivable. We also received \$17.8 million from the U.S. government related to our manufacturing expansion contract.

Recent Business Highlights

- Received purchase orders in July 2023 under existing contracts for delivery of IntelliSwab® devices. These orders are expected to generate at least \$70 million of revenue in the second half of 2023.
- Signed a collaboration to work on a multi-year project with the Regeneron Genetics Center® (RGC), a wholly-owned subsidiary of Regeneron Pharmaceuticals, Inc. that focuses on early gene discovery and functional genomics. RGC has chosen the OraGeneDx® device for all saliva collection requirements, along with leveraging OraSure's in-house kitting and single-order fulfillment services to remodel its DNA collection workflow.
- Continued progress on consolidating our manufacturing footprint to drive operating efficiencies, including re-shoring some of our capacity to the United States. We continue to make progress on the installation and testing of new equipment and automation capabilities at our new Opus Way facility in Bethlehem, Pa., in addition to our existing OraQuick® device automated production. As discussed in prior quarters, we expect this phase of the expansion to be completed in 2023, with additional facility consolidation to follow.
- Signed an agreement with the International Vaccine Institute (IVI) to utilize our Colli-Pee® first-void urine collection kits as part of a research study to understand the burden of human papillomavirus (HPV) among girls and women in low and lower middle-income countries.
- On track to achieve operating cash flow breakeven for the core business by the end of 2024.

Financial Guidance

The Company is guiding to Q3 2023 revenue of \$72 to \$77 million, which includes core revenue of \$37 to \$39 million and IntelliSwab® revenue of \$35 to \$38 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.

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.

Financial Data (Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Results of Operations				
Net revenues	\$ 85,441	\$ 80,231	\$ 240,404	\$ 147,938
Cost of products and services sold	59,070	52,434	148,218	95,842
Gross profit	26,371	27,797	92,186	52,096
Operating expenses:				
Research and development	7,661	9,463	18,221	18,097
Sales and marketing	8,535	11,684	20,677	24,401
General and administrative	16,424	17,579	34,135	36,735
Loss on impairment	215	10,542	1,320	10,542
Change in fair value of acquisition-related contingent consideration	(35)	—	(59)	(36)
Total operating expenses	32,800	49,268	74,294	89,739
Operating income (loss)	(6,429)	(21,471)	17,892	(37,643)
Other income	1,467	1,713	4,140	1,881
Income (loss) before income taxes	(4,962)	(19,758)	22,032	(35,762)
Income tax expense (benefit)	(166)	(1,169)	(391)	2,767
Net income (loss)	\$ (4,796)	\$ (18,589)	\$ 22,423	\$ (38,529)
Earnings (loss) per share:				
Basic	\$ (0.07)	\$ (0.26)	\$ 0.31	\$ (0.53)
Diluted	\$ (0.07)	\$ (0.26)	\$ 0.30	\$ (0.53)
Weighted average shares:				
Basic	73,324	72,496	73,219	72,361
Diluted	73,324	72,496	74,115	72,361

	Three Months Ended June 30,			Six Months Ended June 30,			
	2023	2022	% Change	2023	2022	% Change	
COVID-19 Diagnostics	\$ 47,477	\$ 43,114	10 %	\$ 165,731	\$ 65,250	154 %	
Diagnostics	19,834	14,048	41	36,924	25,471	45	
Molecular Products	13,050	17,581	(26)	25,992	35,514	(27)	
Other products and services	2,993	2,956	1	6,087	6,069	—	
Molecular Services	1,354	1,204	12	2,733	2,938	(7)	
COVID-19 Molecular Products	30	264	(89)	185	9,161	(98)	
Net product and services revenues	84,738	79,167	7	237,652	237,652	144,403	65
Non-product and services revenues	703	1,064	(34)	2,752	3,535	(22)	
Net revenues	\$ 85,441	\$ 80,231	6 %	\$ 240,404	\$ 147,938	63 %	

Condensed Consolidated Balance Sheets (Unaudited)

	<u>June 30, 2023</u>	<u>December 31, 2022</u>
<u>Assets</u>		
Cash and cash equivalents	\$ 185,936	\$ 83,980
Short-term investments	—	26,867
Accounts receivable, net	52,750	70,797
Inventories	73,284	95,704
Other current assets	29,597	47,842
Property, plant and equipment, net	49,282	59,413
Intangible assets, net	10,665	11,694
Goodwill	35,606	35,104
Other noncurrent assets	16,474	12,779
Total assets	<u>\$ 453,594</u>	<u>\$ 444,180</u>
<u>Liabilities and Stockholders' Equity</u>		
Accounts payable	\$ 17,753	\$ 38,020
Deferred revenue	1,841	2,273
Other current liabilities	26,826	28,770
Other non-current liabilities	13,035	10,692
Stockholders' equity	394,139	364,425
Total liabilities and stockholders' equity	<u>\$ 453,594</u>	<u>\$ 444,180</u>

Additional Financial Data (Unaudited)

	<u>Six Months Ended June 30,</u>	
	<u>2023</u>	<u>2022</u>
Capital expenditures	\$ 6,927	\$ 59,243
Proceeds from funding under government contract ⁽¹⁾	\$ 17,793	\$ 33,962
Depreciation and amortization	\$ 14,011	\$ 7,464
Stock-based compensation	\$ 5,012	\$ 6,804
Cash provided by (used in) operating activities	\$ 63,270	\$ (45,489)

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

Consolidated Statement of Cash Flows (Unaudited)

	Six Months Ended June 30,	
	2023	2022
OPERATING ACTIVITIES:		
Net income (loss)	\$ 22,423	\$ (38,529)
Adjustments to reconcile net income (loss) to net cash (used in) provided by operating activities:		
Stock-based compensation	5,012	6,804
Depreciation and amortization	14,011	7,464
Loss on impairments	1,320	10,542
Other non-cash amortization	1	313
Provision for credit losses	(478)	(152)
Unrealized foreign currency gain (loss)	106	(62)
Interest expense on finance leases	28	55
Deferred income taxes	(1,815)	361
Loss on sale of fixed assets	—	718
Change in the estimated fair value of acquisition-related contingent consideration	(59)	(36)
Payment of acquisition-related contingent consideration	(19)	—
Changes in assets and liabilities:		
Accounts receivable	18,652	(18,646)
Inventories	22,556	(18,179)
Prepaid expenses and other assets	5,495	(4,416)
Accounts payable	(22,187)	11,485
Deferred revenue	(450)	(252)
Accrued expenses and other liabilities	(1,326)	(2,959)
Net cash provided by (used in) operating activities	63,270	(45,489)
INVESTING ACTIVITIES:		
Purchases of investments	—	—
Proceeds from maturities and redemptions of investments	27,305	23,017
Purchases of property and equipment	(2,893)	(25,440)
Purchase of property and equipment under government contracts	(4,034)	(33,803)
Proceeds from funding under government contract ⁽¹⁾	17,793	33,962
Net cash provided by (used in) investing activities	38,171	(2,264)
FINANCING ACTIVITIES:		
Cash payments for lease liabilities	(320)	(392)
Proceeds from exercise of stock options	66	15
Payment of acquisition-related contingent consideration	(46)	(208)
Repurchase of common stock	(1,663)	(1,954)
Net cash used in financing activities	(1,963)	(2,539)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	2,478	(311)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	101,956	(50,603)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	83,980	116,762
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 185,936	\$ 66,159

(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 second 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/Bla2ec244bbd894460808bcc1818c5136e>

About IntelliSwab®

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

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

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

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; 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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenue	\$ 85,441	\$80,231	\$ 240,404	\$ 147,938
GAAP Cost of products and services sold	59,070	52,434	148,218	95,842
<i>GAAP Gross Margin</i>	30.9 %	34.6 %	38.3 %	35.2 %
Stock compensation	155	155	289	305
Amortization of acquisition-related intangible assets	132	132	264	264
Reduction in workforce severance	334	—	369	—
Transformation related expenses	120	544	281	915
Accelerated depreciation	6,950	—	—	—
Inventory reserve for excess levels	1,804	3,794	1,804	4,369
Non-GAAP Cost of Goods Sold	49,575	47,809	145,211	89,989
<i>Non-GAAP Gross Margin</i>	42.0 %	40.4 %	39.6 %	39.2 %
GAAP Operating Income (Loss)	(6,429)	(21,471)	17,892	(37,643)
Stock compensation	2,357	2,447	5,012	6,804
Amortization of acquisition-related intangible assets	466	501	932	1,002
Reduction in workforce severance	629	—	3,264	—
Accelerated depreciation	6,950	—	—	—
Inventory reserve for excess levels	1,804	3,794	1,804	4,369
Loss on impairment	215	10,542	1,320	10,542
Transformation related expenses	232	902	681	5,055
Executive severance expense	—	1,531	—	2,992
Strategic alternative costs	—	197	—	848
Government grant accounting	537	395	1,588	616
Change in fair value of acquisition-related contingent consideration	(35)	—	(59)	(36)
Non-GAAP Operating Income (Loss)	6,726	(1,162)	32,434	(5,451)
GAAP Net Income (Loss)	(4,796)	(18,589)	\$ 22,423	(38,529)
Stock compensation	2,357	2,447	5,012	4,509
Amortization of acquisition-related intangible assets	466	501	932	1,002
Reduction in workforce severance	629	—	3,264	—
Accelerated depreciation	6,950	—	—	—
Inventory reserve for excess levels	1,804	3,794	1,804	4,369
Loss on impairment	215	10,542	1,320	10,542
Transformation related expenses	232	902	681	5,055
Executive severance expense	—	1,531	—	2,992
Strategic alternative costs	—	197	—	848
Change in fair value of acquisition-related contingent consideration	(35)	—	(59)	(36)
Tax effect of Non-GAAP adjustments	(1,218)	(1,156)	(1,168)	(1,245)
Non-GAAP Net Income (Loss)	\$ 6,604	\$ 169	\$ 34,209	\$ (10,493)
GAAP Earnings (Loss) Per Share:	\$ (0.07)	\$ (0.26)	\$ 0.30	\$ (0.53)
Non-GAAP Earnings (Loss) Per Share:	\$ 0.09	\$ 0.00	\$ 0.46	\$ (0.15)
Diluted Shares Outstanding	74,290	72,496	74,115	72,361

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
- 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 be found at: <https://orasure.gcs-web.com/gAAP-non-gAAP-reconciliation>

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