

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 9, 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 August 9, 2022, OraSure Technologies, Inc. (the “Company”) issued a press release announcing its consolidated financial results for the quarter ended June 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 August 9, 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 Scott Gleason, the Company’s Senior Vice President, Investor Relations and Corporate Communications, discussed the Company’s consolidated financial results for the quarter ended June 30, 2022, and described certain business developments. A copy of the slide presentation used during the conference call is furnished as Exhibit 99.2 to this Form 8-K and is incorporated herein by reference.

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="#"><u>Press Release, dated August 9, 2022, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter ended June 30, 2022 and certain other matters.</u></a>
99.2	<a href="#"><u>Slide Presentation for OraSure Technologies, Inc. Second Quarter 2022 Analyst/Investor Conference Call Held August 9, 2022.</u></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: August 9, 2022

By: /s/ Carrie Eglinton-Manner

Carrie Eglinton-Manner

President and Chief Executive Officer



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**OraSure Reports 2Q22 Record Revenue of \$80.2 Million Growing 39% Year-Over-Year**

*InteliSwab® revenue of \$43.1 million in Q2, up 95% sequentially with significant scaling in production*

*InteliSwab® gross margins improve sequentially by over 2,000 basis points*

*GAAP gross margin of 34.4%, a decrease of 200 basis points sequentially; non-GAAP gross margins improve 250 basis points sequentially to 40.1% despite headwinds*

*Q2 GAAP EPS of (\$0.26) and non-GAAP EPS of (\$0.00)*

*Company expects to generate positive cash flow in the 4Q22*

*Announces strategic transformation, including appointment of new Chief Financial Officer and changes in the Board of Directors to occur in November*

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

BETHLEHEM, PA, August 9, 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 June 30, 2022.

"This quarter we delivered strong revenue growth driven by InteliSwab® which helped offset headwinds in our core business. We have commenced our strategic transformation with a three-part approach intended to strengthen our foundation, elevate our existing lines of business and accelerate growth. Our team also made significant progress in cost productivity and manufacturing efficiency priorities which we believe will lead to positive cash flow later this calendar year," said OraSure President and CEO Carrie Eglinton Manner.

She continued, "Our teams are committed to innovating and operating with disciplined execution and accountability across the organization. We see an important strategic niche for OraSure as a Company leveraging our strengths in the face of current shifts in healthcare delivery. We are dedicated to facilitating testing and sample collection for patients at the point of care. In further evolving our organization's strategic plan, we will provide updates on our progress. We are committed to driving sustained profitable growth over the long-term and to unlocking shareholder value."

## Financial Highlights

- Net revenues for the second quarter of 2022 were \$80.2 million, a 39% increase from the second quarter of 2021 and a new record for the Company.
- Total revenues from the Company's Diagnostic business unit were \$60.4 million during the second quarter of 2022 and grew 213% relative to the same period last year. Revenue growth was driven by IntelliSwab® which grew 95% sequentially and offset a 10% decline in the base Diagnostic business.
- Total product and service revenues for the Company's Molecular Solutions business unit were \$19.8 million during the second quarter of 2022, an increase of 1% sequentially and a decline of 48% from the second quarter of 2021. The reduction from 2Q21 was driven predominantly by changes in COVID-19 laboratory testing and the associated drop in the Company's COVID-19 molecular collection kits.
- GAAP gross margins in the quarter were 34.4% compared to 53.2% in the second quarter of last year. On a non-GAAP basis, gross margins this quarter improved 250 basis points sequentially to 40.1% based predominantly on improvements in IntelliSwab® manufacturing which offset the impact of product mix changes.
- GAAP operating loss in the second quarter of 2022 was \$21.3 million compared to operating income of \$1.8 million in the second quarter of last year and GAAP operating loss of 16.0 million in the first quarter of 2022. The Company's GAAP operating loss included the impact of the \$3.8 million inventory reserve and \$10.5 million in expenses tied to goodwill impairment and long-lived asset impairment. On a non-GAAP basis, the Company's operating income improved by \$5.2 million sequentially to a \$1.4 million loss reflecting the significant improvements in IntelliSwab® gross margins and expense control.
- Cash flow used in operations in the quarter was \$9.7 million due mostly to working capital changes associated with the IntelliSwab® scale-up. Cash and investments totaled \$95.8 million as of June 30, 2022.

## Recent Business Highlights

### IntelliSwab® COVID-19 Testing

- IntelliSwab® revenue in the quarter grew to \$43.1 million representing over 95% sequential growth relative to the first quarter.
- Production volumes of IntelliSwab® scaled dramatically during the second quarter, and the Company has current capacity to produce approximately 1.6 million tests per week. The Company expects this capacity to nearly double by early 2023 given the opening of a new facility, hiring of new employees, and validation of additional production equipment.
- Weekly production output for IntelliSwab® has increased approximately 14X since launch based upon dozens of processing step enhancements which have dramatically improved yield. Gross margins for IntelliSwab® improved by over 2,000 basis points in the quarter based upon these manufacturing efficiencies and better overhead absorption.
- OraSure has now received more than \$400 million in delivery orders from the US Defense Logistics Agency (DLA) under the Company's procurement contract supporting the U.S. Department of Health and Human Services (HHS). The Company has been informed that HHS/DLA can continue to provide shipping instructions against these Delivery Orders past the contract expiration date of September 13, 2022.

### **Diagnostics Business Results (excluding IntelliSwab®)**

- Excluding IntelliSwab® revenue, Diagnostics base business revenue was \$17.3 million in the quarter and declined 10% compared to the prior year quarter. Year-to-date Diagnostics base business revenue was relatively flat.
- International Diagnostics revenue was \$7.8M in Q2, a 9% decline compared to the prior year period. Over half of the international revenue decline was due to the one-time restock in Q2 2021 of HCV professional tests in Asia as COVID-19 receded. In addition, the expiration of the Bill and Melinda Gates Foundation subsidy for HIV self-tests occurred in the second quarter of last year. Excluding this subsidy international revenue declined 5% in the quarter.
- U.S. Diagnostics revenue, excluding IntelliSwab®, declined 10% year-over-year due to the lapping of revenue associated with the Center for Disease Control's, "Let's Stop HIV Together," home testing program in Q2 2021. This program procured our OraQuick® HIV OTC tests and sent them to consumer's homes in Q1 and Q2 of 2021.

### **Molecular Solutions**

- Core collection kits declined 21% in the quarter on a year-over-year basis, as expected following timing shifts which positively impacted Q1 results. YTD core collection kits were relatively flat and grew 1% sequentially relative to the first quarter.
- Sales of OraSure's sample collection devices for molecular/PCR COVID-19 testing decreased significantly year-over-year to \$0.3 million in the second quarter of 2022 compared to \$12.0 million in the prior year period. The decline is due to the continued transition to COVID-19 point of care solutions and decreases in laboratory testing following reimbursement changes.
- Total microbiome revenue, including kits and services, was \$3.0 million in the quarter and declined 45% relative to the second quarter of last year. During the quarter, kits and services revenue was negatively impacted by the timing of customer clinical trials, shifts in research funding and the market exit of a key customer.
- 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 3Q22 revenue of \$90 to \$95 million representing 67% to 76% growth relative to the third quarter of last year. The Company also anticipates continued improvements in gross margins, and improved cash flow from operations in the third quarter. As such, the Company is guiding to having positive cash flow from operations beginning in the fourth quarter of this fiscal year.

### **New Chief Financial Officer**

OraSure has appointed Kenneth J. McGrath as the Company's new Chief Financial Officer, effective August 8, 2022. Mr. McGrath replaces Scott Gleason, who has served as the interim Chief Financial Officer and will continue in his role leading Investor Relations and Corporate Communications going forward. Mr. McGrath joined Quest Diagnostics in February 2014 and most recently served as Vice President in Finance, where he led an organization responsible for over \$7 billion in revenue. He helped build Quest's Advanced Diagnostics business accelerating growth while improving profitability with expanded capabilities and new innovation. His expertise also includes value creation via partnerships and successfully assessing and integrating multiple

acquisitions. Mr. McGrath's finance operating responsibility also spanned information technology, R&D and medical functions, as well as commercial regions amongst other responsibilities. Prior to his time at Quest, Mr. McGrath held various leadership positions in finance operating roles at Johnson & Johnson Inc. He began his career at Ford Motor Company, received an M.B.A from the University of Michigan and a B.S from the University of Notre Dame, and is a CFA Charterholder.

#### **Changes to Board of Directors**

- As part of OraSure's strategic transformation, we are also announcing important changes to our Board of Directors. On August 8, 2022, each of Michael Celano, Chairman of the Board, Ronny Lancaster, and Eamonn Hobbs resigned from the Board, to be effective November 8, 2022. Upon the effectiveness of such resignations, we will reduce our Board size from 10 to 7. We thank Mr. Celano, Mr. Lancaster, and Mr. Hobbs for their many committed years of service.
- In addition, effective November 8, 2022, Mara G. Aspinall will be appointed as Chair of the Board. Ms. Mara G. Aspinall, MBA, is a diagnostic industry leader and pioneer. Ms. Aspinall is Managing Director of Health Catalysts Group and BlueStone Venture Partners following her 30-year operating career in diagnostics where she served in many executive roles, including Chief Executive of Ventana Medical Systems, now Roche Tissue Diagnostics, as well as Genzyme Genetics. An author and frequent speaker, Ms. Aspinall co-founded the Biomedical Diagnostics Master Degree program at Arizona State University.

#### **Inducement Awards**

On August 8, 2022, OraSure granted Ken McGrath, OraSure's newly appointed Chief Financial Officer, an inducement award of 131,883 shares of restricted stock. The restricted stock granted to Mr. McGrath will vest in three equal annual installments, on the first, second and third anniversaries of the grant date, subject in each case to Mr. McGrath's continued employment through the relevant vesting date.

In addition, on August 8, 2022, OraSure granted Zachary Wert, the Company's newly appointed Senior Vice President, Global Operations, an inducement award of 49,456 shares of restricted stock. The restricted stock granted to Mr. Wert will vest in full on August 8, 2023, subject to Mr. Wert's continued employment through that date.

The inducement awards for each of Mr. McGrath and Mr. Wert were approved by OraSure's Board of Directors, and were granted pursuant to Nasdaq Listing Rule 5635(c)(4), as an inducement material their acceptance of employment with OraSure.

**Financial Data (Unaudited)**

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2022	2021	2022	2021
<b>Results of Operations</b>				
Net revenues	\$ 80,231	\$ 57,607	\$ 147,938	\$ 116,189
Cost of products and services sold	52,647	26,934	96,082	47,190
Gross profit	27,584	30,673	51,856	68,999
Operating expenses:				
Research and development	9,068	7,682	17,481	16,674
Sales and marketing	11,684	10,420	24,401	19,950
General and administrative	17,579	10,993	36,735	21,181
Goodwill and long-lived assets impairment charges	10,542	-	10,542	-
Change in fair value of acquisition-related contingent consideration	-	(220)	(36)	(1,026)
Total operating expenses	48,873	28,875	89,123	56,779
Operating income (loss)	(21,289)	1,798	(37,267)	12,220
Other income	1,318	448	1,265	329
Income (loss) before income taxes	(19,971)	2,246	(36,002)	12,549
Income tax expense	(1,169)	3,610	2,767	10,139
Net income (loss)	\$ (18,802)	\$ (1,364)	\$ (38,769)	\$ 2,410
Earnings (loss) per share:				
Basic	\$ (0.26)	\$ (0.02)	\$ (0.54)	\$ 0.03
Diluted	\$ (0.26)	\$ (0.02)	\$ (0.54)	\$ 0.03
Weighted average shares:				
Basic	72,496	71,983	72,361	71,931
Diluted	72,496	71,983	72,361	72,683

	Three Months Ended			Six Months Ended		
	June 30,			June 30,		
	2022	2021	% Change	2022	2021	% Change
<b>DIAGNOSTICS</b>						
<b>Infectious Disease Testing Revenues</b>						
Domestic HIV	\$ 3,741	\$ 4,135	(10) %	\$ 7,506	\$ 9,050	(17) %
International HIV	6,616	6,809	(3)	11,017	10,672	3
Net HIV revenues	10,357	10,944	(5)	18,523	19,722	(6)
Domestic HCV	2,537	2,571	(1)	4,574	3,754	22
International HCV	1,154	1,729	(33)	2,374	2,914	(19)
Net HCV revenues	3,691	4,300	(14)	6,948	6,668	4
Net OraQuick® revenues	14,048	15,244	(8)	25,471	26,390	(3)
COVID-19	43,114	89	NM	65,250	262	NM
Other infectious disease revenues	184	290	(37)	460	342	35
Total Infectious Disease	57,346	15,623	267	91,181	26,994	238
<b>Risk Assessment</b>	2,630	2,629	—	5,191	4,591	13
<b>Other non-product revenues</b>	479	1,059	(55)	2,393	2,272	5
<b>TOTAL DIAGNOSTIC NET REVENUE</b>	<b>60,455</b>	<b>19,311</b>	<b>213</b>	<b>98,765</b>	<b>33,857</b>	<b>192</b>
<b>MOLECULAR SOLUTIONS</b>						
Genomics	\$ 15,486	\$ 19,498	(21)	\$ 30,578	\$ 30,316	1
Microbiome	1,832	2,447	(25)	3,822	4,198	(9)
COVID-19	264	11,981	(98)	9,161	39,953	(77)
Laboratory services	1,204	3,114	(61)	2,938	5,611	(48)
Other product and services revenues	405	449	(10)	1,532	657	133
Net product and service revenues	19,191	37,489	(49)	48,031	80,735	(41)
Other non-product and service revenues	585	807	(28)	1,142	1,597	(28)
<b>TOTAL MOLECULAR SOLUTIONS NET REVENUE</b>	<b>19,776</b>	<b>38,296</b>	<b>(48)</b>	<b>49,173</b>	<b>82,332</b>	<b>(40)</b>
<b>TOTAL NET REVENUES</b>	<b>\$ 80,231</b>	<b>\$ 57,607</b>	<b>39 %</b>	<b>\$ 147,938</b>	<b>\$ 116,189</b>	<b>27 %</b>

**Condensed Consolidated Balance Sheets (Unaudited)**

	<u>June 30, 2022</u>		<u>December 31, 2021</u>	
<u>Assets</u>				
Cash and cash equivalents	\$	66,159	\$	116,762
Short-term investments		29,625		36,279
Accounts receivable, net		62,886		45,323
Inventories		71,304		53,138
Other current assets		37,332		36,929
Property, plant and equipment, net		93,697		88,164
Intangible assets, net		12,851		14,343
Goodwill		36,038		40,279
Long-term investments		-		17,009
Other noncurrent assets		19,362		12,764
Total assets	\$	<u>429,254</u>	\$	<u>460,990</u>
<u>Liabilities and Stockholders' Equity</u>				
Accounts payable	\$	36,226	\$	28,024
Deferred revenue		2,660		2,936
Other current liabilities		26,600		37,104
Other non-current liabilities		19,576		12,393
Stockholders' equity		344,192		380,533
Total liabilities and stockholders' equity	\$	<u>429,254</u>	\$	<u>460,990</u>

**Additional Financial Data (Unaudited)**

	<u>Six Months Ended</u>			
	<u>June 30,</u>			
	<u>2022</u>		<u>2021</u>	
Capital expenditures	\$	25,281	\$	22,929
Depreciation and amortization	\$	7,777	\$	5,524
Stock-based compensation	\$	6,804	\$	2,937
Cash used in operating activities	\$	45,489	\$	3,472

**Conference Call**

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's second 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, Lisa Nibauer, President Diagnostics, Kathleen Weber, President Molecular Solutions, 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 dial (866) 374-5140 and reference Conference ID #11565698 or 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<sup>®</sup> COVID-19 rapid tests. The FDA has authorized the IntelliSwab<sup>®</sup> COVID-19 Rapid Test for Over-the-Counter (OTC) use without a prescription. The FDA has also authorized the IntelliSwab<sup>®</sup> COVID-19 Rapid Test Pro for professional use in point of care (POC) CLIA-waived settings, and the IntelliSwab<sup>®</sup> 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. IntelliSwab<sup>®</sup>'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<sup>®</sup> 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<sup>®</sup> 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).

## Important Information

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 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		Three Months Ended	
	Mar 31,	June 30,	Mar 31,	June 30,
	2022	2022	2021	2021
Revenue	\$ 67,707	\$ 80,231	\$ 58,582	\$ 57,607
GAAP Cost of Goods Sold	43,435	52,647	20,256	26,934
<i>GAAP Gross Margin</i>	36%	34%	65%	53%
Stock compensation	150	155	62	72
Amortization of acquisition-related intangible assets	132	132	132	132
Transformation related expenses	371	544	-	-
Inventory reserve for excess levels	575	3,794	-	-
Non-GAAP Cost of Goods Sold	42,207	48,022	20,062	26,730
<i>Non-GAAP Gross Margin</i>	38%	40%	66%	54%
GAAP Operating Income (Loss)	(15,978)	(21,289)	10,422	1,798
Stock compensation	2,062	2,447	1,464	1,474
Amortization of acquisition-related intangible assets	501	501	705	718
Inventory reserve for excess levels	575	3,794	-	-
Goodwill and long-lived assets impairment charges	-	10,542	-	-
Transformation related expenses	4,153	902	-	-
Severance expense	1,461	1,531	-	-
Strategic alternative costs	651	197	-	-
Change in fair value of acquisition-related contingent consideration	(36)	-	(806)	(220)
Non-GAAP Operating Income (Loss)	(6,611)	(1,375)	11,785	3,770
GAAP Net Income (Loss)	(19,967)	(18,802)	3,774	(1,364)
Stock compensation	2,062	2,447	1,464	1,474
Amortization of acquisition-related intangible assets	501	501	705	718
Inventory reserve for excess levels	575	3,794	-	-
Goodwill and long-lived assets impairment charges	-	10,542	-	-
Transformation related expenses	4,153	902	-	-
Severance expense	1,461	1,531	-	-
Strategic alternative costs	651	197	-	-
Change in fair value of acquisition-related contingent consideration	(36)	-	(806)	(220)
Tax effect of Non-GAAP adjustments	(89)	(1,156)	(80)	21
Non-GAAP Net Income (Loss)	\$ (10,689)	\$ (44)	\$ 5,057	\$ 629
GAAP Earnings (Loss) Per Share:	\$ (0.28)	\$ (0.26)	\$ 0.05	\$ (0.02)
Non-GAAP Earnings (Loss) Per Share:	\$ (0.15)	\$ (0.00)	\$ 0.07	\$ 0.01
Diluted Shares Outstanding	72,194	72,496	72,766	71,983

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.
- Goodwill and long-live assets impairment charge: 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: one-time 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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# OraSure 2Q22 Earnings

August 9, 2022



# Required Disclosures

## Forward Looking Statement

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 genomics 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. Those 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.

## Non-GAAP Financial Measures

NON-GAAP FINANCIAL MEASURES In this presentation, the Company's financial results are provided in accordance with accounting principles generally accepted in the United States ("GAAP") and using certain non-GAAP financial measures. Management believes that presentation of operating results using 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. Management also uses non-GAAP financial measures to establish budgets and to manage the Company's business. A reconciliation of the GAAP to non-GAAP financial results is provided under the investor section of OraSure's corporate website at [www.orasure.com](http://www.orasure.com).



## 2Q22 Financial Results – Record Revenue and Improved Profitability



FINANCIAL METRIC	2Q22 RESULTS	1Q22 RESULTS	2Q21 RESULTS	SEQUENTIAL GROWTH RATE	YEAR-OVER-YEAR GROWTH RATE
Quarterly Revenue	\$80.2 million	\$67.7 million	\$57.6 million	18%	39%
GAAP EPS / Non-GAAP EPS	(\$0.26)/(\$0.00)	(\$0.28)/(\$0.15)	(\$0.02)/\$0.01	NM	NM

- IntelliSwab® revenue grew 95% sequentially
- IntelliSwab® gross margins increased over 2,000 basis points sequentially
- Non-GAAP gross margins increased 250 basis points sequentially
- Most cash use tied to working capital adjustments due to the IntelliSwab® ramp
- Achieved neutral Non-GAAP net income in the quarter



# Key Elements of Strategic Transformation

2H CY22

CY23

CY24

**Strengthen**

**Elevate**

**Accelerate**

**Innovate & operate with disciplined execution & accountability**



# Record Diagnostic Revenue With 95% Sequential Growth in IntelliSwab®

FINANCIAL METRIC	2Q22 RESULTS	1Q22 RESULTS	2Q21 RESULTS	SEQUENTIAL GROWTH RATE	YEAR-OVER-YEAR GROWTH RATE
Total Diagnostics	\$60.4 million	\$38.3 million	\$19.3 million	58%	213%
IntelliSwab® Revenue	\$43.1 million	\$22.1 million	---	95%	NM
Core ex IntelliSwab®	\$17.3 million	\$16.2 million	\$19.2 million	7%	(10%)



# Significant Improvements Continue in IntelliSwab® Production Process



14-fold increase in weekly production volume since last year

Gross margins for IntelliSwab® increase 2,000+ basis points sequentially

Current production capacity of 1.6M tests per week ... plans to double capacity in 2023

## STILL TO COME:

- Transition from air to ocean freight
- Packaging reconfiguration
- Additional automation and process improvement
- Production via "Super Factory"



# US Government Continues Support for IntelliSwab®

## Continued Procurement as part of OraSure's Defense Logistics Agency/HHS contract

- Consistent ongoing testing needed in congregate settings
- Evens out demand, enables shipments even during low points between surges



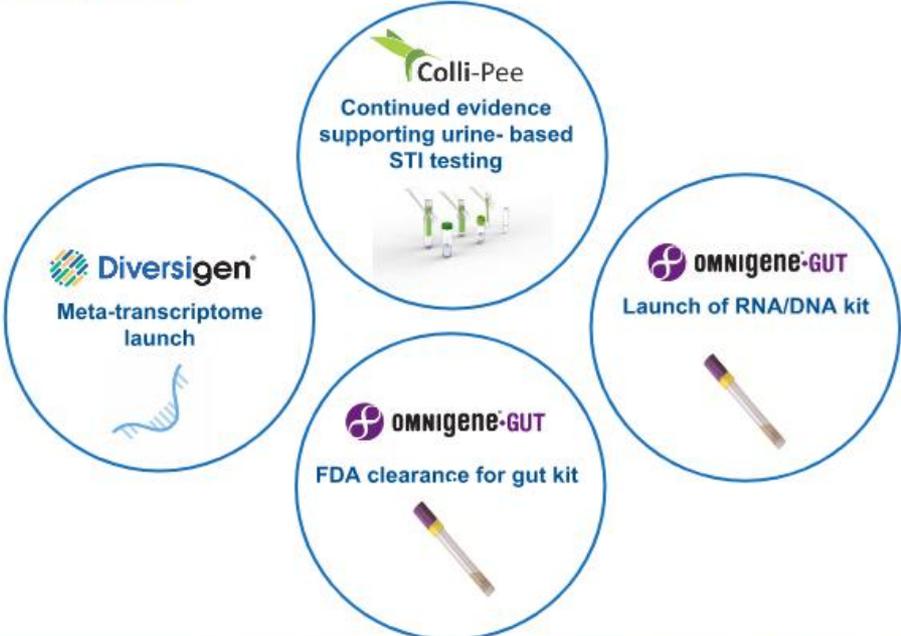
# Molecular Solutions Revenue In Line With Expectations



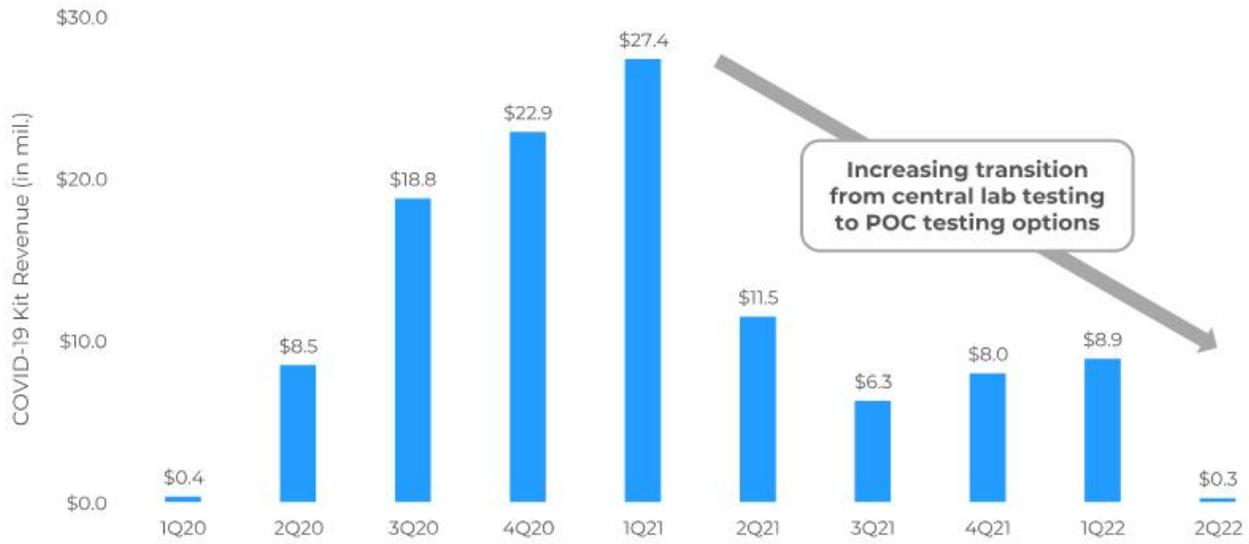
FINANCIAL METRIC	2Q22 RESULTS	1Q22 RESULTS	2Q21 RESULTS	SEQUENTIAL GROWTH RATE	YEAR-OVER-YEAR GROWTH RATE
Core Molecular Kits	\$17.3 million	\$21.9 million	\$17.1 million	1%	(21%)
COVID-19 Collection Kits	\$0.3 million	\$12.0 million	\$8.9 million	NM	NM
Microbiome Services	\$1.2 million	\$3.1 million	\$1.7 million	(31%)	(61%)



# Enabling Multi-Omic Discovery and Diagnostics Through Innovation



# Molecular Solutions COVID-19 Kit Revenue



# Consolidated Revenue by Quarter

Record Revenue in 2Q22 ... 39% YoY Growth



# Financial Results

	Three Months Ended	
	June 30,	
	2022	2021
<b>Results of Operations</b>		
Net revenues	\$ 80,231	\$ 57,607
Cost of products and services sold	52,647	26,934
Gross profit	27,584	30,673
Operating expenses:		
Research and development	9,068	7,682
Sales and marketing	11,684	10,420
General and administrative	17,579	10,993
Goodwill and long-lived assets impairment charges	10,542	-
Change in fair value of acquisition-related contingent consideration	-	(220)
Total operating expenses	48,873	28,875
Operating income (loss)	(21,289)	1,798
Other income	1,318	448
Income (loss) before income taxes	(19,971)	2,246
Income tax expense	(1,169)	3,610
Net income (loss)	\$ (18,802)	\$ (1,364)
Earnings (loss) per share:		
Basic	\$ (0.26)	\$ (0.02)
Diluted	\$ (0.26)	\$ (0.02)
Weighted average shares:		
Basic	72,496	71,983
Diluted	72,496	71,983



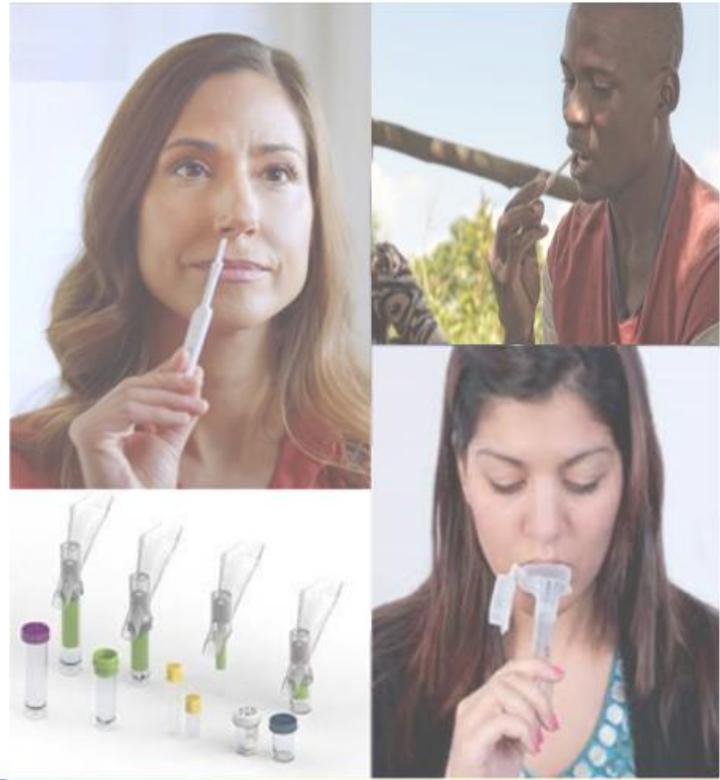
## 3Q22 Financial Guidance

GUIDANCE METRIC	FINANCIAL GUIDANCE
3Q22 Total Revenue	\$90 - \$95 million
3Q22 Gross Margins	Continued improvement from 2Q22
3Q22 Cash Utilization	Continued improvement from 2Q22



## Summary

- Momentum in strategic transformation ... innovating and operating with disciplined execution and accountability
- Significant improvements achieved in IntelliSwab<sup>®</sup> production and manufacturing efficiency ... 2,000+ basis point sequential increase in IntelliSwab<sup>®</sup> gross margins
- Neutral non-GAAP net income ... on the path to positive cash flow in Q4 2022
- Strong fundamental backdrop for the business as healthcare delivery shifts to decentralized testing solutions



## Smart Science Made Simple



# Q&A



OraSure Technologies

ONAGENOTEK™

 Diversigen

 novoSanis