



OraSure Technologies, Inc.

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## OraSure Reports Q1 '24 Revenue of \$54.1 Million

Q1 GAAP EPS of \$(0.05); Q1 Non-GAAP EPS of \$0.04

*Restructuring initiatives expected to result in \$15 million of annualized expense reductions once fully implemented and position OraSure to achieve cash flow breakeven for core business by end of 2024*

*Delivered initial orders for Syphilis Health Check™ as part of our distribution agreement with Diagnostics Direct*

BETHLEHEM, PA, May 8, 2024 (GLOBE NEWSWIRE) – OraSure Technologies, Inc. (NASDAQ: OSUR), a leader in point-of-care and home diagnostic tests and sample management solutions, today announced its financial results for the three months ended March 31, 2024.

“Our Q1 results were consistent with our expectations, and our transformation continues with three recent important initiatives to further streamline the business and focus on our strengths. We are winding down our microbiome laboratory and analytical sequencing services business, insourcing third-party manufacturing activities into our Bethlehem facilities, and closing our site in Belgium. These actions are expected to result in meaningful cost savings this year and contribute to achieving our target to break-even in cash flow from operations for our core business by the end of 2024,” said OraSure President and CEO Carrie Eglinton Manner.

She continued, “Over the last 18 months, we have strengthened the foundation of our organization, and we are excited to help power the potential of precision health. Our stronger balance sheet provides us the flexibility to invest in our innovation roadmap, including current partnerships and inorganic opportunities that leverage our existing capabilities, and positions OraSure to accelerate profitable long-term growth.”

### Financial Highlights

	Three Months Ended March 31,		
	2024	2023	% Change
Core Business <sup>1</sup>	\$ 31,004	\$ 36,554	(15) %
COVID-19	23,128	118,409	(80)
<b>Total Net Revenue</b>	<b>\$ 54,132</b>	<b>\$ 154,963</b>	<b>(65) %</b>

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

	Three Months Ended March 31,		
	2024	2023	% Change
Net revenues	\$ 54,132	\$154,963	(65) %
Gross profit	24,065	65,815	(63)
Gross margin	44.5 %	42.5 %	
Non-GAAP gross profit	24,447	66,277	(63)
Non-GAAP gross margin	45.2 %	42.8 %	
Operating income (loss)	(7,093)	24,321	NM
Operating margin	(13.1)%	15.7 %	
Non-GAAP operating income (loss)	(325)	32,658	NM
Non-GAAP operating margin	(0.6)%	21.1 %	
Net income (loss)	(3,584)	27,219	NM
Non-GAAP net income (loss)	3,086	34,556	(91)
GAAP EPS	\$ (0.05)	\$ 0.37	NM
Non-GAAP EPS	\$ 0.04	\$ 0.47	(91)

NM – not meaningful

- Total net revenues for the first quarter of 2024 decreased 65% to \$54.1 million from \$155.0 million in the first quarter of 2023.
- Core revenue (all revenue excluding COVID-19 revenue) of \$31.0 million in the first quarter decreased 15% year-over-year. Diagnostics revenue in the first quarter decreased 4% year-over-year and Molecular Sample Management Solutions revenue decreased 16%.
- COVID-19 revenue of \$23.1 million in the first quarter decreased 80% year-over-year, which was in line with our expectations as volumes under our government contracts taper down.
- GAAP gross margin percentage was 44.5% in the first quarter of 2024 compared to 42.5% in the first quarter of 2023. Non-GAAP gross margin in the first quarter of 2024 was 45.2% compared to 42.8% in the first quarter of 2023<sup>1</sup>. On a year-over-year basis, gross margin benefited from increased average selling price on IntelliSwab® and lower manufacturing scrap expense.
- GAAP operating loss in the first quarter of 2024 was \$7.1 million compared to operating income of \$24.3 million in the first quarter of 2023. Non-GAAP operating loss was \$0.3 million in the first quarter of 2024 compared to Non-GAAP operating income of \$32.7 million in the first quarter of 2023.
- Cash, cash equivalents, and short-term investments were \$263.8 million as of March 31, 2024. The \$26.6 million decrease in our cash balance during the first quarter of 2024 was primarily driven by our \$28.3 million investment in Sapphiros, a next-generation consumer diagnostics company, which we announced in January. Cash Flow from Operations in the first quarter of 2024 was \$6.7 million.

### Recent Business Developments

- During the second quarter, we initiated steps to wind down and exit our microbiome laboratory and analytical sequencing services business (Diversigen) by the end of Q3 2024. This action is expected to result in more than \$10 million of annualized cost savings upon completion. Diversigen generated \$4 million of revenue over the last 12 months. OraSure will

<sup>1</sup> 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.

continue to produce and sell microbiome collection kits as part of our Sample Management Solutions.

- Commenced projects to insource production of certain sample management products from external contract manufacturers into our manufacturing Center of Excellence in Bethlehem, PA over the next 18 months. Upon completion, this transition is expected to result in \$5 million of annualized cost savings through improved operating efficiency and further leveraging of our existing infrastructure.
- Initiated steps to close our Novosanis site in Belgium by the end of 2024 in order to drive further integration into our existing infrastructure. OraSure will continue to develop and sell the Colli-Pee® urine collection device as part of our Sample Management Solutions.
- Successfully launched our sales and distribution partnerships with Diagnostics Direct and Anaerobe Systems, among others, which allow us to enter new market segments and expand the portfolio of products we can provide to our customers.
- Remain on track to achieve operating cash flow break-even for the core business by the end of 2024.
- Published our 2023-2024 “OraSure Cares” ESG report, which highlights our progress in advancing Environmental, Social, and Governance-related initiatives that are meaningful to our internal and external stakeholders.

### **Financial Guidance**

The Company is guiding to Q2 2024 revenue of \$50 to \$55 million, which includes core revenue of \$33 to \$36 million and InteliSwab® revenue of \$17 to \$19 million. Our Q2 2024 guidance includes approximately \$650 thousand of revenue from the Diversigen business that we plan to exit.

## Financial Data (Unaudited)

	Three Months Ended March 31,	
	2024	2023
<b>Results of Operations</b>		
Net revenues	\$ 54,132	\$ 154,963
Cost of products and services sold	30,067	89,148
Gross profit	24,065	65,815
Operating expenses:		
Research and development	7,738	10,560
Sales and marketing	8,448	12,142
General and administrative	11,634	17,711
Loss on impairment	3,338	1,105
Change in fair value of acquisition-related contingent consideration	—	(24)
Total operating expenses	31,158	41,494
Operating income (loss)	(7,093)	24,321
Other income	3,491	2,673
Income (loss) before income taxes	(3,602)	26,994
Income tax benefit	(18)	(225)
Net income (loss)	\$ (3,584)	\$ 27,219
Earnings (loss) per share:		
Basic	\$ (0.05)	\$ 0.37
Diluted	\$ (0.05)	\$ 0.37
Weighted average shares:		
Basic	73,947	73,112
Diluted	73,947	73,966

	Three Months Ended March 31,		
	2024	2023	% Change
COVID-19 Diagnostics	\$ 23,097	\$ 118,254	(80)%
Diagnostics	16,380	17,090	(4)
Molecular Sample Management Solutions	10,822	12,942	(16)
Other products and services	2,576	3,094	(17)
Molecular Services	873	1,379	(37)
COVID-19 Molecular Products	31	155	(80)
Net product and services revenues	53,779	152,914	(65)
Non-product and services revenues	353	2,049	(83)
Net revenues	\$ 54,132	\$ 154,963	(65)%

## Condensed Consolidated Balance Sheets (Unaudited)

	<u>March 31, 2024</u>	<u>December 31, 2023</u>
<u>Assets</u>		
Cash and cash equivalents	\$ 247,145	\$ 290,407
Short-term investments	16,627	—
Accounts receivable, net	34,037	40,171
Inventories	43,180	47,614
Other current assets	7,516	8,267
Property, plant and equipment, net	42,597	45,420
Intangible assets, net	1,010	1,206
Goodwill	35,172	35,696
Investment in equity method investee	28,333	—
Other noncurrent assets	11,941	14,064
Total assets	<u>\$ 467,558</u>	<u>\$ 482,845</u>
<u>Liabilities and Stockholders' Equity</u>		
Accounts payable	\$ 12,683	\$ 13,151
Deferred revenue	1,597	1,559
Other current liabilities	14,825	24,826
Other non-current liabilities	12,202	12,638
Stockholders' equity	426,251	430,671
Total liabilities and stockholders' equity	<u>\$ 467,558</u>	<u>\$ 482,845</u>

## Additional Financial Data (Unaudited)

	<u>Three Months Ended March 31,</u>	
	<u>2024</u>	<u>2023</u>
Capital expenditures	\$ 1,579	\$ 3,958
Depreciation and amortization	\$ 2,725	\$ 3,696
Stock-based compensation	\$ 2,968	\$ 2,655
Cash provided by operating activities	\$ 6,738	\$ 6,002

## Consolidated Statement of Cash Flows (Unaudited)

	Three Months Ended March 31,	
	2024	2023
<b>OPERATING ACTIVITIES:</b>		
Net income (loss)	\$ (3,584)	\$ 27,219
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Stock-based compensation	2,968	2,655
Depreciation and amortization	2,725	3,696
Loss on impairments	3,338	1,105
Other non-cash amortization	6	—
Provision for credit losses	(85)	(67)
Unrealized foreign currency (gain) loss	(119)	44
Interest expense on finance leases	7	15
Deferred income taxes	53	—
Change in the estimated fair value of acquisition-related contingent consideration	—	(24)
Payment of acquisition-related contingent consideration	—	(19)
Changes in assets and liabilities:		
Accounts receivable	6,199	(36,613)
Inventories	4,337	18,540
Prepaid expenses and other assets	603	5,299
Accounts payable	(68)	(12,097)
Deferred revenue	47	(279)
Accrued expenses and other liabilities	(9,688)	(3,472)
Net cash provided by operating activities	<u>6,738</u>	<u>6,002</u>
<b>INVESTING ACTIVITIES:</b>		
Purchases of short-term investments	(25,850)	(22,330)
Purchase of equity method investee	(28,333)	—
Proceeds from maturities and redemptions of short-term investments	9,234	27,304
Purchases of property and equipment	(1,579)	(1,191)
Purchase of property and equipment under government contracts	—	(2,767)
Net cash provided by (used in) investing activities	<u>(46,528)</u>	<u>1,016</u>
<b>FINANCING ACTIVITIES:</b>		
Cash payments for lease liabilities	(50)	(148)
Proceeds from exercise of stock options	215	66
Payment of acquisition-related contingent consideration	—	(46)
Repurchase of common stock	(1,462)	(1,203)
Net cash used in financing activities	<u>(1,297)</u>	<u>(1,331)</u>
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	(2,175)	527
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(43,262)	6,214
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	290,407	83,980
CASH AND CASH EQUIVALENTS, END OF PERIOD	<u>\$ 247,145</u>	<u>\$ 90,194</u>

## Conference Call

The Company will host a conference call and audio webcast to discuss the Company's first quarter 2024 results and certain business developments, beginning today at 4:45 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/BI6ea5c5c7630d4ba196be212024e8c2e6>

## 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](http://www.orasure.com).

## About InteliSwab®

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

This product has not been FDA cleared or approved, but it has been authorized by the FDA under an EUA. The emergency use of this product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. This product is only authorized for the duration of the declaration that

circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb- 3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Development of the 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.

### **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 and guidance, 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, including from insourcing third party manufacturing and exiting microbiome services; 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 or have manufactured products in accordance with applicable specifications, performance standards and quality requirements; ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; ability to comply with applicable regulatory requirements; ability to effectively resolve warning letters, audit observations and other findings or comments from the FDA or other regulators; the impact of the novel coronavirus ("COVID-19") pandemic on the Company's business, supply chain, labor force, ability to successfully develop new products, validate the expanded use of existing collector products, receive necessary regulatory approvals and authorizations and commercialize such products for COVID-19 testing, and demand for our COVID-19 testing products ; changes in relationships, including disputes or disagreements, with strategic partners or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements; ability to meet increased demand for the Company's products; impact of replacing distributors; inventory levels at distributors and other customers; ability of the Company to achieve its financial and strategic objectives and continue to increase its revenues, including the ability to expand international sales and the ability to continue to reduce costs; impact of competitors, competing products and technology changes; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products; market acceptance of oral fluid or urine testing, collection or other products; market acceptance and uptake of microbiome informatics, microbial genetics technology and related analytics services; changes in market acceptance of products based on product performance or other factors, including changes in testing guidelines, algorithms or other recommendations by the Centers for Disease Control and Prevention or other agencies; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical products and components; availability of related products produced by third parties or products required for use of our products; impact of contracting with the U.S. government; impact of negative economic conditions; ability to maintain sustained profitability; ability to utilize net operating loss



carry forwards or other deferred tax assets; volatility of the Company's stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to attract and retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; cybersecurity breaches or other attacks involving our systems or those of our third-party contractors and IT service providers; the impact of terrorist attacks, civil unrest, hostilities and war ; and general political, business and economic conditions, including inflationary pressures and banking stability. These and other factors that could affect our results are discussed more fully in our SEC filings, including our registration statements, Annual Report on Form 10-K for the year ended December 31, 2023, 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 March 31,	
	2024	2023
Revenue	\$ 54,132	\$ 154,963
GAAP Cost of products and services sold	30,067	89,148
<i>GAAP Gross Margin</i>	44.5%	42.5%
Stock compensation	151	134
Amortization of acquisition-related intangible assets	—	132
Reduction in workforce severance	231	35
Transformation related expenses	—	161
Non-GAAP Cost of Goods Sold	29,685	88,686
<i>Non-GAAP Gross Margin</i>	45.2%	42.8%
GAAP Operating Income (Loss)	(7,093)	24,321
Stock compensation	2,967	2,655
Amortization of acquisition-related intangible assets	59	466
Reduction in workforce severance	404	2,635
Loss on impairment	3,338	1,105
Transformation related expenses	—	449
Government grant accounting	—	1,051
Change in fair value of acquisition-related contingent consideration	—	(24)
Non-GAAP Operating Income (Loss)	(325)	32,658
GAAP Net Income (Loss)	(3,584)	27,219
Stock compensation	2,967	2,655
Amortization of acquisition-related intangible assets	59	466
Reduction in workforce severance	404	2,635.00
Loss on impairment	3,338	1,105
Transformation related expenses	—	449
Change in fair value of acquisition-related contingent consideration	—	(24)
Tax effect of Non-GAAP adjustments	(98)	51
Non-GAAP Net Income	\$ 3,086	\$ 34,556
GAAP Earnings (Loss) Per Share:	\$ (0.05)	\$ 0.37
Non-GAAP Earnings Per Share:	\$ 0.04	\$ 0.47
Diluted Shares Outstanding	73,947	73,966
Diluted Shares Outstanding Used For Computing Non-GAAP Earnings (Loss) Per Share	75,628	73,966

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
- 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
- Loss on impairment: charges related to the write down of Company's PP&E and leased assets
- Transformation related expenses: transitory costs such as consulting and professional fees related to transformation initiatives

- Government contract accounting: As required under International Accounting Standard Board IAS 20, *Accounting for Government Contracts and Disclosure of Government Assistance*, our operating expenses associated with the Department of Defense expansion contract are reflected in operating expenses with offsetting reimbursement reflected in other income
- Change in fair value of acquisition-related contingent consideration: changes in the fair value of contingent consideration liability associated with estimate changes in reaching contingent consideration metrics
- Tax impact associated with non-GAAP adjustments – tax expense/(benefit) due to non-GAAP adjustments

A reconciliation of our non-GAAP measures to their most directly comparable GAAP measures can also be found at: <https://orasure.gcs-web.com/gAAP-non-gAAP-reconciliation>

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