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OraSure Reports Fourth Quarter 2024 Financial Results

BETHLEHEM, PA, February 25, 2025 (GLOBE NEWSWIRE) – OraSure Technologies, Inc. (NASDAQ: OSUR), a leader in point-of-need and home diagnostic tests and sample management solutions, today announced its financial results for the three months ended December 31, 2024.

“Our Q4 revenue was consistent with our expectations, including 10% growth in our core revenue. We continue to see signs of gradual recovery in our key end markets, and we are diversifying our business by expanding our product portfolio and adding new customers, offset by elevated uncertainty for some of our existing customers related to government funding sources,” said OraSure President and CEO Carrie Eglinton Manner. “We made tremendous progress in our strategic transformation in 2024, which gives us confidence that OTI is positioned to deliver growth in our core business and drive further productivity gains.”

She added, “Our strong balance sheet has allowed us to significantly advance our innovation strategy, including the acquisition of Sherlock Biosciences, which brings to our pipeline an advanced molecular platform that we expect will expand access to diagnostic insights through convenient, effortless tests. Overall, we continue to progress operationally to leverage our differentiated products and our strong customer relationships to drive profitable long-term growth and create shareholder value.”

Financial Highlights

	For the Three Months Ended December 31,			For the Years Ended December 31,		
	2024	2023	% Change	2024	2023	% Change
Core Business ⁽¹⁾	\$ 36,482	\$ 33,310	10 %	\$ 138,950	\$ 143,219	(3) %
Molecular Services	13	907	(99)	1,705	4,474	(62)
COVID-19	950	41,664	(98)	45,172	257,779	(82)
Total Net Revenues	\$ 37,445	\$ 75,881	(51) %	\$ 185,827	\$ 405,472	(54) %

⁽¹⁾ Includes Diagnostics, Sample Management Solutions, Risk Assessment Testing, other products and services revenues, and non-product and services revenues.

	For the Three Months Ended December 31,			For the Years Ended December 31,		
	2024	2023	% Change	2024	2023	% Change
Net revenues	\$ 37,445	\$ 75,881	(51)%	\$ 185,827	\$ 405,472	(54)%
Gross profit	13,566	35,126	(61)	79,390	171,652	(54)
Gross margin	36.2 %	46.3 %		42.7 %	42.3 %	
Non-GAAP gross profit	15,000	35,264	(57)	82,490	173,262	(52)
Non-GAAP gross margin	40.1 %	46.5 %		44.4 %	42.7 %	
Operating income (loss)	(12,418)	3,898	NM	(28,250)	32,684	NM
Operating margin	(33.2)%	5.1 %		(15.2)%	8.1 %	
Non-GAAP operating income (loss)	(6,745)	11,151	NM	(6,422)	62,350	NM
Non-GAAP operating margin	(18.0)%	14.7 %		(3.5)%	15.4 %	
Net income (loss)	(10,794)	20,073	NM	(19,500)	53,655	NM
Non-GAAP net income (loss)	(4,230)	13,521	NM	3,943	66,311	(94)
Diluted GAAP EPS	\$ (0.14)	\$ 0.27	NM	\$ (0.26)	\$ 0.72	NM
Diluted Non-GAAP EPS	\$ (0.06)	\$ 0.18	NM	\$ 0.05	\$ 0.89	(94)

NM – not meaningful

- Total net revenues for the fourth quarter of 2024 decreased 51% to \$37.4 million from \$75.9 million in the fourth quarter of 2023 primarily due to the decline in COVID-19 revenues.
- Core revenues (all revenues excluding COVID-19 and Molecular Services revenues) of \$36.5 million in the fourth quarter increased 10% year-over-year. Diagnostics revenues in the fourth quarter increased 9% year-over-year to \$18.8 million and Sample Management Solutions revenues increased 14% to \$14.8 million.
- COVID-19 revenues of \$1.0 million in the fourth quarter decreased 98% year-over-year primarily due to the completion of our largest government contract earlier in 2024.
- GAAP gross margin was 36.2% in the fourth quarter of 2024 compared to 46.3% in the fourth quarter of 2023. Non-GAAP gross margin in the fourth quarter of 2024 was 40.1% compared to 46.5% in the fourth quarter of 2023¹. On a year-over-year basis, gross margin was impacted by the decline in COVID-19 revenues and the higher mix of international revenues.
- GAAP operating loss in the fourth quarter of 2024 was \$12.4 million compared to operating income of \$3.9 million in the fourth quarter of 2023. Non-GAAP operating loss was \$6.7 million in the fourth quarter of 2024 compared to non-GAAP operating income of \$11.2 million in the fourth quarter of 2023.
- Cash and cash equivalents were \$267.8 million as of December 31, 2024. Cash flow from operations in the fourth quarter of 2024 was \$0.1 million. During the fourth quarter, we deployed \$5.0 million for the acquisition of Sherlock Biosciences.

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.

Recent Business Developments

- OTI acquired Sherlock Biosciences in December to expand our innovation pipeline with the addition of a molecular diagnostics platform that, subject to approval by the U.S. Food and Drug Administration (FDA), is expected to provide rapid results with strong sensitivity and specificity in a disposable format that will be well-suited for over-the-counter usage. Sherlock's first molecular self-test, for Chlamydia Trachomatis (CT) and Neisseria Gonorrhoeae (NG), is in clinical trials and is expected to be submitted to the FDA by the end of 2025 for review.
- Received FDA approval for a labeling change to the OraQuick® HIV Self-Test that will increase access to HIV testing for adolescents. The change expands the approved age range for the OraQuick® HIV Self-Test to include individuals 14 years of age and older. Previously the test was approved for use in those 17 and older.
- Received an award through the Rapid Response Partnership Vehicle (RRPV) for the development of a Marburg Virus Disease (MVD) rapid antigen test. The RRPV is a Consortium funded by the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS). The initial contract award, valued at approximately \$7.5 million over multiple years in the base period with potential value up to \$11 million, funds the development to achieve FDA 510(k) clearance of a single-use lateral flow immunoassay intended for the qualitative detection of antigens from viruses within the Marburg virus genus.
- Made significant progress in exiting our Risk Assessment testing business. We plan to continue to support our Risk Assessment customers and wind down remaining inventory during the first half of 2025.

Financial Guidance

The Company is guiding to Q1 2025 revenues of \$27.5 million to \$31.5 million. The Company anticipates Core revenues in Q1 2025 of \$27 million to \$31 million, which includes approximately \$1 million of Risk Assessment testing revenues. The Company anticipates COVID-19 revenues in Q1 2025 of approximately \$0.5 million.

Conference Call

The Company will host a conference call and audio webcast to discuss the Company's fourth quarter 2024 results and certain business developments, beginning today at 5 p.m. Eastern Time. 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 OTI'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 OTI'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.

For participants interested in asking a question during the 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/BI400ff7eb0f2149dfa53af33625f6bdfb>

OTI intends to use the Investor Relations Section of its website as a means of disclosing material non-public information (MNPI) and for complying with its disclosure obligations under Regulation FD. Accordingly, investors should monitor OTI's website in addition to following its press releases, SEC filings, public conference calls, presentations, and webcasts.

Financial Data (Unaudited)

	For the Three Months Ended December 31,		For the Years Ended December 31,	
	2024	2023	2024	2023
Results of Operations				
Net revenues	\$ 37,445	\$ 75,881	\$ 185,827	\$ 405,472
Cost of products and services sold	23,879	40,755	106,437	233,820
Gross profit	13,566	35,126	79,390	171,652
Operating expenses:				
Research and development	6,087	6,991	26,047	33,728
Sales and marketing	6,992	6,906	30,986	36,319
General and administrative	12,905	14,005	46,215	58,191
Loss on impairments	—	3,326	4,392	10,829
Change in the estimated fair value of acquisition-related contingent consideration	—	—	—	(99)
Total operating expenses	25,984	31,228	107,640	138,968
Operating income (loss)	(12,418)	3,898	(28,250)	32,684
Other income	2,911	16,822	12,249	23,574
Income (loss) before income taxes	(9,507)	20,720	(16,001)	56,258
Income tax expense	758	647	1,799	2,603
Loss on equity investment	(529)	—	(1,700)	—
Net income (loss)	\$ (10,794)	\$ 20,073	\$ (19,500)	\$ 53,655
Income (loss) per share:				
Basic	\$ (0.14)	\$ 0.27	\$ (0.26)	\$ 0.73
Diluted	\$ (0.14)	\$ 0.27	\$ (0.26)	\$ 0.72
Weighted average shares outstanding:				
Basic	74,597	73,499	74,434	73,348
Diluted	74,597	75,013	74,434	74,389

	For the Three Months Ended December 31,			For the Years Ended December 31,		
	2024	2023	% Change	2024	2023	% Change
Consolidated Net Revenues						
Diagnostics	\$ 18,768	\$ 17,219	9 %	\$ 75,917	\$ 73,694	3 %
Sample Management Solutions	14,809	13,044	14	51,046	54,274	(6)
COVID-19 Diagnostics	950	41,617	(98)	45,136	257,493	(82)
Risk Assessment Testing	2,055	2,196	(6)	8,354	9,736	(14)
Other products and services	636	526	21	2,417	2,265	7
Molecular Services	13	907	(99)	1,705	4,474	(62)
COVID-19 Molecular Products	—	47	(100)	36	286	(87)
Net product and services revenues	37,231	75,556	(51)	184,611	402,222	(54)
Non-product and services revenues	214	325	(34)	1,216	3,250	(63)
Net revenues	\$ 37,445	\$ 75,881	(51)%	\$ 185,827	\$ 405,472	(54)%

Condensed Consolidated Balance Sheets (Unaudited)

	December 31, 2024	December 31, 2023
<u>Assets</u>		
Cash and cash equivalents	\$ 267,763	\$ 290,407
Accounts receivable, net	23,816	40,171
Inventories	34,197	47,614
Other current assets	7,444	8,267
Property, plant and equipment, net	45,105	45,420
Intangible assets, net	17,134	1,206
Goodwill	41,831	35,696
Investment in equity method investee	28,300	—
Other noncurrent assets	15,269	14,064
Total assets	<u>\$ 480,859</u>	<u>\$ 482,845</u>
<u>Liabilities and Stockholders' Equity</u>		
Accounts payable	\$ 8,173	\$ 13,151
Deferred revenue	2,961	1,559
Other current liabilities	22,349	24,826
Other noncurrent liabilities	37,038	12,638
Stockholders' equity	410,338	430,671
Total liabilities and stockholders' equity	<u>\$ 480,859</u>	<u>\$ 482,845</u>

Additional Financial Data (Unaudited)

	For the Years Ended December 31,	
	2024	2023
Capital expenditures	\$ 3,797	\$ 10,303
Proceeds from funding under government contract ⁽¹⁾	—	48,669
Depreciation and amortization	10,872	20,936
Stock-based compensation	11,920	10,729
Cash provided by operating activities	\$ 27,374	\$ 141,583

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

Consolidated Statement of Cash Flows (Unaudited)

	For the Years Ended December 31,	
	2024	2023
OPERATING ACTIVITIES:		
Net (loss) income	\$ (19,500)	\$ 53,655
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Stock-based compensation	11,920	10,729
Depreciation and amortization	10,872	20,936
Loss on impairments	4,392	10,829
Other non-cash amortization	(564)	3
Provision for credit losses	71	(462)
Unrealized foreign currency gain	(263)	103
Interest expense on finance leases	22	51
Loss on equity investment	1,700	—
Deferred income taxes	(657)	102
Loss on sale of fixed assets	563	—
Change in the estimated fair value of acquisition-related contingent consideration	—	(99)
Payment of acquisition-related contingent consideration	—	(19)
Changes in assets and liabilities:		
Accounts receivable	15,872	31,116
Inventories	13,096	48,228
Prepaid expenses and other assets	4,089	(2,499)
Accounts payable	(7,577)	(26,976)
Deferred revenue	(219)	(730)
Accrued expenses and other liabilities	(6,443)	(3,384)
Net cash provided by operating activities	27,374	141,583
INVESTING ACTIVITIES:		
Purchases of short-term investments	(53,244)	(74,652)
Investment in equity method investee	(30,000)	—
Proceeds from maturities and redemptions of short-term investments	53,052	102,440
Purchases of property and equipment	(3,797)	(5,802)
Acquisition of business, net of cash acquired	(5,037)	—
Purchase of property and equipment under government contracts	—	(4,501)
Proceeds from funding under government contract ⁽¹⁾	—	48,669
Net cash (used in) provided by investing activities	(39,026)	66,154
FINANCING ACTIVITIES:		
Cash payments for lease liabilities	(842)	(1,345)
Proceeds from exercise of stock options	214	269
Payment of acquisition-related contingent consideration	—	(46)
Repurchase of common stock	(3,548)	(1,901)
Net cash used in financing activities	(4,176)	(3,023)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	(6,816)	1,713
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(22,644)	206,427
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	290,407	83,980
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 267,763	\$ 290,407

About OraSure Technologies

OraSure Technologies, Inc. (“OraSure” and “OTI”) transforms health through actionable insight and powers the shift that connects people to healthcare wherever they are. OraSure improves access, quality, and value of healthcare with innovation in effortless tests and sample management solutions. OraSure, together with its wholly-owned subsidiaries, DNA Genotek Inc. and Sherlock Biosciences, Inc., is a leader in the development, manufacture, and distribution of rapid diagnostic tests and sample collection and stabilization devices 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, and direct to consumers. For more information on OraSure Technologies, please visit www.orasure.com

About Marburg Virus Disease (MVD) rapid antigen test

The Marburg Virus Disease (MVD) rapid antigen test project 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 (ASPR); Biomedical Advanced Research and Development Authority (BARDA), under Other Transaction Number: 75A50123D00005, and the Project Identifier is RRPV-24-06-DxR2-007 (OraSure).

Forward Looking Statements

This press release contains certain forward-looking statements, including with respect to products, product candidate 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 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 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; impact of replacing distributors; inventory levels at distributors and other customers; our ability to achieve its financial and strategic objectives and increase our 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 our products; 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 achieve and maintain sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of our 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, suppliers and customers; the impact of terrorist attacks, civil unrest, hostilities and war; and general political, business and economic conditions, including inflationary pressures, the imposition of tariffs 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 gross profit, non-GAAP net income (loss), 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)

	For the Three Months Ended December 31,		For the Years Ended December 31,	
	2024	2023	2024	2023
Revenue	\$ 37,445	\$ 75,881	\$ 185,827	\$ 405,472
GAAP Cost of products and services sold	23,879	40,755	106,437	233,820
<i>GAAP Gross Margin</i>	<i>36.2%</i>	<i>46.3%</i>	<i>42.7%</i>	<i>42.3%</i>
Stock compensation	195	138	734	564
Amortization of acquisition-related intangible assets	—	—	—	396
Reduction in workforce severance	239	—	1,366	369
Transformation related expenses	—	—	—	281
Inventory reserve for product line discontinuance	1,000	—	1,000	—
Non-GAAP Cost of Goods Sold	22,445	40,617	103,337	232,210
<i>Non-GAAP Gross Margin</i>	<i>40.1%</i>	<i>46.5%</i>	<i>44.4%</i>	<i>42.7%</i>
GAAP Operating Income (Loss)	(12,418)	3,898	(28,250)	32,684
Stock compensation	2,741	3,127	11,919	10,729
Amortization of acquisition-related intangible assets	103	150	279	1,549
Reduction in workforce severance	849	—	3,258	3,265
Inventory reserve for product line discontinuance	1,000	—	1,000	—
Loss on impairment	—	3,326	4,392	10,829
Transformation related expenses	—	—	—	707
Transaction costs	980	650	980	650
Government grant accounting	—	—	—	2,036
Change in fair value of acquisition-related contingent consideration	—	—	—	(99)
Non-GAAP Operating Income (Loss)	(6,745)	11,151	(6,422)	62,350
GAAP Net Income (Loss)	(10,794)	20,073	\$ (19,500)	53,655
Stock compensation	2,741	3,127	11,919	10,729
Amortization of acquisition-related intangible assets	103	150	279	1,549
Reduction in workforce severance	849	—	3,258	3,264
Inventory reserve for product line discontinuance	1,000	—	1,000	—
Loss on impairment	—	3,326	4,392	10,829
Transformation related expenses	—	—	—	707
Transaction costs	980	650	980	650
Change in fair value of acquisition-related contingent consideration	—	—	—	(99)
Loss on equity investment	529	—	1,700	—
Additional profit from government contract	—	(12,802)	—	(12,802)

Tax effect of non-GAAP adjustments	362	(1,003)	(85)	(2,171)
Non-GAAP Net Income (Loss)	\$ (4,230)	\$ 13,521	\$ 3,943	\$ 66,311
GAAP Earnings (Loss) Per Share:	\$ (0.14)	\$ 0.27	\$ (0.26)	\$ 0.72
Non-GAAP Earnings (Loss) Per Share:	\$ (0.06)	\$ 0.18	\$ 0.05	\$ 0.89
Diluted Shares Outstanding	74,597	75,013	74,434	74,389
Diluted Shares Outstanding Used For Computing Non-GAAP Earnings (Loss) Per Share	74,597	75,013	75,329	74,389

The 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: termination benefits associated with the Company's workforce reduction associated with certain business events
- Inventory reserve for product line discontinuance: represents the write down of inventory associated with the risk assessment line of business that is discontinued
- Loss on impairment: charges related to the write down of Company's intangibles, PP&E, or 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
- Loss on equity investment: we have excluded our proportionate share of our equity method investee's net loss as we do not have direct control over the investee's operations or resulting revenue and expenses
- 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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