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OraSure Announces Third Quarter 2025 Financial Results

BETHLEHEM, PA, November 5, 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 September 30, 2025.

“In Q3 we delivered \$27.1 million of revenue. While some of our customers continue to experience elevated levels of uncertainty related to funding for public health programs and research, we remain confident in our opportunities to return to growth in 2026, driven by diversification in our customer base and contributions from planned launches of new products in both rapid diagnostics and sample management solutions,” said Carrie Eglinton Manner, President and CEO of OTI.

She continued, “OTI’s focus on decentralizing diagnostics and connecting people to care that is more accessible, convenient, private, and personalized is well-aligned with important long-term trends in the healthcare industry. We believe that this strategy and our capabilities position us for sustainable, long-term growth. Additionally, our strong balance sheet provides us with flexibility to navigate the current short-term turbulence while we advance our innovation roadmap and prepare for important new products that are expected to launch next year, including our Sherlock over-the-counter molecular self-test for Chlamydia and Gonorrhoeae and our Colli-Pee urine self-collection for sexually transmitted infections.”

Financial Highlights (\$ in 000’s, except per share amounts)

	For the Three Months Ended September 30,			For the Nine Months Ended September 30,		
	2025	2024	%	2025	2024	% Change
Core Business ⁽¹⁾	\$ 26,996	\$ 35,840	(25)%	\$ 85,818	\$ 96,203	(11)%
COVID-19	89	2,155	(96)	574	44,222	(99)%
Risk Assessment Testing	—	1,911	(100)	1,866	6,265	(70)%
Molecular Services	—	9	(100)	—	1,692	(100)%
Total Net Revenues	\$ 27,085	\$ 39,915	(32)%	\$ 88,258	\$ 148,382	(41)%

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

	For the Three Months Ended September 30,			For the Nine Months Ended September 30,		
	2025	2024	% Change	2025	2024	% Change
Net revenues	\$ 27,085	\$ 39,915	(32)%	\$ 88,258	\$ 148,382	(41)%
Gross profit	11,772	17,070	(31)	37,230	65,824	(43)
Gross margin	43.5 %	42.8 %		42.2 %	44.4 %	
Non-GAAP gross profit	11,980	17,272	(31)	37,960	67,490	(44)
Non-GAAP gross margin	44.2 %	43.3 %		43.0 %	45.5 %	
Operating loss	(16,090)	(5,999)	NM	(51,866)	(15,832)	NM
Operating margin	(59.4)%	(15.0)%		(58.8)%	(10.7)%	
Non-GAAP operating (loss) income	(12,709)	(2,699)	NM	(41,162)	324	NM
Non-GAAP operating margin	(46.9)%	(6.8)%		(46.6)%	0.2 %	
Net loss	(13,712)	(4,507)	NM	(49,445)	(8,706)	NM
Non-GAAP net (loss) income	(9,831)	(689)	NM	(37,164)	8,173	NM
Diluted GAAP EPS	\$ (0.19)	\$ (0.06)	NM	\$ (0.67)	\$ (0.12)	NM
Diluted Non-GAAP EPS	\$ (0.13)	\$ (0.01)	NM	\$ (0.50)	\$ 0.11	NM

NM – not meaningful

- Total net revenues for the third quarter of 2025 decreased 32% to \$27.1 million from \$39.9 million in the third quarter of 2024.
- Core revenues (all revenues excluding COVID-19, Molecular Services, and Risk Assessment Testing revenues) of \$27.0 million in the third quarter decreased 25% year-over-year. Diagnostics revenues in the third quarter decreased 34% year-over-year to \$14.5 million, with the decline attributable to lower revenue from our HIV tests. Sample Management Solutions revenues in the third quarter decreased 20% year-over-year to \$10.3 million, with the decline attributable to a large customer in the consumer genomics segment.
- GAAP gross margin was 43.5% in the third quarter of 2025 compared to 42.8% in the third quarter of 2024. Non-GAAP gross margin in the third quarter of 2025 was 44.2% compared to 43.3% in the third quarter of 2024¹.
- GAAP operating loss in the third quarter of 2025 was \$16.1 million compared to operating loss of \$6.0 million in the third quarter of 2024. Non-GAAP operating loss was \$12.7 million in the third quarter of 2025 compared to non-GAAP operating loss of \$2.7 million in the third quarter of 2024.
- Cash and cash equivalents were \$216 million as of September 30, 2025.
- OTI deployed \$5 million during the third quarter to repurchase approximately 1.5 million shares of our common stock.

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

- Signed a definitive agreement to acquire BioMedomics. The transaction expands OTI's diagnostic portfolio by adding SickleSCAN®, a rapid, point-of-need test for sickle cell disease that is currently sold outside the U.S. We believe OTI can significantly expand the reach and adoption of SickleSCAN® by leveraging our international sales channels and our existing relationships with national health programs.
- Extended our relationship with the Together Take Me Home program, a collaboration funded by the U.S. federal government that makes HIV self-tests available through the mail in order to reach at-risk populations.
- Selected by the ENDO1000 project to provide devices for collection and stabilization of a variety of samples including saliva, urine, stool, and vaginal swab. The ENDO1000 project is a U.K.-wide initiative aimed at accelerating discovery and advancing data-driven research into the diagnosis and personalized treatment of endometriosis.
- Appointed Steven K. Boyd to our Board of Directors as part of our ongoing refreshment efforts. Mr. Boyd is a seasoned investor who brings a valuable shareholder perspective and more than two decades of public markets experience across healthcare.
- Appointed Jack Kenny as Chair of our Board. Mr. Kenny has served as a director since September 2024. Mr. Kenny succeeds Mara Aspinall, who stepped down from the Board after more than eight years of service.

Financial Guidance

The Company is guiding to Q4 2025 Total revenues of \$25 million to \$28 million, which includes less than \$100 thousand of COVID-19 testing revenues.

Conference Call

The Company will host a conference call and audio webcast to discuss the Company's third quarter 2025 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.

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, \$ in 000's, except per share amounts)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2025	2024	2025	2024
Results of Operations				
Net revenues	\$ 27,085	\$ 39,915	\$ 88,258	\$ 148,382
Cost of products and services sold	15,313	22,845	51,028	82,558
Gross profit	11,772	17,070	37,230	65,824
Operating expenses:				
Research and development	10,106	5,623	31,110	19,960
Sales and marketing	6,299	7,615	19,533	23,994
General and administrative	11,081	9,831	37,859	33,310
Loss on impairments	—	—	—	4,392
Change in the estimated fair value of acquisition-related contingent consideration	376	—	1,587	—
Gain on sale of assets	—	—	(993)	—
Total operating expenses	27,862	23,069	89,096	81,656
Operating loss	(16,090)	(5,999)	(51,866)	(15,832)
Other income	2,799	2,781	5,712	9,338
Loss before income taxes and equity investment	(13,291)	(3,218)	(46,154)	(6,494)
Income tax expense	47	678	1,591	1,041
Loss before equity investment	(13,338)	(3,896)	(47,745)	(7,535)
Loss on equity investment	(374)	(611)	(1,700)	(1,171)
Net loss	\$ (13,712)	\$ (4,507)	\$ (49,445)	\$ (8,706)
Loss per share:				
Basic	\$ (0.19)	\$ (0.06)	\$ (0.67)	\$ (0.12)
Diluted	\$ (0.19)	\$ (0.06)	\$ (0.67)	\$ (0.12)
Weighted average shares outstanding:				
Basic	73,004	74,583	74,131	74,330
Diluted	73,004	74,583	74,131	74,330

	For the Three Months Ended September 30,			For the Nine Months Ended September 30,		
	2025	2024	% Change	2025	2024	% Change
Consolidated Net Revenues						
Diagnostics	\$ 14,499	\$ 22,023	(34)%	\$ 51,410	\$ 57,162	(10)%
Sample Management Solutions	10,306	12,806	(20)	29,271	36,237	(19)
Other product and services	442	748	(41)	1,059	1,838	(42)
COVID-19 Diagnostics	89	2,155	(96)	574	44,186	(99)
Risk Assessment Testing	—	1,911	(100)	1,866	6,265	(70)
Molecular Services	—	9	(100)	—	1,692	(100)
Net product and services revenues	25,336	39,652	(36)	84,180	147,380	(43)
Non-product and services revenues	1,749	263	565	4,078	1,002	307
Net revenues	\$ 27,085	\$ 39,915	(32)%	\$ 88,258	\$ 148,382	(41)%

Condensed Consolidated Balance Sheets (Unaudited, \$ in 000's)

	September 30, 2025	December 31, 2024
<u>Assets</u>		
Cash and cash equivalents	\$ 216,478	\$ 267,763
Accounts receivable, net	24,300	23,816
Inventories	33,401	34,197
Other current assets	8,832	7,444
Property, plant and equipment, net	40,795	45,105
Intangible assets, net	17,202	17,435
Goodwill	41,313	40,330
Investment in equity method investee	26,600	28,300
Other noncurrent assets	14,177	15,269
Total assets	<u>\$ 423,098</u>	<u>\$ 479,659</u>
<u>Liabilities and Stockholders' Equity</u>		
Accounts payable	\$ 6,360	\$ 8,173
Deferred revenue	1,879	2,961
Acquisition-related contingent consideration obligation	17,232	—
Other current liabilities	14,777	22,349
Other noncurrent liabilities	20,870	35,838
Stockholders' equity	361,980	410,338
Total liabilities and stockholders' equity	<u>\$ 423,098</u>	<u>\$ 479,659</u>

Additional Financial Data (Unaudited, \$ in 000's)

	For the Nine Months Ended September 30,	
	2025	2024
Capital expenditures	\$ 3,275	\$ 3,341
Depreciation and amortization	7,789	8,380
Stock-based compensation	8,687	9,178
Cash (used in) provided by operating activities	\$ (40,027)	\$ 27,265

Consolidated Statement of Cash Flows (Unaudited, \$ in 000's)

	For the Nine Months Ended September 30,	
	2025	2024
OPERATING ACTIVITIES:		
Net loss	\$ (49,445)	\$ (8,706)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Stock-based compensation	8,687	9,178
Depreciation and amortization	7,789	8,380
Loss on impairments	—	4,392
Other non-cash amortization	(221)	(569)
Provision for credit losses	(176)	521
Unrealized foreign currency loss (gain)	294	(154)
Interest expense on finance leases	6	20
Loss on equity investment	1,700	1,171
Deferred income taxes	(86)	165
Gain on sale of fixed assets	(993)	(121)
Change in the estimated fair value of acquisition-related contingent consideration	1,587	—
Changes in assets and liabilities:		
Accounts receivable	(16)	12,658
Inventories	894	8,659
Prepaid expenses and other assets	(1,915)	2,622
Accounts payable	(1,733)	(3,431)
Deferred revenue	(1,085)	66
Accrued expenses and other liabilities	(5,314)	(7,586)
Net cash (used in) provided by operating activities	<u>(40,027)</u>	<u>27,265</u>
INVESTING ACTIVITIES:		
Purchases of short-term investments	—	(53,244)
Investment in equity method investee	—	(30,000)
Proceeds from maturities and redemptions of short-term investments	—	53,052
Proceeds from sale of assets	888	—
Purchases of property and equipment	(3,275)	(3,341)
Net cash used in investing activities	<u>(2,387)</u>	<u>(33,533)</u>
FINANCING ACTIVITIES:		
Cash payments for finance lease liabilities	(43)	(746)
Proceeds from exercise of stock options	—	214
Repurchase of common stock	(10,001)	—
Payment of taxes related to net share settlement of equity awards	(1,786)	(3,533)
Net cash used in financing activities	<u>(11,830)</u>	<u>(4,065)</u>
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	2,959	(1,503)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(51,285)	(11,836)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	267,763	290,407
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 216,478	\$ 278,571

About OraSure Technologies

OraSure Technologies, Inc. (“OraSure” and “OTI”) transforms health through actionable insight and decentralizes diagnostics to connect 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

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 our products and services, 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; significant customer concentrations that exist or may develop in the future; 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; 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 and services; ability to achieve the anticipated benefits from the BioMedomics transaction; 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 increase our gross margins; 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, trade secrets 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 on international sales; 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 incidents and other disruptions involving our computer systems or those of our third-party IT service providers, suppliers and customers; the impact of terrorist attacks, civil unrest, hostilities and war; and general political, business and economic conditions, including interest rates, inflationary pressures, capital market disruptions, changes in governmental agencies, international tariffs, trade protection measures, economic sanctions and economic slowdowns or recessions. 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, 2024, 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 September 30,		For the Nine Months Ended September 30,	
	2025	2024	2025	2024
Net Revenues	\$ 27,085	\$ 39,915	\$ 88,258	\$ 148,382
GAAP Cost of Products and Services Sold	15,313	22,845	51,028	82,558
<i>GAAP Gross Margin</i>	<i>43.5%</i>	<i>42.8%</i>	<i>42.2%</i>	<i>44.4%</i>
Stock compensation	208	195	584	539
Inventory reserve for product line discontinuance	—	—	146	—
Reduction in workforce severance	—	7	—	1,127
Non-GAAP Cost of Goods Sold	15,105	22,643	50,298	80,892
<i>Non-GAAP Gross Margin</i>	<i>44.2%</i>	<i>43.3%</i>	<i>43.0%</i>	<i>45.5%</i>
GAAP Operating Loss	(16,090)	(5,999)	(51,866)	(15,832)
Stock compensation	2,835	2,888	8,687	9,178
Amortization of acquisition-related intangible assets	58	59	171	176
Inventory reserve for product line discontinuance	—	—	146	—
Reduction in workforce severance	—	353	—	2,410
Executive severance expense	—	—	751	—
Loss on impairment	—	—	—	4,392
Gain on sale of assets under product line discontinuance	—	—	(750)	—
Transaction costs	112	—	112	—
Change in fair value of acquisition-related contingent consideration	376	—	1,587	—
Non-GAAP Operating (Loss) Income	(12,709)	(2,699)	(41,162)	324
GAAP Net Loss	(13,712)	(4,507)	(49,445)	(8,706)
Stock compensation	2,835	2,888	8,687	9,178
Amortization of acquisition-related intangible assets	58	59	171	176
Inventory reserve for product line discontinuance	—	—	146	—
Reduction in workforce severance	—	353	—	2,409
Executive severance expense	—	—	751	—
Loss on impairment	—	—	—	4,392
Gain on sale of assets under product line discontinuance	—	—	(750)	—
Transaction costs	112	—	112	—
Change in fair value of acquisition-related contingent consideration	376	—	1,587	—
Loss on equity investment	374	611	1,700	1,171
Tax effect of non-GAAP adjustments	126	(93)	(123)	(447)
Non-GAAP Net (Loss) Income	\$ (9,831)	\$ (689)	\$ (37,164)	\$ 8,173
GAAP Loss Per Share:	\$ (0.19)	\$ (0.06)	\$ (0.67)	\$ (0.12)
Non-GAAP (Loss) Earnings Per Share:	\$ (0.13)	\$ (0.01)	\$ (0.50)	\$ 0.11
Diluted Shares Outstanding	73,004	74,583	74,131	74,330
Diluted Shares Outstanding Used For Computing Non-GAAP (Loss) Earnings Per Share	73,004	74,583	74,131	75,328

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

- Inventory reserve for product line discontinuance: represents inventory associated with discontinued line of business
- Reduction in workforce severance: termination benefits associated with the Company's workforce reduction associated with certain business events
- Executive severance expense: expenses associated with the departure of an executive
- Loss on impairment: charges related to the write down of Company's intangibles, PP&E, or leased assets
- Gain on sale of assets under product line discontinuance: represents the gain on the sale of fixed assets associated with the risk assessment line of business that was discontinued and sold to a 3rd party
- Transaction costs: expenses associated with due diligence of targets
- Change in fair value of acquisition-related contingent consideration: changes in the fair value of contingent consideration liability associated with an adjustment for the passage of time
- 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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