



Q4-24 Earnings Summary

Financial Highlights

	FY22	1Q23	2Q23	3Q23	4Q23	FY23	1Q24	2Q24	3Q24	4Q24	FY24
Total Revenue	\$387.5	\$155.0	\$85.4	\$89.2	\$75.9	\$405.5	\$54.1	\$54.3	\$39.9	\$37.4	\$185.8
YoY Growth	65.8%	129.0%	6.5%	-23.4%	-38.4%	4.6%	-65.1%	-36.4%	-55.3%	-50.7%	-54.2%
Core Revenue	\$136.8	\$35.1	\$36.5	\$38.2	\$33.3	\$143.1	\$30.1	\$34.6	\$37.8	\$36.5	\$139.0
YoY Growth	-5.6%	-0.3%	3.1%	6.8%	0.4%	4.6%	-14.2%	-5.4%	-1.1%	9.6%	-2.9%
COVID-19 Revenue	\$243.4	\$118.5	\$47.5	\$50.2	\$41.7	\$257.9	\$23.1	\$18.9	\$2.2	\$1.0	\$45.2
YoY Growth	216.5%	282.3%	9.5%	-37.3%	-53.2%	6.0%	-80.5%	-60.1%	-95.7%	-97.7%	-82.5%
Molecular Svcs Revenue	\$7.3	\$1.4	\$1.4	\$0.8	\$0.9	\$4.5	\$0.9	\$0.8	\$0.0	\$0.0	\$1.7
YoY Growth	-38.4%	282.3%	9.5%	-37.3%	-53.2%	-38.7%	-36.7%	-40.2%	-98.9%	-98.6%	-61.9%
GAAP Gross Profit	\$148.4	\$65.8	\$26.4	\$44.3	\$35.1	\$171.6	\$24.1	\$24.7	\$17.1	\$13.6	\$79.4
Gross Margin	38.3%	42.5%	30.9%	49.7%	46.3%	42.3%	44.5%	45.4%	42.8%	36.2%	42.7%
Non-GAAP Gross Profit	\$155.3	\$66.3	\$35.9	\$44.6	\$37.7	\$184.5	\$24.4	\$25.8	\$17.3	\$15.0	\$82.5
Non-GAAP Gross Margin	40.1%	42.8%	42.0%	50.0%	49.7%	45.5%	45.2%	47.4%	43.3%	40.1%	44.4%
GAAP Operating Profit	\$(22.2)	\$24.3	\$(6.4)	\$10.9	\$3.9	\$32.7	\$(7.1)	\$(2.7)	\$(6.0)	\$(12.4)	\$(28.2)
Operating Margin	-5.7%	15.7%	-7.5%	12.2%	5.1%	8.1%	-13.1%	-5.0%	-15.0%	-33.2%	-15.2%
Non-GAAP Operating Profit	\$22.5	\$32.7	\$6.7	\$20.6	\$13.6	\$73.6	\$(0.3)	\$3.3	\$(2.7)	\$(6.7)	\$(6.4)
Non-GAAP Operating Margin	5.8%	21.1%	7.9%	23.1%	18.0%	18.2%	-0.6%	6.2%	-6.8%	-18.0%	-3.5%
GAAP EPS	\$(0.24)	\$0.37	\$(0.07)	\$0.15	\$0.27	\$0.72	\$(0.05)	\$(0.01)	\$(0.06)	\$(0.14)	\$(0.26)
Non-GAAP EPS	\$0.36	\$0.47	\$0.09	\$0.27	\$0.22	\$1.04	\$0.04	\$0.08	\$(0.01)	\$(0.06)	\$0.05

Key Quarterly Takeaways

Q4 Total Revenue and Core Revenue were in the top half of our guidance range.

Q4 Core revenue grew 10% year-over-year, with Diagnostics revenue increasing 9% to \$18.8 million and Sample Management revenue growing 14% to \$14.8 million.

Acquired Sherlock Biosciences to expand our innovation pipeline with the addition of a molecular diagnostics platform.

Generated positive cash flow from operations for our Core business for the 2nd consecutive quarter.

Provided Q1-25 financial guidance for revenue of \$27.5 to \$31.5 million, which includes Core revenue of \$27 to \$31 million and COVID-19 revenue of \$0.5 million.

Cash and equivalents balance of \$268 million as of Dec. 30.

Business Highlights

- Total revenue in Q4 of \$37.4 million was in the top half of our guidance range of \$36 to \$38 million.
- Core revenue in Q4 of \$36.5 million was in the top half of our guidance range of \$35 to \$37 million.
- Acquired Sherlock Biosciences in December to expand our innovation pipeline with the addition of a molecular diagnostics platform that, subject to approval by the 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.
- Received an award through the Rapid Response Partnership Vehicle (RRPV) for the development of a Marburg Virus Disease (MVD) rapid antigen test. 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.
- Generated positive Operating Cash Flow in the 4th quarter, including positive cash flow generation in our Core business for the 2nd consecutive quarter.
- Ended Q4 with zero debt and \$268 million of total cash and cash equivalents.

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.

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

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>	36.2%	46.3%	42.7%	42.3%
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>	40.1%	46.5%	44.4%	42.7%
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	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	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 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>