



Q3 2023 Earnings Summary

Financial Highlights

	1Q21	2Q21	3Q21	4Q21	FY21	1Q22	2Q22	3Q22	4Q22	FY22	1Q23	2Q23	3Q23
Total Revenue	\$58.6	\$57.6	\$53.9	\$63.6	\$233.7	\$67.7	\$80.2	\$116.5	\$123.1	\$387.5	\$155.0	\$85.4	\$89.2
YoY Growth	85.5%	96.9%	12.3%	1.2%	36.1%	15.5%	39.2%	116.1%	93.6%	65.8%	129.0%	6.5%	-23.4%
COVID-19 Revenue	\$27.4	\$12.4	\$13.9	\$23.2	\$76.9	\$31.0	\$43.4	\$80.0	\$89.0	\$243.4	\$118.5	\$47.5	\$50.2
YoY Growth	NM	46.4%	-24.6%	3.1%	55.6%	13.1%	250.0%	475.5%	283.6%	216.5%	282.3%	9.5%	-37.3%
Core Revenue	\$31.2	\$45.2	\$40.0	\$40.4	\$156.8	\$36.7	\$36.8	\$36.5	\$34.1	\$144.1	\$36.6	\$37.9	\$39.0
YoY Growth	-1.3%	117.4%	35.3%	0.1%	28.2%	17.6%	-18.6%	-8.8%	-15.6%	-8.1%	-0.3%	3.1%	6.8%
GAAP Gross Profit	\$38.3	\$30.7	\$21.5	\$27.1	\$117.6	\$24.3	\$27.8	\$46.5	\$49.8	\$148.4	\$65.8	\$26.4	\$44.3
Gross Margin	65.4%	53.3%	39.9%	42.6%	50.3%	35.9%	34.7%	39.9%	40.5%	38.3%	42.5%	30.9%	49.7%
Non-GAAP Gross Profit	\$38.5	\$30.9	\$23.6	\$28.7	\$121.7	\$25.5	\$32.4	\$47.0	\$50.4	\$155.3	\$66.3	\$35.9	\$44.6
Non-GAAP Gross Margin	65.7%	53.6%	43.8%	45.1%	52.1%	37.7%	40.4%	40.3%	40.9%	40.1%	42.8%	42.0%	50.0%
GAAP Operating Profit	\$10.4	\$1.8	\$(13.0)	\$(9.4)	\$(10.2)	\$(16.2)	\$(21.5)	\$0.9	\$14.6	\$(22.2)	\$24.3	\$(6.4)	\$10.9
Operating Margin	17.7%	3.1%	-24.1%	-14.8%	-4.4%	-23.9%	-26.8%	0.8%	11.9%	-5.7%	15.7%	-7.5%	12.2%
Non-GAAP Operating Profit	\$11.8	\$3.8	\$(8.8)	\$(1.3)	\$5.4	\$(6.6)	\$(1.2)	\$11.7	\$18.6	\$22.5	\$32.7	\$6.7	\$20.6
Non-GAAP Operating Margin	20.1%	6.6%	-16.3%	-2.0%	2.3%	-9.7%	-1.5%	10.0%	15.1%	5.8%	21.1%	7.9%	23.1%
GAAP EPS	\$0.05	\$(0.02)	\$(0.21)	\$(0.14)	\$(0.32)	\$(0.28)	\$(0.26)	\$0.08	\$0.22	\$(0.24)	\$0.37	\$(0.07)	\$0.15
Non-GAAP EPS	\$0.07	\$0.01	\$(0.15)	\$(0.03)	\$(0.11)	\$(0.15)	\$0.00	\$0.14	\$0.36	\$0.36	\$0.47	\$0.09	\$0.27

Key Quarterly Takeaways

Q3 Core Revenue grew 7% year-over-year, driven by strong HIV sales in the U.S. and international markets.

Continued to execute on our IntelliSwab® contracts, which generated \$50 million of revenue in Q3.

Completed the final project milestones related to the expansion of our Opus Way facility, and in Q4 we received the final \$24 million of milestone payments for this project.

Cash and cash equivalents balance increased to \$225 million, a \$39 million increase compared to the prior quarter.

Expanded the portfolio of tests that we can offer to our customers through new distribution partnerships in the areas of International infectious disease testing and point-of-care substance abuse testing.

Improved profitability with Q3 GAAP EPS of \$0.15 and non-GAAP EPS of \$0.27

Provided Q4-23 financial guidance for revenue of \$71 to \$76 million, which includes Core revenue of \$33 to \$35 million and IntelliSwab® revenue of \$38 to \$41 million.

Business Highlights

- Diagnostics revenue grew 59% year-over-year in Q3, driven by strong growth in HIV testing in both U.S. and international markets.
- Molecular products revenue in Q3 decreased 4% y/y, but grew 17% on a sequential basis. We are seeing signs of stabilization with current customers, as well as positive momentum in establishing new partnerships and extending existing relationships.
- IntelliSwab® revenue of \$50 million was above our guidance range of \$35 to \$38 million, driven by stronger-than-anticipated volumes. We have visibility to order trends that are expected to complete the remaining portion of our contract during the first half of 2024.
- Delivered gross margin expansion in Q3, driven by operating efficiencies and lower manufacturing scrap expense.
- We are focused on driving efficiencies across our business, including consolidation of facilities, leveraging of automation, and controlling our non-production costs, which puts us on track to exceed the \$15 million of annualized cost savings announced in Q1 2023.
- Generated \$37 million of operating cash flow in Q3, as well as collecting \$6.5 million from the U.S. government related to our manufacturing expansion contract.
- We continue to make progress on our path to achieve operating cash flow break-even in our core business by the end of 2024.
- With our stronger balance sheet, we are investing in our internal innovation roadmap and evaluating external opportunities to expand our portfolio in order to accelerate long-term growth.

Forward Looking Statements

This press release contains certain forward-looking statements, including with respect to products, product development activities, regulatory submissions and authorizations, revenue growth, cost savings, cash flow, increasing margins and other matters. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include, but are not limited to: our ability to satisfy customer demand; ability to reduce our spending rate, capitalize on manufacturing efficiencies and drive profitable growth; ability to achieve the anticipated cost savings as a result of our business restructuring; ability to market and sell products, whether through our internal, direct sales force or third parties; impact of significant customer concentration in the genomics business; failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our products; ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements; ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; ability to comply with applicable regulatory requirements; ability to effectively resolve warning letters, audit observations and other findings or comments from the U.S. Food and Drug Administration (“FDA”) or other regulators; the impact of the novel coronavirus (“COVID-19”) pandemic on the Company's business, supply chain, labor force, ability to successfully develop new products, validate the expanded use of existing collector products, receive necessary regulatory approvals and authorizations and commercialize such products for COVID-19 testing, and demand for our COVID-19 testing products ; changes in relationships, including disputes or disagreements, with strategic partners or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements; ability to meet increased demand for the Company's products; impact of replacing distributors; inventory levels at distributors and other customers; ability of the Company to achieve its financial and strategic objectives and continue to increase its revenues, including the ability to expand international sales and the ability to continue to reduce costs; impact of competitors, competing products and technology changes; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products; market acceptance of oral fluid or urine testing, collection or other products; market acceptance and uptake of microbiome informatics, microbial genetics technology and related analytics services; changes in market acceptance of products based on product performance or other factors, including changes in testing guidelines, algorithms or other recommendations by the Centers for Disease Control and Prevention (“CDC”) or other agencies; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical products and components; availability of related products produced by third parties or products required for use of our products; impact of contracting with the U.S. government; impact of negative economic conditions; ability to maintain sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of the Company's stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to attract and retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks, civil unrest, hostilities and war ; and general political, business and economic conditions, including inflationary pressures. These and other factors that could affect our results are discussed more fully in our SEC filings, including our registration statements, Annual Report on Form 10-K for the year ended December 31, 2022, 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.

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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue	\$ 89,187	\$ 116,463	\$ 329,591	\$ 264,401
GAAP Cost of products and services sold	44,847	69,949	193,065	165,791
<i>GAAP Gross Margin</i>	<i>49.7%</i>	<i>39.9%</i>	<i>41.4%</i>	<i>37.3%</i>
Stock compensation	137	(114)	426	191
Amortization of acquisition-related intangible assets	132	132	396	396
Reduction in workforce severance	—	—	369	—
Transformation related expenses	—	419	281	1,334
Accelerated depreciation	—	—	6,950	—
Inventory reserve for excess levels	—	—	1,804	4,369
Non-GAAP Cost of Goods Sold	44,578	69,512	182,839	159,501
<i>Non-GAAP Gross Margin</i>	<i>50.0%</i>	<i>40.3%</i>	<i>44.5%</i>	<i>39.7%</i>
GAAP Operating Income (Loss)	10,894	866	28,786	(36,777)
Stock compensation	2,590	2,296	7,602	6,805
Amortization of acquisition-related intangible assets	467	468	1,399	1,470
Reduction in workforce severance	—	—	3,264	—
Accelerated depreciation	—	—	6,950	—
Inventory reserve for excess levels	—	—	1,804	4,369
Loss on impairment	6,183	6,559	7,503	17,101
Transformation related expenses	26	616	707	5,671
Executive severance expense	—	558	—	3,550
Strategic alternative costs	—	—	—	848
Government grant accounting	448	331	2,036	947
Change in fair value of acquisition-related contingent consideration	(40)	—	(99)	(36)
Non-GAAP Operating Income (Loss)	20,568	11,694	59,952	3,948
GAAP Net Income (Loss)	11,159	5,595	\$ 33,582	(32,934)
Stock compensation	2,590	2,296	7,602	6,805
Amortization of acquisition-related intangible assets	467	468	1,399	1,470
Reduction in workforce severance	—	—	3,264	—
Accelerated depreciation	—	—	6,950	—
Inventory reserve for excess levels	—	—	1,804	4,369
Loss on impairment	6,183	6,559	7,503	17,101
Transformation related expenses	26	616	707	5,671
Executive severance expense	—	558	—	3,550
Strategic alternative costs	—	—	—	848
Change in fair value of acquisition-related contingent consideration	(40)	—	(99)	(36)
Tax effect of Non-GAAP adjustments	(438)	(6,092)	(1,606)	(7,337)
Non-GAAP Net Income (Loss)	\$ 19,947	\$ 10,000	\$ 61,106	\$ (493)
GAAP Earnings (Loss) Per Share:	\$ 0.15	\$ 0.08	\$ 0.45	\$ (0.45)
Non-GAAP Earnings (Loss) Per Share:	\$ 0.27	\$ 0.14	\$ 0.82	\$ (0.01)
Diluted Shares Outstanding	74,349	72,785	74,197	72,448

Following is a description of the adjustments made to GAAP financial measures:

- Stock Compensation: non-cash equity-based compensation provided to OraSure employees and directors excluding accelerated stock compensation as required under former employees' employment agreements
- Amortization of acquisition-related intangible assets: represents recurring amortization charges resulting from the acquisition of intangible assets associated with our business combinations
- Reduction in workforce severance: one-time termination benefits associated with the Company's workforce reduction
- Inventory reserve for excess levels: reserves recorded for inventory balances that are deemed excess based on current forecasts and expirations dates
- Loss on impairment: charges related to the write down of Company's PP&E
- Transformation related expenses: transitory costs such as consulting and professional fees related to transformation initiatives
- Accelerated depreciation: reduction in the useful life of certain assets to fully depreciate those assets which were identified as having no future use beyond the period presented due to a manufacturing site closure
- Strategic alternative costs: one-time expenses such as legal and banking fees tied to the Company's strategic alternative process
- Executive severance expenses: expenses tied to executive severance agreements including accelerated stock compensation
- 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

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