OraSure Technologies, Inc.

Q4 2023 Earnings Summary

Financial Highlights

	1Q21	2Q21	3Q21	4Q21	FY21	1Q22	2Q22	3Q22	4Q22	FY22	1Q23	2Q23	3Q23	4Q23	FY23
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	$75.9	$405.5
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%*	*-38.4%*	*4.6%*
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	$41.7	$257.9
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%*	*-53.2%*	*6.0%*
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	$34.2	$147.7
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%*	*0.4%*	*2.5%*
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	$35.1	$171.6
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%*	*46.3%*	*42.3%*
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	$37.7	$184.5
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%*	*49.7%*	*45.5%*
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	$3.9	$32.7
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%*	*5.1%*	*8.1%*
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	$13.6	$73.6
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%*	*18.0%*	*18.2%*
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	$0.27	$0.72
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	$0.22	$1.04

Key Quarterly Takeaways

Q4 Core Revenue grew 0.4% year-over-year, driven by strong HIV sales in the U.S. and international markets, partially offset by a decline in non-product revenue.

Continued to execute on our InteliSwab® contracts, which generated $42 million of revenue in Q4.

Delivered significant gross margin expansion in Q4 on a y/y basis, driven by operating efficiencies and cost reduction initiatives.

Cash and cash equivalents balance increased to $290 million, a $65 million increase compared to the prior quarter.

Entered into a strategic distribution relationship and investment in Sapphiros, a next generation consumer diagnostics company, which is expected to strengthen our portfolio of collection devices and diagnostic tests.

Improved profitability with Q4 GAAP EPS of $0.27 and non-GAAP EPS of $0.22

Provided Q1-24 financial guidance for revenue of $50 to $54 million, which includes Core revenue of $29 to $31 million and InteliSwab® revenue of $21 to $23 million.

Business Highlights

- Diagnostics revenue grew 19% year-over-year in Q4, driven by strong growth in HIV testing in both U.S. and international markets.
- Molecular sample management solutions revenue in Q4 increased 9% y/y. Over the past few quarters, we have signed multi-year contract extensions with several of our largest customers.
- InteliSwab® revenue in Q4 of $42 million was above our guidance range of $38 to $41 million, driven by stronger-than-anticipated volumes. We expect to fulfill the remaining portion of our largest InteliSwab® contract during the first half of 2024.
- We exceeded our target of $15 million of annualized cost savings in 2023, and we have identified opportunities that we expect will drive additional productivity enhancements and cost reductions in 2024 and beyond.
- Generated $41 million of operating cash flow in Q4, as well as collecting $24 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.
- We are entering the U.S. syphilis testing market via a strategic distribution agreement with Diagnostics Direct.
- We established new distribution relationships to expand our offerings in sample management solutions and substance abuse testing.
- 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 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: Sapphiros' and its related entities' ability to seek and obtain regulatory approval for products in development; 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 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, such as Sapphiros, 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, 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 December 31,		Years Ended December 31,	
	2023	2022	2023	2022
Revenue	$ 75,881	$ 123,078	$ 405,472	$ 387,479
GAAP Cost of products and services sold	40,755	73,250	233,820	239,041
GAAP Gross Margin	*46.3%*	*40.5%*	*42.3%*	*38.3%*
Stock compensation	138	140	564	331
Amortization of acquisition-related intangible assets	—	132	396	528
Reduction in workforce severance	—	—	369	—
Transformation related expenses	—	265	281	1,599
Accelerated depreciation	516	—	7,466	—
Inventory reserve for excess levels	1,957	—	3,761	4,369
Non-GAAP Cost of Goods Sold	38,144	72,713	220,983	232,214
Non-GAAP Gross Margin	*49.7%*	*40.9%*	*45.5%*	*40.1%*
GAAP Operating Income (Loss)	3,898	14,621	32,684	(22,156)
Stock compensation	3,127	2,349	10,729	9,154
Amortization of acquisition-related intangible assets	150	467	1,549	1,937
Reduction in workforce severance	—	—	3,264	—
Accelerated depreciation	516	—	7,466	—
Inventory reserve for excess levels	1,957	—	3,761	4,369
Loss on impairment	3,326	—	10,829	17,101
Transformation related expenses	—	520	707	6,191
Executive severance expense	—	300	—	3,850
Strategic alternative costs	—	—	—	848
Transaction costs	650	—	650	—
Government grant accounting	—	475	2,036	1,422
Change in fair value of contingent consideration	—	(152)	(99)	(188)
Non-GAAP Operating Income	13,624	18,580	73,576	22,528
GAAP Net Income (Loss)	20,073	15,801	$ 53,655	(17,133)
Stock compensation	3,127	2,349	10,729	9,154
Amortization of acquisition-related intangible assets	150	467	1,549	1,937
Reduction in workforce severance	—	—	3,264	—
Accelerated depreciation	516	—	7,466	—
Inventory reserve for excess levels	1,957	—	3,761	4,369
Loss on impairment	3,326	—	10,829	17,101
Transformation related expenses	—	520	707	6,191
Executive severance expense	—	300	—	3,850
Strategic alternative costs	—	—	—	848
Transaction costs	650	—	650	—
Change in fair value of contingent consideration	—	(152)	(99)	(188)
Additional profit from government contract	(12,802)	—	(12,802)	—
Tax effect of Non-GAAP adjustments	(518)	6,997	(2,124)	(340)
Non-GAAP Net Income (Loss)	$ 16,479	$ 26,282	$ 77,585	$ 25,789

GAAP Earnings (Loss) Per Share:	$	0.27	$	0.22	$	0.72	$	(0.24)
Non-GAAP Earnings (Loss) Per Share:	$	0.22	$	0.36	$	1.04	$	0.36
Diluted Shares Outstanding		75,013		73,248		74,389		72,505

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 expiration dates
- Loss on impairment: charges related to the write down of Company's PP&E, goodwill and intangible assets
- Transaction costs: costs related to mergers and acquisition transactions or strategic investments
- 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 that were identified as having no future use beyond the period presented
- 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
- Additional profit from government contracts: income earned under a fixed-firm contract as a result of spending below the original budgeted amount expected under the contract
- 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 be found at: https://orasure.gcs-web.com/gaap-non-gaap-reconciliation