OraSure Reports 1Q23 Record Revenue of $155.0 Million; Announces New Collaborations as Company Increasingly Focuses on Core Growth

May 10, 2023

InteliSwab® test revenue of $118.3 million in Q1, up 33% sequentially; Company delivers cost savings and begins to taper InteliSwab® test production and expenses

Gross margins increase 200 basis points sequentially despite mix/pricing headwinds

Signs three new molecular partnerships supporting cancer diagnostics, women's health testing, and microbiome services

Q1 GAAP EPS of $0.37; Non-GAAP EPS of $0.47

Improved cash position with $112.4 million in cash and cash equivalents; Company anticipates additional favorable impact from working capital in 2023

Management to Host Analyst/Investor Call and Webcast Today at 5:00 p.m. ET

BETHLEHEM, Pa., May 10, 2023 (GLOBE NEWSWIRE) -- OraSure Technologies, Inc. (NASDAQ: OSUR), a leader in point-of-care and home diagnostic tests, specimen collection devices, and microbiome laboratory and analytical services, today announced its financial results for the three months ended March 31, 2023.

"This quarter we once again delivered clear progress on our transformation journey. First, to Strengthen Our Foundation we reduced our non-production workforce in Q1 by 11% in accordance with our planned $15 million in annual savings, and we will deliver additional cost savings in the near-term as COVID-19 volumes have begun to taper. We also significantly increased gross margins despite mix/pricing headwinds and implemented new packaging changes on InteliSwab® tests which are expected to result in savings of approximately $0.50 per test. With facility consolidation, implementation of additional automation, and manufacturing process upgrades, we plan to further drive efficiencies and believe we will achieve our goal to breakeven in cash flow from operations for the core business in 2024," said OraSure President and CEO Carrie Eglinton Manner.

She continued, "The most important point of streamlining our cost structure is building a solid foundation to Elevate Core Growth across the enterprise. We made progress on our product pipeline as we work to expand our infectious disease and sexual health portfolio of assays and to extend our leadership in molecular products. Additionally, this quarter we signed three new molecular partnerships following our recent deals with Quest Diagnostics and Grifols which make us increasingly confident in the long-term trajectory of our molecular portfolio. Overall, we believe the steps we've taken this quarter have further positioned the Company to drive profitable growth and deliver additional shareholder value."

Financial Highlights

	Three Months Ended March 31,		
	2023	**2022**	**% Change**
Core Business	$ 36,554	$ 36,675	0 %
COVID-19	118,409	31,032	282
Total Net Revenue	$ 154,963	$ 67,707	129 %

	Three Months Ended March 31,		
	2023	**2022**	**% Change**
Net revenues	$ 154,963	$ 67,707	129 %
Gross profit	65,815	24,299	171
Gross margin	42.5%	35.9%	
Non-GAAP gross profit	66,277	25,527	160
Non-GAAP gross margin	42.8%	37.7%	
Operating income (loss)	24,321	(16,172)	NM
Operating margin	15.7%	-23.9%	
Non-GAAP operating income (loss)	32,658	(6,584)	NM
Non-GAAP operating income (loss)	21.1%	-9.7%	
Net income (loss)	27,219	(19,940)	NM
Non-GAAP net income (loss)	34,454	(10,662)	NM

GAAP EPS	$	0.37	$	(0.28)	NM
Non-GAAP EPS	$	0.47	$	(0.15)	NM %

NM – not meaningful

- Net revenues for the first quarter of 2023 were $155.0 million, a 129% increase from the first quarter of 2022 and a new record for the Company.
- Total InteliSwab® test revenue of $118.3 million increased 33% sequentially as the Company delivered record test volume supporting the Federal government's school testing program during the quarter. Given Q2 2023 InteliSwab® volume tapering, OraSure has now begun to scale-down its COVID-19 production. The Company is also in the process of closing an overseas production operation as part of its broader strategy to consolidate manufacturing.
- Core revenue (excluding COVID-19 revenues) grew sequentially in the quarter. Core growth was driven by strong HIV sales as the Company began delivering orders under the "Let's Stop HIV Together," program and strong international HIV test sales due to carryover from the fourth quarter. Molecular product sales also increased sequentially 7% but declined year-over-year as the Company continued to see some disruption amongst its large customers.
- GAAP gross margin percentage was 42.5% in the quarter compared to 35.9% in the first quarter of 2022. GAAP gross margins increased 200 basis points on a sequential basis. Non-GAAP gross margins in the quarter were 42.8% compared to 37.7% in the first quarter of 2022 and non-GAAP gross margins increased 190 basis points on a sequential basis. On a year-over-year basis, gross margins were negatively impacted primarily by product mix and InteliSwab® test pricing but increased predominantly due to manufacturing efficiencies associated with InteliSwab® test production and decreased scrap expense.
- GAAP operating income in the first quarter was $24.3 million which compares to a ($16.2) million operating loss in the first quarter of 2022 and increased $9.8 million on a sequential basis. Non-GAAP operating income was $32.7 million in the quarter compared to a ($6.6) million non-GAAP operating loss in the first quarter of 2022 and increased by $14.1 million on a sequential basis. This was driven by higher revenue and improved gross margins.
- Cash and short-term investments increased to $112.4 million as of March 31, 2023. Working capital also continued to increase meaningfully in the first quarter as the Company delivered increased InteliSwab® tests. Management believes increased working capital will improve its cash balance as InteliSwab® revenues taper in the future.

Recent Business Highlights

- Delivered first OraQuick® HIV Self Tests under the "Let's Stop HIV Together" program in partnership with Emory University and the United States Center for Disease Control and Prevention.
- Completed transition to the new packaging and labeling configuration for InteliSwab® and began shipping the new configuration in March 2023. The packaging changes are expected to drive per test cost savings of approximately $0.50 which includes the impact from lower shipping costs based upon the smaller packaging configuration that are expected to reduce total truckloads by approximately 50%.
- Announced a new collaboration with Ziwig®, a French biotech company commercializing Ziwig Endotest®, a breakthrough innovation using salivary miRNA to diagnose endometriosis. This painful condition, which on average takes 8 years to diagnose, impacts quality of life and in some cases, fertility, for the 190 million women in the world who suffer from it.
- Signed a partnership deal with Novozymes, a global biotechnology company and world-leader in biosolutions, to provide a full service offering in support of their BiomeFx™ product. BiomeFx™ is a personalized health microbiome test, which leverages insights from the gut and vaginal microbiome to empower participants to lead healthier lives. Microbiome samples will be collected using sample collection kits from OraSure's DNA Genotek subsidiary and microbiome sequencing and analytic services will be provided by Diversigen. The service launched in April 2023.
- Signed a commercial collaboration with nRichDX, to validate and co-promote the Company's products for their liquid biopsy applications using first-void urine samples collected by Colli-Pee® urine collection device. The companies are evaluating applications for use such as sexually-transmitted infections, human papillomavirus (HPV), and early-stage cancer detection.
- Received acceptance for a publication in a peer-reviewed journal for a Colli-Pee® study conducted in partnership with Manchester University and Aquarius Population Health, a UK-based organization. The study compared three HPV sample collection methods including 1) routine clinician-collected cervical sample, 2) self-collected first-void (FV) urine using the OraSure/Novosanis Colli-Pee® device; and 3) self-collected vaginal swab in 10,000 women who were eligible for the NHS Cervical Screening Programme. Notably, the study concluded that self-sampling for routine primary human papillomavirus (HPV) cervical cancer screening with Colli-Pee® device could provide a less costly alternative to clinician-collected sampling (32% reduction) and other self-sampling approaches (4.4% reduction). This could support expanding the reach of affordable, Colli-Pee®-mediated cervical cancer screening to underserved women at scale in the UK, and possibly elsewhere.

Financial Guidance

The Company is guiding toward 2Q23 revenue of $62 to $67 million. Given lower April ordering activity from the U.S. government in respect to the school testing program, OraSure is guiding to InteliSwab® revenue of $25 to $30 million in the second quarter representing current government

program orders. The Company is actively working with its public health partners on a path to ensure warm-base manufacturing and infectious disease outbreak readiness utilizing existing funds appropriated under its InteliSwab® contracts. Additionally, the Company anticipates experiencing some temporary margin headwinds in Q2 2023 predominantly due to InteliSwab® pricing mix. Furthermore, in support of its goal to achieve cash flow from operations breakeven by 2024, the Company plans to deliver additional cost savings beyond the $15 million announced in Q1 2023.

Financial Data (Unaudited)

	Three Months Ended March 31,	
	2023	**2022**
Results of Operations		
Net revenues	$ 154,963	$ 67,707
Cost of products and services sold	89,148	43,408
Gross profit	65,815	24,299
Operating expenses:		
Research and development	10,560	8,634
Sales and marketing	12,142	12,717
General and administrative	17,711	19,156
Loss on impairment	1,105	—
Change in fair value of acquisition-related contingent consideration	(24)	(36)
Total operating expenses	41,494	40,471
Operating income (loss)	24,321	(16,172)
Other income	2,673	168
Income (loss) before income taxes	26,994	(16,004)
Income tax expense (benefit)	(225)	3,936
Net income (loss)	$ 27,219	$ (19,940)
Earnings (loss) per share:		
Basic	$ 0.37	$ (0.28)
Diluted	$ 0.37	$ (0.28)
Weighted average shares:		
Basic	73,112	72,194
Diluted	73,966	72,194

	Three Months Ended March 31,		
	2023	**2022**	**% Change**
COVID-19 Diagnostics	$ 118,254	$ 22,136	434%
Diagnostics	17,090	11,423	50
COVID-19 Molecular Products	155	8,896	(98)
Molecular Products	12,942	17,933	(28)
Molecular Services	1,379	1,733	(20)
Other products and services	3,094	3,115	(1)
Net product and services revenues	152,914	65,236	134
Non-product and services revenues	2,049	2,471	(17)
Total Net Revenue	$ 154,963	$ 67,707	129%

Condensed Consolidated Balance Sheets (Unaudited)

	March 31, 2023	**December 31, 2022**
Assets		
Cash and cash equivalents	$ 90,194	$ 83,980
Short-term investments	22,178	26,867
Accounts receivable, net	107,445	70,797
Inventories	77,189	95,704
Other current assets	46,589	47,842
Property, plant and equipment, net	57,343	59,413
Intangible assets, net	11,184	11,694
Goodwill	35,204	35,104
Long-term investments	—	—

Other noncurrent assets	12,089	12,779
Total assets	$ 459,415	$ 444,180
Liabilities and Stockholders' Equity		
Accounts payable	$ 27,396	$ 38,020
Deferred revenue	1,989	2,273
Other current liabilities	25,738	28,770
Other non-current liabilities	10,113	10,692
Stockholders' equity	394,179	364,425
Total liabilities and stockholders' equity	$ 459,415	$ 444,180

Additional Financial Data (Unaudited)

	Three Months Ended March 31,	
	2023	2022
Capital expenditures	$ 3,958	$ 22,074
Depreciation and amortization	$ 3,696	$ 3,682
Stock-based compensation	$ 2,655	$ 3,524
Cash provided by (used in) operating activities	$ 6,002	$ (35,821)

Conference Call

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's first quarter 2023 results and certain business developments, beginning today at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). On the call will be Carrie Eglinton Manner, President and Chief Executive Officer, Ken McGrath, Chief Financial Officer, and Scott Gleason, SVP Investor Relations and Corporate Communications. The call will include prepared remarks by management and a question and answer session.

In order to listen to the conference call, please register to obtain a dial in and pin at the following link:

https://register.vevent.com/register/BI1408073fde3e47ab889cfdc791e65ccf

To listen to the webcast, go to OraSure Technologies' web site, www.orasure.com, and click on the Investor Relations page. Please click on the webcast link and follow the prompts for registration and access 10 minutes prior to the call. A replay of the call will be archived on OraSure Technologies' web site shortly after the call has ended and will be available for 14 days. It is recommended to dial-in 15 to 20 minutes prior to the call start to reduce waiting times. If a participant will be listen-only, they are encouraged to listen via the webcast on OraSure's Investor Relations page.

About InteliSwab®

OraSure has received Emergency Use Authorizations (EUA) from the FDA for its InteliSwab® COVID-19 rapid tests. The U.S. Food and Drug Administration ("FDA") has authorized the InteliSwab ® COVID-19 Rapid Test for Over-the-Counter (OTC) use without a prescription. The FDA has also authorized the InteliSwab® COVID-19 Rapid Test Pro for professional use in point of care (POC) CLIA-waived settings, and the InteliSwab® COVID-19 Rapid Test Rx for Prescription Home Use. These remarkably simple COVID-19 lateral flow tests use samples self-collected from the lower nostrils. The InteliSwab® test's unique design incorporates a built-in swab fully integrated into the test stick. After users swab their lower nostrils, the test stick is swirled in a pre-measured buffer solution, and the result appears right on the test stick within 30 minutes, with no instruments, batteries, smartphone or laboratory analysis needed to see the result. With less than one minute of "hands-on time," it is as simple as "Swab, Swirl, and See."

This product has not been FDA cleared or approved, but it has been authorized by the FDA under an EUA. The emergency use of this product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. This product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb- 3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Multiple government agencies, including the U.S. Department of Defense (DoD) and Department of Health and Human Services (HHS) are working to address COVID-19 testing needs. Development of the InteliSwab® COVID-19 Rapid Test 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; Biomedical Advanced Research and Development Authority, under contract number 75A50120C00061 and 75A50121C00078, utilizing Health Care Enhancement Act (HCEA) funding. The DoD's Defense Assisted Acquisition (DA2) Cell led the manufacturing expansion effort for the InteliSwab® COVID-19 rapid test in coordination with the Department of the Air Force's Acquisition COVID-19 Task Force (DAF ACT). The manufacturing effort was funded through the American Rescue Plan Act (ARPA) to enable and support domestic industrial base expansion for critical medical resources.

About OraSure Technologies

OraSure Technologies empowers the global community to improve health and wellness by providing access to accurate, essential information through effortless tests, collection kits and services. OraSure, together with its wholly-owned subsidiaries, DNA Genotek, Diversigen, and Novosanis, provides its customers with end-to-end solutions that encompass tools, services and diagnostics. The OraSure family of companies is a leader in the development, manufacture, and distribution of rapid diagnostic tests, sample collection and stabilization devices, and molecular services solutions

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, commercial entities 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 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 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 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 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.

OraSure Technologies GAAP to Non-GAAP Reconciliation ($ in 000's)

	Three Months Ended March 31,	
	2023	**2022**
Revenue	$ 154,963	$ 67,707
GAAP Cost of products and services sold	89,148	43,408
GAAP Gross Margin	*42.5%*	*35.9%*
Stock compensation	134	150

Amortization of acquisition-related intangible assets	132	132
Reduction in workforce severance	35	—
Transformation related expenses	161	371
Inventory reserve for excess levels	—	575
Non-GAAP Cost of Goods Sold	88,686	42,180
Non-GAAP Gross Margin	*42.8%*	*37.7%*
	-	
GAAP Operating Income (Loss)	24,321	(16,172)
Stock compensation	2,655	2,062
Amortization of acquisition-related intangible assets	466	501
Reduction in workforce severance	2,635	—
Inventory reserve for excess levels	—	575
Loss on impairment	1,105	—
Transformation related expenses	449	4,153
Executive severance expense	—	1,461
Strategic alternative costs	—	651
Government grant accounting	1,051	221
Change in fair value of acquisition-related contingent consideration	(24)	(36)
Non-GAAP Operating Income (Loss)	32,658	(6,584)
GAAP Net Income (Loss)	27,219	(19,940)
Stock compensation	2,655	2,062
Amortization of acquisition-related intangible assets	466	501
Reduction in workforce severance	2,635	—
Inventory reserve for excess levels	—	575
Loss on impairment	1,105	—
Transformation related expenses	449	4,153
Executive severance expense	—	1,461
Strategic alternative costs	—	651
Change in fair value of acquisition-related contingent consideration	(24)	(36)
Tax effect of Non-GAAP adjustments	(51)	(89)
Non-GAAP Net Income (Loss)	$ 34,454	$ (10,662)
GAAP Earnings (Loss) Per Share:	$ 0.37	($ 0.28)
Non-GAAP Earnings (Loss) Per Share:	$ 0.47	($ 0.15)
Diluted Shares Outstanding	73,966	72,194

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
- 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

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

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