



OraSure Technologies, Inc.

OraSure Technologies Reports 2Q21 Revenue of \$57.6 Million Driven by Strong Rebound in Core Business

August 3, 2021

- Excluding COVID-19 product revenues, revenues for the second quarter grew 122% YoY and 48% sequentially as the Company's core business began to return to pre-pandemic revenue levels
- Company received three Emergency Use Authorizations (EUAs) from the U.S. Food and Drug Administration (FDA) for its *InteliSwab™* COVID-19 Rapid Tests for Non-Prescription (OTC), Professional Point-of-Care and Prescription Home Use

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

BETHLEHEM, Pa., Aug. 03, 2021 (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 June 30, 2021.

"This quarter, OraSure once again demonstrated strong financial performance highlighted by a recovery in our core business as the Company began to return to pre-pandemic revenue levels. Importantly, we have now received three EUAs for our *InteliSwab™* COVID-19 Rapid Tests, signed up two major distributors, and established a significant pipeline of sales inquiries. This represents a significant achievement as we continue to demonstrate the ability of the Company to develop and launch new products," said Stephen Tang, Ph.D., President and CEO of OraSure Technologies.

Dr. Tang continued, "As we look to the second half of the year we believe the business is well positioned for year-over-year growth given the commercial launch of *InteliSwab™*. We are responding to strong global customer interest for *InteliSwab™* tests and anticipate exiting the year at a significant revenue run rate. Newer areas such as our microbiome kits and services business are becoming increasingly important to our growth story and achieved record revenue in the second quarter. Overall, we are highly focused on spurring innovation, strengthening our product pipeline, and deploying capital through strategically sound acquisitions that leverage our commercial infrastructure to drive long-term sustained growth and value for our stockholders."

Financial Highlights

- Net revenues for the second quarter of 2021 were \$57.6 million, a 97% increase from the second quarter of 2020. Excluding COVID-19 product revenues, revenues for the quarter increased 122% YoY and 48% sequentially as the company began to return to pre-pandemic revenue levels.
- Total revenues from the Company's Diagnostic business unit were \$19.3 million during the second quarter of 2021 and grew 85% relative to the same period last year. Revenue growth was driven predominantly by higher global OraQuick® HIV and OraQuick® HCV sales as clinics returned to testing for these critical diseases, along with higher risk assessment testing due to an increase in workplace testing.
- Total product and service revenues for the Company's Molecular Solutions business unit were \$38.3 million during the second quarter of 2021, an increase of 103% from the second quarter of 2020. The increase was driven by strengthening demand for genomic collection kits from commercial and academic customers, growth in microbiome collection kits and services, and modestly higher COVID-19 collection kit sales.
- Gross margin percentage in the second quarter was 53.2% compared to 59.0% in the prior year. Gross margins were negatively impacted by the build out of manufacturing capacity to support the *InteliSwab™* COVID-19 Rapid Test launch as well as the higher mix of HIV testing revenue from international markets which carries a lower gross margin than the corporate average. We also saw an impact from increased labor and material costs.
- Operating income in the second quarter was \$1.8 million compared to a loss of (\$9.4) million in the second quarter of last year. Improved operating profit was driven by higher revenues and expense control with total operating expenses only increasing 8% year-over-year despite the 97% overall revenue growth.
- Net loss for the second quarter of 2021 was (\$1.4) million, or (\$0.02) per share on a fully-diluted basis, compared to a net loss of (\$10.5) million, or (\$0.16) per share on a fully-diluted basis, for the second quarter of 2020.
- Cash flow used in operations in the quarter was (\$3.4) million. Cash and investments totaled \$229.4 million at June 30, 2021.

Recent Business Highlights

COVID-19 Testing

- OraSure received three Emergency Use Authorizations (EUA) from the U.S. Food and Drug Administration (FDA) for its *InteliSwab™* COVID-19 Rapid Tests. The FDA has authorized these tests for Over-the-Counter (OTC) use without a prescription. 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. The OTC and POC tests can be used for those with or without symptoms, when tested twice over two to three days, with 24-36 hours between tests.

- As anticipated, due to the timing of EUA for *InteliSwab™* and the time required for product relabeling, OraSure did not recognize *InteliSwab™* sales in the second quarter of 2021. OraSure signed distribution agreements for this product with two major U.S. distributors for US clinical and physician office channels. Additionally, we currently have significant customer inquiries, including inquiries from over 15 different countries that will accept FDA EUA product with appropriate country specific documents and labeling.
- Following discussions with the FDA and their de-prioritization of antibody testing in the U.S., OraSure has decided to no longer pursue EUAs for its oral fluid COVID-19 antibody test. The Company will continue to offer the product for research use only and has several labs interested in COVID antibody surveillance and research applications.

Infectious Disease and Risk Assessment Testing

- Global OraQuick® HIV sales in the second quarter were \$10.9 million versus \$7.1 million in the prior year period. Sales increased due to improved domestic HIV sales along with continued strong double-digit international test volume growth.
- OraSure Technologies was selected by the Centers for Disease Control and Prevention (CDC) to distribute 100,000 HIV self-test kits to individuals who request them. The program sent out OraQuick® In-Home HIV Tests, which allow an individual to detect antibodies to both HIV-1 and HIV-2 with an oral test, and provide results in 20 minutes, at home.
- Global OraQuick® HCV sales grew 208% to \$4.3 million in the second quarter compared to \$1.4 million in the second quarter of 2020 as professional testing was reinstated in many countries.
- Risk assessment testing revenue grew 71% in the second quarter to \$2.6 million based primarily upon increased workplace drugs-of-abuse testing as economic conditions and hiring have improved.

Molecular Solutions

- Genomics collection kit revenue of \$19.6 million for the second quarter of 2021 grew 203% YoY. The growth was driven predominantly by growth in the key markets of consumer genomics, disease risk management, companion animal and research.
- Sales of OraSure's sample collection devices for molecular/PCR COVID-19 testing increased year-over-year to \$11.5 million in the second quarter of 2021 compared to \$8.5 million in the prior year period. However, on a sequential basis total sales declined by \$15.9 million as total U.S. PCR based test volumes for COVID-19 declined meaningfully from the March 2021 quarter to the June 2021 quarter.
- A new study was published in [Gynecologic Oncology](#) where the data indicated the ability of Colli-Pee®, OraSure's proprietary urine sample collection technology, to facilitate test results for human papilloma virus (HPV) using first-void urine samples from patients. In the study of approximately 500 women, the accuracy of testing utilizing Abbott's RealTime High Risk HPV assay was statistically equivalent using Colli-Pee® first-void urine-based samples as compared to clinician collected cervical tissue cell samples.
- Total microbiome revenue, including kits and services, was \$6.0 million in the quarter and grew 94% relative to the second quarter of last year. OraSure's Diversigen business now supports over 50 commercial customers including over 30 biopharmaceutical customers with 20 ongoing clinical trials.

Third Quarter 2021 Guidance

The Company expects third quarter 2021 net revenues to range from \$45 million to \$50 million.

The Company has also provided guidance for *InteliSwab™* for the full year stating that it now anticipates total *InteliSwab™* sales through December 2021 of approximately \$30 million with the preponderance of revenue coming in the fourth quarter of calendar year 2021.

The Company expects fiscal year 2021 total revenue of approximately \$230 million.

Financial Data (Unaudited)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2021	2020	2021	2020
Results of Operations				
Net revenues	\$ 57,607	\$ 29,259	\$ 116,189	\$ 60,855
Cost of products and services sold	26,934	11,995	47,190	27,460
Gross profit	30,673	17,264	68,999	33,395
Operating expenses:				
Research and development	7,682	6,924	16,674	12,568
Sales and marketing	10,420	10,121	19,950	17,490

General and administrative	10,993	10,280	21,181	20,334
Change in fair value of acquisition-related contingent consideration	(220)	(660)	(1,026)	450
Total operating expenses	28,875	26,665	56,779	50,842
Operating income (loss)	1,798	(9,401)	12,220	(17,447)
Other income	448	216	329	1,646
Income (loss) before income taxes	2,246	(9,185)	12,549	(15,801)
Income tax expense	3,610	1,309	10,139	2,021
Net income (loss)	\$ (1,364)	\$ (10,494)	\$ 2,410	\$ (17,822)
Earnings (loss) per share:				
Basic	\$ (0.02)	\$ (0.16)	\$ 0.03	\$ (0.28)
Diluted	\$ (0.02)	\$ (0.16)	\$ 0.03	\$ (0.28)
Weighted average shares:				
Basic	71,983	64,745	71,931	63,335
Diluted	71,983	64,745	72,683	63,335

	Three Months Ended			Six Months Ended		
	June 30,			June 30,		
	2021	2020	% Change	2021	2020	% Change
DIAGNOSTICS						
Infectious Disease Testing Revenues						
Domestic HIV	\$ 4,135	\$ 3,197	29 %	\$ 9,050	\$ 7,414	22 %
International HIV	6,809	3,883	75	10,672	10,832	(1)
Net HIV revenues	10,944	7,080	55	19,722	18,246	8
Domestic HCV	2,571	757	240	3,754	2,251	67
International HCV	1,729	641	170	2,914	1,738	68
Net HCV revenues	4,300	1,398	208	6,668	3,989	67
Net OraQuick® revenues	15,244	8,478	80	26,390	22,235	19
Other infectious disease revenues	379	259	46	604	1,165	(48)
Total Infectious Disease	15,623	8,737	79	26,994	23,400	15
Risk Assessment	2,629	1,533	71	4,591	4,533	1
Other non-product revenues	1,059	157	575	2,272	286	694
TOTAL DIAGNOSTIC NET REVENUE	\$ 19,311	\$ 10,427	85 %	\$ 33,857	\$ 28,219	20 %
MOLECULAR SOLUTIONS						
Genomics	\$ 19,582	\$ 6,471	203 %	\$ 30,646	\$ 14,863	106
Microbiome	2,853	853	234	4,941	2,430	103
COVID-19	11,491	8,472	36	38,880	8,866	339
Laboratory services	3,114	2,222	40	5,611	5,053	11
Other product and services revenues	449	49	816	657	78	742
Net product and service revenues	37,489	18,067	107	80,735	31,290	158
Other non-product and service revenues	807	765	5	1,597	1,346	19
TOTAL MOLECULAR SOLUTIONS NET REVENUE	\$ 38,296	\$ 18,832	103 %	\$ 82,332	\$ 32,636	152
TOTAL NET REVENUES	\$ 57,607	\$ 29,259	97 %	\$ 116,189	\$ 60,855	91 %

Condensed Consolidated Balance Sheets (Unaudited)

	June 30, 2021	December 31, 2020
<u>Assets</u>		
Cash and cash equivalents	\$ 158,120	\$ 160,802
Short-term investments	35,185	48,599
Accounts receivable, net	35,259	38,835
Inventories	48,170	31,863
Other current assets	8,316	8,794

Property, plant and equipment, net	72,034	51,860
Intangible assets, net	16,241	17,904
Goodwill	40,810	40,351
Long-term investments	36,131	47,718
Other non-current assets	14,783	7,746
Total assets	<u>\$ 465,049</u>	<u>\$ 454,472</u>

Liabilities and Stockholders' Equity

Accounts payable	\$ 22,119	\$ 17,407
Deferred revenue	4,240	4,811
Contingent consideration obligation	219	402
Other current liabilities	19,994	23,869
Non-current contingent consideration obligation	800	2,049
Other non-current liabilities	12,861	7,363
Stockholders' equity	404,816	398,571
Total liabilities and stockholders' equity	<u>\$ 465,049</u>	<u>\$ 454,472</u>

Additional Financial Data (Unaudited)

	Six Months Ended	
	June 30,	
	2021	2020
Capital expenditures	\$ 22,929	\$ 6,037
Depreciation and amortization	\$ 5,524	\$ 4,600
Stock-based compensation	\$ 2,937	\$ 4,048
Cash used in operating activities	\$ 3,472	\$ 2,184

Conference Call

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's second quarter 2021 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 Dr. Stephen S. Tang, President and Chief Executive Officer, and Roberto Cuca, Chief Financial Officer. The call will include prepared remarks by management and a question and answer session.

In order to listen to the conference call, please dial (888) 771-4371 (Domestic) or (847) 585-4405 (International) and reference Conference ID # 50205303 or 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. A replay of the call can also be accessed until midnight, August 17, 2021, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID # 50205303.

It is recommended to dial-in at most 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 OraSure Technologies

OraSure Technologies empowers the global community to improve health and wellness by providing access to accurate, essential information. 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, pharma, commercial entities and direct to consumers. For more information on OraSure Technologies, please visit www.orasure.com.

Important Information

This press release contains certain forward-looking statements, including with respect to expected revenues, products, product development activities, regulatory submissions and authorizations 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: ability to successfully manage and integrate acquisitions of other companies in a manner that complements or leverages our existing business, or otherwise expands or enhances our portfolio of products and our end-to-end service offerings, and the diversion of management's attention from our ongoing business and regular business responsibilities to effect such integration; the expected economic benefits of acquisitions (and increased returns for our stockholders), including that the anticipated synergies, revenue enhancement strategies and other benefits from the acquisitions may not be fully realized or may take longer to realize than expected and our actual integration costs may exceed our estimates; impact of increased or different risks arising from the acquisition of companies located in foreign countries; 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 our business and our 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; 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; ability to identify, complete, integrate and realize the full benefits of future acquisitions; 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 and civil unrest; and general political, business and economic conditions. 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, 2020, 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.

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