OraSure Technologies, Inc. Announces First Quarter 2021 Financial Results and Provides COVID-19 Update

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First Quarter 2021 Net Revenues of $59 Million Increased 85% Over 2020, Driven by $27 Million in Sales of Sample Collection Devices for COVID-19 Molecular Testing

EUA Application Submitted in Q1 to FDA for COVID-19 Rapid Antigen Test for Both Prescription Home Use and Professional Use in Point of Care Settings

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

BETHLEHEM, Pa., May 05, 2021 (GLOBE NEWSWIRE) -- OraSure Technologies, Inc. (NASDAQ: OSUR), a leader in point-of-care diagnostic tests, specimen collection devices, and microbiome laboratory and analytical services, today announced its financial results for the three months ended March 31, 2021.

“OraSure had another strong quarter, as the Company delivered double-digit year-over-year revenue growth for the third quarter in a row. Our sample collection devices for COVID-19 molecular testing continue to make a significant contribution to our revenues. Moreover, we have submitted our COVID-19 rapid antigen test to the US Food and Drug Administration for Emergency Use Authorization, and look forward to bringing a prescription home test and a professional test for point of care use to market,” said Stephen Tang, Ph.D., President and CEO of OraSure Technologies.

Dr. Tang continued, “As coronavirus variants continue to spread, we believe convenient, safe and accurate COVID-19 testing will continue to play a key role in identifying those who are infected and helping to safely reopen workplaces, schools, and other places where people gather. We are confident in the market potential for our COVID products, as well as the resilience of our other business segments as demonstrated by the strong first quarter performance of our commercial genomics, microbiome, and domestic HIV testing business. Given the overall strong financial performance of our business, the EUA applications pending before the FDA and our solid financial foundation, we are confident that OraSure is well positioned for continued success.”

Financial Highlights

- Net revenues for the first quarter of 2021 were $58.6 million, an 85% increase from the first quarter of 2020. Net product and services revenues were $56.6 million, an 83% increase from the first quarter of 2020.
- Total product and service revenues for the Company’s molecular business unit were $43.2 million during the first quarter of 2021, an increase of 227% from the first quarter of 2020. This increase included $27.4 million in sales of sample collection devices for COVID-19 molecular testing.
- The Company’s genomics business grew 32% year over year, driven by demand in the Disease Risk Management, Companion Animal and Academic Research markets. The Microbiome kits business grew 32% driven by sales to commercial accounts.
- Domestic HIV revenues of $5.3 million grew 26% year over year, driven by HIV OTC test sales.
- International HIV and HCV revenues declined 42% over the prior year, due to several large distributor orders which occurred in Q1 2020 and variations in timing as compared to 2021 ordering.
- Net income for the first quarter of 2021 was $3.8 million, or $0.05 per share on a fully-diluted basis, compared to a net loss of $7.3 million, or $0.12 per share on a fully-diluted basis, for the first quarter of 2020.
- Cash and investments totaled $240.5 million at March 31, 2021.

COVID-19 Update

Antigen:

- **OraSure has submitted an Emergency Use Authorization (EUA) application to the U.S. Food and Drug Administration (FDA) for its COVID-19 rapid antigen test for both Prescription Home Use, and Professional Use in point of care (POC) CLIA-waived settings.**
    - These lateral flow, rapid diagnostic tests are designed to detect active COVID-19 infection with a simple, easy-to-use workflow, using samples self-collected from the lower nostrils. After users swab their lower nostrils, the test stick is swirled in a pre-measured buffer solution. No instrumentation, batteries, smart phone or laboratory analysis is needed to read the result, which appears on the test stick a short time later.
    - Subject to receipt of EUA, the Company intends to market the COVID-19 Prescription Home Test and a Professional Test for use in POC CLIA-waived settings.
    - With a simple design and straightforward workflow, the Company believes its tests are well suited for use by individuals at home, as well as by health care providers, employers, pharmacies, universities, and for deployment

into underserved communities when prescribed by a healthcare provider. The simple, user-friendly nature of the test can make testing more accessible and convenient in areas where medical personnel, infrastructure and supplies may be lacking.
  - The Company has started manufacturing the COVID-19 antigen tests as it awaits EUA.
  - The Company also intends to pursue an over-the-counter (OTC) indication for the rapid antigen test.

Molecular/PCR:

- **Sales of sample collection devices for molecular/PCR COVID-19 testing in the first quarter continued to grow sequentially.**
  - Use of DNA Genotek molecular sample collection kits continued to grow in the first quarter of 2021, with demand driven by both high-volume repeat orders from existing customers and demand from new customers engaged in back-to-work and back-to-school testing programs around the world.
  - The ORAcollect®·RNA saliva collection device has been used in more than two million COVID-19 tests developed by DNA Genotek customer Quadrant Biosciences in partnership with SUNY Upstate Medical University, up from the one million administered tests SUNY announced in February 2021. This test has been used extensively by State University of New York campuses since the start of the fall 2020 semester.

Antibody:

- **OraSure has collected all the data necessary to resubmit the two requested EUA applications for its oral fluid antibody test. At the FDA's request, the Company plans to submit separate EUAs for the ELISA microplate assay and the OraSure Oral Antibody Collection Device.**
  - To date, no oral fluid antibody tests have received EUA; OraSure's test has the potential to be the first.
  - With this test, individuals would use the OraSure Oral Antibody Collection Device to self-collect an oral fluid sample under the observation of a healthcare professional. The sample would then be placed into the buffer vial for storage and transport, and then later dispensed onto the OraSure Sars-CoV-2 ELISA microplate for testing in a laboratory.
  - This lab-based antibody test can aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating prior infection.
  - OraSure continues to sell its antibody test for research use only.

Manufacturing:

- **OraSure's initiative to increase manufacturing capacity to meet demand for COVID-19 sample collection kits and tests continues.**
  - The Company is expanding installed manufacturing capacity for the rapid antigen test to 70 million tests per year in the third quarter of 2021 (including tests for HIV, HCV and Ebola).
  - OraSure plans additional expansion of 50 million rapid antigen tests, bringing installed capacity to 120 million tests per year (including tests for HIV, HCV and Ebola) by the second quarter of 2022. The Company expects this additional capacity to support sales outside of the U.S.
  - Capacity expansion for the Company's molecular sample collection kits has increased beyond its original projections. The Company is expanding installed capacity of its molecular sample collection devices to a rate of approximately 80 million units annually in the second quarter of 2021, ahead of the 75 million annual units previously communicated, and further to 105 million units annually by the end of 2021, including non-COVID kits.
  - Installation of new lines for the oral-fluid antibody test will bring total capacity to 20 million units per year by the end of the year, including existing products.

Financial Results for the Three Months Ended March 31, 2021

Net revenues for the first quarter of 2021 of $58.6 million increased 85% from the comparable period of 2020, primarily as a result of strong sales of molecular sample collection kits for COVID-19 testing, higher genomics product sales and increased sales by the Company's domestic HIV testing business, partially offset by declines in revenues of our international HIV products due to order timing and risk assessment products due to the impact of COVID-19 on the overall risk assessment testing market in the US.

Gross profit percentage was 65% for the three months ended March 31, 2021 compared to 51% for the three months ended March 31, 2020. Gross profit in the current quarter benefited from an improved product mix associated with higher gross profit percentage product sales.

For the three months ended March 31, 2021, operating expenses were $27.9 million, an increase of $3.7 million from the $24.2 million reported for the three months ended March 31, 2020, largely due to increased investment in the development and sale of the Company's COVID products. Operating expenses were also impacted by a benefit of $806,000 representing the change in the estimated fair value of acquisition-related contingent consideration compared to an expense of $1.1 million recorded the same period of 2020.

The Company generated operating income of $10.4 million in the first quarter of 2021 compared to an operating loss of $8.1 million in the first quarter of 2020.

During the first quarters of 2021 and 2020, the Company recorded income tax expense of $6.5 million and $712,000, respectively.

Second Quarter 2021 Guidance

The Company expects second quarter 2021 net revenues to range from $55 million to $60 million.

Financial Data (Unaudited)

	Three Months Ended March 31,	
	2021	**2020**
Results of Operations		
Net revenues	$ 58,582	$ 31,596
Cost of products and services sold	20,256	15,465
Gross profit	38,326	16,131
Operating expenses:		
Research and development	8,992	5,644
Sales and marketing	9,530	7,369
General and administrative	10,188	10,054
Change in fair value of acquisition-related contingent consideration	(806)	1,110
Total operating expenses	27,904	24,177
Operating income (loss)	10,422	(8,046)
Other income (expense)	(119)	1,430
Income (loss) before income taxes	10,303	(6,616)
Income tax expense	6,529	712
Net income (loss)	$ 3,774	$ (7,328)
Earnings (loss) per share:		
Basic	$ 0.05	$ (0.12)
Diluted	$ 0.05	$ (0.12)
Weighted average shares:		
Basic	71,878	61,927
Diluted	72,766	61,927

	Three Months Ended March 31,				
	Dollars			Percentage of Total Net Revenues	
	2021	**2020**	**% Change**	**2021**	**2020**
Market					
Infectious disease testing	$ 11,371	$ 14,664	(22) %	20 %	46 %
Risk assessment testing	1,962	3,000	(35)	3	9
Molecular solutions	43,246	13,222	227	74	43
Net product and service revenues	56,579	30,886	83	97	98
Other	2,003	710	182	3	2
Net revenues	$ 58,582	$ 31,596	85 %	100 %	100 %

	Three Months Ended March 31,		
	2021	**2020**	**% Change**
Infectious Disease Testing Revenues			
Domestic HIV	$ 5,293	$ 4,216	26 %
International HIV	3,486	6,949	(50)
Net HIV revenues	8,779	11,165	(21)
Domestic HCV	1,182	1,494	(21)
International HCV	1,184	1,097	8
Net HCV revenues	2,366	2,591	(9)
Other product revenues	226	908	(75)

Net product revenues	$ 11,371	$ 14,664	(22) %

	Three Months Ended March 31,		
	2021	2020	% Change
Molecular Solutions Revenues			
Genomics	$ 11,064	$ 8,393	32 %
Microbiome	2,088	1,577	32
COVID-19	27,389	394	N/A
Laboratory services	2,497	2,415	3
Other product and service revenues	208	443	(53)
Net product and service revenues	43,246	13,222	227
Other	790	582	36
Net revenues	$ 44,036	$ 13,804	219 %

Condensed Consolidated Balance Sheets (Unaudited)

	March 31, 2021	December 31, 2020
Assets		
Cash and cash equivalents	$ 177,676	$ 160,802
Short-term investments	29,080	48,599
Accounts receivable, net	36,391	38,835
Inventories	40,348	31,863
Other current assets	8,913	8,794
Property, plant and equipment, net	64,943	51,860
Intangible assets, net	16,945	17,904
Goodwill	40,493	40,351
Long-term investments	33,706	47,718
Other non-current assets	7,999	7,746
Total assets	$ 456,494	$ 454,472
Liabilities and Stockholders' Equity		
Accounts payable	$ 20,731	$ 17,407
Deferred revenue	4,580	4,811
Contingent consideration obligation	365	402
Other current liabilities	18,967	23,869
Non-current contingent consideration obligation	874	2,049
Other non-current liabilities	7,434	7,363
Stockholders' equity	403,543	398,571
Total liabilities and stockholders' equity	$ 456,494	$ 454,472

Additional Financial Data (Unaudited)

	Three Months Ended March 31,	
	2021	2020
Capital expenditures	$ 11,061	$ 2,595
Depreciation and amortization	$ 2,489	$ 2,165
Stock-based compensation	$ 1,464	$ 1,376
Cash provided by (used in) operating activities	$ (4,393)	$ 2,499

Conference Call

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's first quarter 2021 quarter 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 844-831-3030 (Domestic) or 315-625-6887 (International) and reference Conference ID # 1349536 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, May 19, 2021, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID # 1349536.

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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