OraSure Technologies, Inc. Announces 2020 Full-Year and Fourth Quarter Financial Results and Provides COVID-19 Update

March 1, 2021

Full-Year 2020 Net Revenues of $172 Million Increased 11% Year-Over-Year, Driven by $50 Million in Sales of Oral Fluid Collection Devices for COVID-19 Molecular Testing

COVID-19 Rapid Antigen Test clinical trials complete; OraSure plans to submit both a Prescription Self-Test and a Professional Test for EUA in Q1

Management to Host Conference Call and Webcast Today at 5:00 p.m. ET

BETHLEHEM, Pa., March 01, 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 and year ended December 31, 2020.

"OraSure continues to successfully navigate the pandemic, with a record-breaking fourth quarter and double-digit full-year revenue growth driven by a strong sequential quarterly increase in sales of our molecular sample collection kits for COVID-19 testing. We expect this strong sustained performance to persist as testing continues to be a key strategy to combat the ongoing pandemic. Our base business was resilient, with demonstrated strength in international HIV testing," said Stephen S. Tang, Ph.D., President and Chief Executive Officer.

Dr. Tang continued, "Importantly, we have made substantial progress on our COVID-19 Rapid Antigen Self-Test and oral fluid antibody test. We expect that OraSure's COVID-19 activities will continue to accelerate the Company's growth and significantly outweigh any negative impact of the pandemic on other parts of our business. We have locked the proprietary assay chemistry and completed development and clinical testing of our rapid antigen test for COVID-19. We accelerated the Prescription Self-Test trials and now plan to submit for both the Professional and Prescription Self-Test for Emergency Use Authorization (EUA) by the end of this month. We are also planning to resubmit two separate EUAs for our lab-based oral fluid antibody test, including additional analytical study data, as requested by the FDA, and look forward to bringing this important product to market as soon as possible."

Financial Highlights

- Net revenues for the fourth quarter of 2020 were $62.9 million, a 27% increase from the fourth quarter of 2019. Net product and services revenues were $60.4 million, a 28% increase from the fourth quarter of 2019.
- Net revenues for the full year 2020 were $171.7 million, an 11% increase over 2019.
- Total product and service revenues for the Company's molecular business unit were $40.3 million during the fourth quarter of 2020, an increase of 58% from the fourth quarter of 2019. This increase included $22.5 million in sales of sample collection devices for COVID-19 molecular testing.
- Total product and service revenues for the Company's molecular business unit were $102.8 million for the full year 2020, an increase of 45% from the full year 2019. The increase included $49.8 million in sales of sample collection devices for COVID-19 molecular testing.
- Full year 2020 international sales of the Company's HIV products grew 16% over the prior year driven by a 21% increase in HIV Self-Test sales in Africa. For the fourth quarter, HIV international revenue was $11.3 million, a 16% increase from the fourth quarter of 2019. This was a record quarter and year for sales of OraSure's HIV self-tests internationally.
- Net income for the fourth quarter of 2020 was $1.9 million, or $0.03 per share on a fully-diluted basis, compared to net income of $2.4 million, or $0.04 per share on a fully-diluted basis, for the fourth quarter of 2019.
- Cash and investments totaled $257.1 million at December 31, 2020.

COVID-19 Update

Molecular/PCR:

- **Sales of sample collection devices for molecular/PCR COVID-19 testing in the fourth quarter showed sequential quarterly growth and persistence of commercial opportunity; the Company's sample collection kits continued to be included in Emergency Use Authorizations (EUAs) granted to customers.**
    - Use of DNA Genotek molecular sample collection kits continued to grow in back-to-work settings, back-to-school programs, laboratory testing and direct-to-consumer offerings. OraSure continues to build its customer base, with high-volume repeat orders from existing customers and demand from new customers.
        - The Company's molecular collection kits are now included in eight EUAs granted by the U.S. Food and Drug Administration (FDA) to DNA Genotek customers for COVID-19 testing.
        - The Company's ORAcollect ® •RNA saliva collection device has been used in the more than one million COVID-19 tests administered by State University of New York campuses since the start of the 2020-2021

academic year. These tests were developed by DNA Genotek customer Quadrant Biosciences.
- The Company's OMNIgene·ORAL and ORAcollect® •RNA saliva collection devices have received interim authorization for use in COVID-19 testing from Health Canada.
- Through OraSure's customer Chronomics, the OMNIgene·ORAL is being utilized as a collection device for the UK Government's "Test to Release for International Travel" COVID-19 testing program.

Antigen:

- **OraSure has finalized all product development and completed clinical studies for its COVID-19 Rapid Antigen Self-Test and now plans FDA EUA submission for both Professional and Prescription Self-Test in the first quarter.**
  - OraSure has locked the proprietary assay chemistry and completed development of its COVID-19 Rapid Antigen Self-Test and has collected all clinical study data to now submit both the Professional version and Prescription Self-Test version for EUA in the first quarter of 2021.
  - Subject to receipt of EUA, this product would test for active COVID-19 infection using nasal samples self-collected from the lower nostrils. The COVID-19 Rapid Antigen Self-Test is designed to be performed anytime, anywhere, with no instrumentation, batteries or laboratory analysis needed to interpret results.
  - Subject to regulatory approvals, the Company intends to market its **Prescription Self-Test** for use by individual consumers (with prescription) at home, or in any location by employers/universities on- or off-site, or by physicians, or public health via remote testing, and its **Professional Test** for use at drive-through sites, physician offices, public health testing sites, and employer/university health centers.
  - After the Company submits the Professional Test and Prescription Self-Test for EUA, it intends to continue plans to pursue an OTC claim.
  - The Company will be manufacturing at risk and intends to launch the tests without delay, subject to authorization.

Antibody:

- **OraSure is working with the FDA to secure Emergency Use Authorization for its lab-based OraSure SARS-CoV-2 Antibody ELISA. Currently no COVID-19 antibody tests that use oral fluid samples have received Emergency Use Authorization. OraSure's test could be the first. Oral fluid samples minimize healthcare professionals' need for personal protective equipment and reduces their exposure to potentially infected patients as compared to blood draws; the test could aid health officials in community surveillance efforts and seroprevalence studies.**
  - 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.
  - At the request of the FDA, the Company plans to resubmit two separate EUAs for the test, one covering the oral fluid specimen collector and one for the microplate assay. In addition, the FDA has requested that additional analytical studies be conducted on sample collection and stability.
  - OraSure continues to sell its antibody test for research use only, which has led to interest from several companies and labs regarding seroprevalence studies in cities or university populations.

Manufacturing:

- **OraSure's initiative to increase manufacturing capacity to meet demand for COVID-19 sample collection kits and tests continues on schedule. Additional expansion planned to support Rapid Antigen Self-Test.**
  - Previously the Company had disclosed that it was expanding manufacturing capacity for the Rapid Antigen Self-Test to 70 million tests per year in the third quarter of 2021 (including tests for HIV, HCV and Ebola).
  - OraSure now plans additional expansion of 50 million Rapid Antigen Self-Tests, bringing 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.
  - As previously disclosed, the Company is expanding capacity of its molecular sample collection devices to a rate of approximately 75 million units annually in the second quarter of 2021 and further to 80 million units in the third quarter, including non-COVID kits.
  - Also as previously disclosed, installation of new lines for the oral-fluid antibody test will bring total capacity to 20 million units per year by the fourth quarter, including existing products.

Financial Results for the Three Months Ended December 31, 2020

Net revenues for the fourth quarter of 2020 of $62.9 million increased 27% from the comparable period of 2019, primarily as a result of strong sales of molecular sample collection kits for COVID-19 testing and increased international sales of the Company's HIV Self-Test partially offset by declines in revenues of our other product lines largely due to the impact of COVID-19.

Gross profit percentage was 61% for the three months ended December 31, 2020 compared to 60% for the three months ended December 31, 2019. 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 December 31, 2020, operating expenses were $30.3 million, an increase of $4.1 million from the $25.8 million reported for the three months ended December 31, 2019, largely due to increased investment in the development of the Company's COVID products.

The Company generated operating income of $7.9 million in the fourth quarter of 2020 compared to operating income of $4.1 million in the fourth quarter of 2019.

During the fourth quarters of 2020 and 2019, the Company recorded income tax expense of $5.7 million and $2.1 million, respectively. Income tax expense in both periods largely consisted of foreign taxes due related to our Canadian subsidiary.

First Quarter 2021 Guidance

The Company expects first quarter 2021 net revenues to range from $55.0 million to $60.0 million.

Financial Data (Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
Results of Operations				
Net revenues	$ 62,855	$ 49,668	$ 171,721	$ 154,605
Cost of products and services sold	24,671	19,829	69,853	60,022
Gross profit	38,184	29,839	101,868	94,583
Operating expenses:				
Research and development	10,457	6,104	31,032	19,629
Sales and marketing	9,120	7,932	34,459	31,869
General and administrative	12,211	11,539	42,653	35,287
Change in fair value of acquisition-related contingent consideration	(1,489)	179	(1,099)	(664)
Gain on sale of business	—	—	—	(10,149)
Total operating expenses	30,299	25,754	107,045	75,972
Operating income (loss)	7,885	4,085	(5,177)	18,611
Other income (expense)	(307)	477	1,653	2,720
Income (loss) before income taxes	7,578	4,562	(3,524)	21,331
Income tax expense	5,718	2,124	11,398	4,675
Net income (loss)	$ 1,860	$ 2,438	$ (14,922)	$ 16,656
Earnings (loss) per share:				
Basic	$ 0.03	$ 0.04	$ (0.22)	$ 0.27
Diluted	$ 0.03	$ 0.04	$ (0.22)	$ 0.27
Weighted average shares:				
Basic	71,723	61,729	67,505	61,675
Diluted	72,817	62,199	67,505	62,170

	Three Months Ended December 31,				
	Dollars			Percentage of Total Net Revenues	
	2020	2019	% Change	2020	2019
Market					
Infectious disease testing	$ 17,602	$ 18,743	(6) %	28 %	38 %
Risk assessment testing	2,526	2,944	(14)	4	6
Molecular solutions	40,281	25,487	58	64	51
Net product and service revenues	60,409	47,174	28	96	95
Royalty income	1,809	2,160	(16)	3	4
Other	637	334	91	1	1
Net revenues	$ 62,855	$ 49,668	27 %	100 %	100 %

	Year Ended December 31,		
	Dollars		Percentage of Total Net Revenues

	2020	2019	% Change	2020	2019
Market					
Infectious disease testing	$ 54,227	$ 58,016	(7) %	32 %	38 %
Risk assessment testing	9,374	12,189	(23)	5	8
Cryosurgical systems	—	7,054	(100)	—	5
Molecular solutions	102,780	70,814	45	60	45
Net product and service revenues	166,381	148,073	12	97	96
Royalty income	3,432	5,116	(33)	2	3
Other	1,908	1,416	35	1	1
Net revenues	$ 171,721	$ 154,605	11 %	100 %	100 %

	Three Months Ended December 31,			Year Ended December 31,		
	2020	2019	% Change	2020	2019	% Change
OraQuick® Revenues						
Domestic HIV	$ 3,861	$ 4,960	(22) %	$ 15,184	$ 17,984	(16) %
International HIV	11,343	9,795	16	29,040	25,108	16
Net HIV revenues	15,204	14,755	3	44,224	43,092	3
Domestic HCV	1,356	2,202	(38)	4,793	8,108	(41)
International HCV	884	1,295	(32)	3,655	4,864	(25)
Net HCV revenues	2,240	3,497	(36)	8,448	12,972	(35)
Net product revenues	$ 17,444	$ 18,252	(4) %	$ 52,672	$ 56,064	(6) %

	Three Months Ended December 31,			Year Ended December 31,		
	2020	2019	% Change	2020	2019	% Change
Molecular Solutions Revenues						
Genomics	$ 13,760	$ 20,761	(34) %	$ 37,141	$ 56,212	(34) %
Microbiome	1,898	1,847	3	6,156	7,172	(14)
COVID-19	22,494	—	N/A	49,802	—	N/A
Laboratory services	2,093	2,820	(26)	9,564	6,767	41
Other product revenues	36	59	(39)	117	663	(82)
Net product and service revenues	40,281	25,487	58	102,780	70,814	45
Other	1,866	2,289	(18)	3,701	5,566	(34)
Net revenues	$ 42,147	$ 27,776	52 %	$ 106,481	$ 76,380	39 %

Condensed Consolidated Balance Sheets (Unaudited)

	December 31, 2020	December 31, 2019
Assets		
Cash and cash equivalents	$ 160,802	$ 75,715
Short-term investments	48,599	80,623
Accounts receivable, net	38,835	36,948
Inventories	31,863	23,155
Other current assets	8,794	8,109
Property, plant and equipment, net	51,860	30,339
Intangible assets, net	17,904	14,674
Goodwill	40,351	36,201
Long-term investments	47,718	33,420
Other non-current assets	7,746	10,111
Total assets	$ 454,472	$ 349,295
Liabilities and Stockholders' Equity		
Accounts payable	$ 17,407	$ 9,567

Deferred revenue	4,811	3,713
Contingent consideration obligation	402	3,500
Other current liabilities	23,869	15,933
Non-current contingent consideration obligation	2,049	112
Other non-current liabilities	7,363	9,325
Stockholders' equity	398,571	307,145
Total liabilities and stockholders' equity	$ 454,472	$ 349,295

Additional Financial Data (Unaudited)

	Year Ended December 31,	
	2020	**2019**
Capital expenditures	$ 26,674	$ 9,314
Depreciation and amortization	$ 9,714	$ 7,730
Stock-based compensation	$ 7,139	$ 4,057
Cash provided by operating activities	$ 5,807	$ 9,804

Conference Call

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's 2020 full year and fourth 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 # 8168847 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 seven days. A replay of the call can also be accessed until midnight, March 15, 2021, by dialing 855-859-2056 (Domestic) or (404) 537-3406 (International) and entering the Conference ID #9459222.

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. Together with its wholly-owned subsidiaries, DNA Genotek, Diversigen and Novosanis, OraSure 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.

Investor contact:	Media contact:
Sam Martin	Jeanne Mell
Argot Partners	OraSure Technologies
212-600-1902	484-353-1575
orasure@argotpartners.com	media@orasure.com

OraSure Technologies, Inc.

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