OraSure Technologies, Inc. Announces 2020 Second Quarter Financial Results and Update on COVID-19 Testing Programs

August 5, 2020

BETHLEHEM, Pa., Aug. 05, 2020 (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 and six months ended June 30, 2020.

“In the second quarter, our work to leverage our scientific and technological expertise against the COVID-19 pandemic has already generated meaningful revenue. Our sample collection devices are being used for the collection, both in at-home and professional settings, and transport of samples for COVID-19 molecular testing. We are also developing a COVID-19 rapid antigen in-home self-test and an ELISA-based oral fluid COVID-19 antibody test, both of which we now expect to launch in the fourth quarter,” said Stephen S. Tang, Ph.D., President and Chief Executive Officer. “We are confident, given our ongoing initiative to scale up our production capacity, that OraSure will be able to deliver substantially increased volumes of collection and testing products, while ensuring that they meet the highest quality standards as we contribute to the fight against this global crisis. At the same time, we have continued to serve our existing customers across our business lines and to identify opportunities for business development that will contribute to longer-term sustainable growth.”

“We further strengthened our balance sheet in June with the completion of an equity offering that included investments from top institutional healthcare investors, bringing us to $265.8 million in cash and investments as of June 30, 2020, with no debt,” said Roberto Cuca, Chief Financial Officer. “Although we are not providing formal guidance for the remainder of 2020 due to the uncertainty of the effect of the pandemic on our operations, we continue to anticipate that sales of our existing and new products for COVID-19 testing will offset the negative impact of the pandemic on our non-COVID-19 business.”

Second Quarter Financial Highlights

- Net revenues for the second quarter of 2020 were $29.3 million, a 25% decrease from the second quarter of 2019. Net product and services revenues were $28.3 million, a 24% decrease from the second quarter of 2019. Excluding cryosurgical revenues, the line of business the Company divested in August 2019, and revenues from the Diversigen subsidiary, which the Company acquired in November 2019, net revenues and product and services revenues declined 21% and 20%, respectively, from the second quarter of 2019.

- Other revenue highlights:

  - Total product and service revenues for the Company’s molecular business unit were $18.1 million during the second quarter of 2020, an increase of 4% from the second quarter of 2019. This increase included $8.5 million in sales of oral fluid collection devices for COVID-19 molecular testing.

  - International sales of the Company’s OraQuick® HIV products decreased 28% compared to the second quarter of 2019. This decrease was due to delays of shipments which moved from the end of the second quarter into the early third quarter.

  - Total laboratory service revenues in the second quarter of 2020 were $2.2 million compared to $1.2 million in the second quarter of 2019. Laboratory services in 2020 include the revenues generated by both of the Company’s laboratory service subsidiaries, which are now operating under the Diversigen brand.

- Net loss for the second quarter of 2020 was $10.5 million, or $0.16 per share on a fully-diluted basis, compared to net income of $4.4 million, or $0.07 per share on a fully-diluted basis, for the second quarter of 2019. Net loss for the second quarter of 2020 included a $660,000 non-cash pre-tax benefit associated with the change in fair value of acquisition-related contingent consideration and $195,000 of acquisition-related transaction costs. Net income in the second quarter of 2019 included a $249,000 non-cash pre-tax charge associated with the change in the fair value of acquisition-related contingent consideration. The impact of these items were negligible to earnings per share in both periods.

- Cash and investments totaled $265.8 million at June 30, 2020, including $95 million in proceeds from an equity offering completed in June.

COVID-19 Program Update

OraSure is well positioned to support multiple modes for COVID-19 testing, including PCR/Molecular, Antigen, and Antibody testing. To support capacity building for the Company’s existing products and anticipated new product launches, the Company is executing on a series of capital investments intended to ensure scaled-up capacity to meet both current and anticipated substantial COVID-19-related demand.

- **Use of existing oral fluid collection devices in molecular COVID-19 testing generated $8.5M in revenue in the second quarter.** In the second quarter, devices from OraSure's DNA Genotek subsidiary, including the ORAcollect RNA collection kit, OMNIgene ORAL saliva collection device, and Oragene®•Dx device, were included in U.S. Food and Drug Administration (FDA) Emergency Use Authorizations (EUAs) granted to four customers. The EUAs granted to Clinical Reference Laboratory (CRL), Biocerna, P23 Labs and Phosphorous enable the Company's devices to be used for supervised and unsupervised COVID-19 sample collection with their EUA assays for the detection of SARS-CoV-2. OraSure's devices are also currently being used as part of several back-to-school and back-to-work programs across the country. The Company expects one or more of its products to be included in several additional EUAs to be granted in the near future.

- **OraQuick Coronavirus Rapid Antigen Self-Test on track for EUA submission and subsequent launch in the fourth quarter.** OraSure is developing a rapid antigen self-test, designed to produce a result for active COVID-19 infection within minutes, with no instrumentation needed to interpret the results and no need to transport samples to a lab for processing, enabling the detection of COVID-19 infection anytime, anywhere. The development of the test is supported by $710,310 of funding from the Biomedical Advanced Research and Development Authority (BARDA), part of the U.S. Department of Health and Human Services (HHS). The test is currently in human clinical testing. Although originally intended for use with oral fluid, this test has been modified to employ an easily and comfortably self-collected lower nostril sample in order to achieve the best possible accuracy. The Company fully expects to meet or exceed applicable FDA performance requirements, with EUA filing and subsequent commercial launch in the fourth quarter, pending regulatory approvals. To date, there are no COVID-19 tests for active infection which provide a result at the point of collection with no need for a diagnostic instrument to interpret the result.

- **OraSure SARS-CoV-2 Antibody test anticipated to launch in the fourth quarter.** The Company is also developing an Enzyme-Linked Immunosorbent Assay (ELISA) using oral fluid to detect human anti-SARS-CoV-2 antibodies that would enable specimen collection in any location, promoting social distancing. The test would utilize the Company's existing OraSure® oral fluid specimen collection device. To date, there are no commercially available anti-SARS-CoV-2 antibody tests using oral fluid samples with automated assays. In June, OraSure received $629,217 in funding from BARDA to support the development of this test. OraSure has completed the final product design and this test is currently in human clinical testing. The Company fully expects to meet or exceed applicable FDA performance requirements for this product, file for EUA, and launch in the fourth quarter, pending regulatory approvals.

  The pan-SARS-coronavirus antigen rapid in-home self-test project has been funded in whole or in part with Federal funds from the Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. 75A50120C00061. The SARS-CoV-2 antibody test has been funded in whole or in part with federal funds from the Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. 75A50120C00122.

Additional Second Quarter Business Highlights

- **Continued progress in executing on innovation-driven growth strategy with purchase of UrSure, Inc., strengthening OraSure's global leadership in the HIV testing field.** In May, the Company announced that it had entered into a definitive agreement to acquire privately-owned UrSure, Inc., a company developing and commercializing products that measure adherence to HIV medications that prevent (Pre-Exposure Prophylaxis or PrEP) and treat HIV. This cash transaction, which approximated $3.1 million, closed in July and supports OraSure's strategy of expanding its core offerings to include additional diagnostic products, particularly point-of-care tests that complement its current infectious disease portfolio and pipeline. OraSure will be able to offer a full HIV portfolio that covers the spectrum from screening to treatment adherence, two pillars of the federal government's "Ending the HIV Epidemic: A Plan for America" initiative.

- **Continued expansion of sample collection products to meet the needs of research and academic institutions.** In June, the Company, through its DNA Genotek subsidiary, introduced the OMNImet™·GUT (ME-200) device for metabolomics, the first and only commercially available research use only device for in-home, self-collection of fecal samples for metabolomics. This product augments the Company's portfolio of multiomic sample collection products.

Financial Results for the Three Months Ended June 30, 2020

Net product and service revenues for the second quarter of 2020 decreased 24% from the comparable period of 2019, primarily as a result of lower sales of the Company's genomics products due to the timing of orders placed by one of the Company's largest genomics customers and due to the impact of the COVID-19 pandemic. The decline is also a result of lower sales of the Company's OraQuick® HIV, OraQuick® HCV, and risk assessment products due to reduced research and testing as a result of the COVID-19 pandemic, and the absence of cryosurgical systems revenues, partially offset by the inclusion of product sales related to COVID-19 and higher laboratory services revenues.

Royalty income from a litigation settlement associated with a molecular collection device was $727,000 and $1.1 million for the second quarters of 2020 and 2019, respectively. Other revenues were $195,000 and $445,000 for the second quarter of 2020 and 2019 respectively.

Gross profit percentage was 59% and 64% for the three months ended June 30, 2020 and 2019, respectively. Gross profit percentage in the second quarter of 2020 was negatively affected by lower labor utilization as the Company increased its manufacturing headcount with full-time and temporary employees to prepare for expected production expansion later in the year, a less favorable overall product mix as a result of higher sales of lower gross profit products and services, and the decline in other revenues which contribute 100% to the Company's gross profit percentage.

For the three months ended June 30, 2020, operating expenses were $26.7 million, an increase of $6.9 million from the $19.7 million reported for the three months ended June 30, 2019. This increase was due primarily to increased spending associated with COVID-19 product development, increased staffing costs, higher bad debt associated with uncollectible customer accounts, higher legal fees, and the inclusion of Diversigen operating expenses, all partially offset by lower spending on market studies, tradeshows and travel.

The Company generated an operating loss of $9.4 million in the second quarter of 2020 compared to operating income of $5.3 million in the second quarter of 2019.

During the second quarter of 2020 and 2019, the Company recorded income tax expense of $1.3 million and $1.4 million, respectively. Income tax expense in both periods largely consists of foreign taxes due.

Financial Results for the Six Months Ended June 30, 2020

Net product and service revenues for the six months ended June 30, 2020 decreased 10% from the comparable period of 2019, primarily as a result of lower sales of the Company's genomics products due to the timing of orders placed by one of the Company's largest genomics customer and due to the impact of the COVID-19 pandemic. The decline is also a result of lower sales of the Company's domestic OraQuick® HIV, OraQuick® HCV, risk assessment, and microbiome products due to reduced research and testing as a result of the COVID-19 pandemic, and the absence of cryosurgical sales, partially offset by the inclusion of product revenues associated with COVID-19 testing, higher laboratory services revenues and increased international sales of the Company's OraQuick® HIV Self-Test.

For the six months ended June 30, 2020, royalty income from a litigation settlement associated with a molecular collection device was $1.2 million compared to $2.2 million for the six months ended June 30, 2019. Other revenues were $460,000 and $1.2 million for the first six months of 2020 and 2019, respectively.

Gross profit percentage was 55% and 63% for the six months ended June 30, 2020 and 2019, respectively. Gross profit percentage in the first six months of 2020 was negatively affected by a less favorable product mix as a result of higher sales of lower gross profit products and services, lower labor utilization rates, increased international freight costs, the decline in other revenues which contribute 100% to the Company's gross profit percentage, and higher scrap and spoilage expense.

For the six months ended June 30, 2020, operating expenses were $50.8 million, an increase of $9.2 million from the $41.6 million reported for the six months ended June 30, 2019. This increase was due primarily to increased spending associated with COVID-19 product development, increased staffing costs, higher bad debt expense associated with uncollectible customer accounts, higher legal fees, and the inclusion of Diversigen operating expenses, all partially offset by lower spending on market studies, tradeshows and travel.

The Company generated an operating loss of $17.4 million in the first six months of 2020 compared to operating income of $1.5 million in the first six months of 2019.

During the first half of 2020, the Company recorded income tax expense of $2.0 million compared to income tax expense of $1.4 million recorded in the first six months of 2019. This tax increase largely reflects the higher pre-tax income generated by the Company's Canadian subsidiary.

For the six months ended June 30, 2020, the Company used $2.2 million in cash from operations compared with $4.7 million generated in the same period of 2019. The Company's cash and investment balance totaled $265.8 million at June 30, 2020, compared to $189.8 million at December 31, 2019.

Full-Year 2020 Guidance

As announced last quarter, the Company has withdrawn its full-year 2020 financial guidance due to the unpredictable impact – both positive and negative – of the ongoing COVID-19 global pandemic on its results of operations, and the Company will not be reinstating financial guidance at this time.

Financial Data

Consolidated Financial Data
(in thousands, except per-share data)
Unaudited

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Results of Operations				
Net revenues	$ 29,259	$ 38,826	$ 60,855	$ 68,948
Cost of products and services sold	11,995	13,808	27,460	25,850
Gross profit	17,264	25,018	33,395	43,098
Operating expenses:				

Research and development	6,924	4,535	12,568	8,906
Sales and marketing	10,121	7,687	17,490	14,982
General and administrative	10,280	7,262	20,334	16,192
Change in fair value of acquisition-related contingent consideration	(660)	249	450	1,544
Total operating expenses	26,665	19,733	50,842	41,624
Operating income (loss)	(9,401)	5,285	(17,447)	1,474
Other income	216	524	1,646	1,048
Income (loss) before income taxes	(9,185)	5,809	(15,801)	2,522
Income tax expense	1,309	1,411	2,021	1,382
Net income (loss)	$ (10,494)	$ 4,398	$ (17,822)	$ 1,140
Income (loss) per share:				
Basic	$ (0.16)	$ 0.07	$ (0.28)	$ 0.02
Diluted	$ (0.16)	$ 0.07	$ (0.28)	$ 0.02
Weighted average shares:				
Basic	64,745	61,709	63,335	61,621
Diluted	64,745	62,128	63,335	62,191

	Three Months Ended June 30,				
	Dollars			Percentage of Total Net Revenues	
	2020	2019	% Change	2020	2019
Market					
Infectious disease testing	$ 8,737	$ 13,348	(35) %	30 %	34 %
Risk assessment testing	1,533	3,097	(51)	5	8
Cryosurgical systems	—	3,518	(100)	—	9
Molecular collection systems	18,067	17,304	4	63	45
Net product and service revenues	28,337	37,267	(24)	98	96
Royalty income	727	1,114	(35)	1	3
Other	195	445	(56)	1	1
Net revenues	$ 29,259	$ 38,826	(25) %	100 %	100 %

	Six Months Ended June 30,				
	Dollars			Percentage of Total Net Revenues	
	2020	2019	% Change	2020	2019
Market					
Infectious disease testing	$ 23,400	$ 25,686	(9) %	38 %	37 %
Risk assessment testing	4,533	5,934	(24)	7	9
Cryosurgical systems	—	6,093	(100)	—	9
Molecular collection systems	31,290	27,886	12	52	40
Net product and service revenues	59,223	65,599	(10)	97	95
Royalty income	1,172	2,198	(47)	2	3

Other	460	1,151	(60)	1	2
Net revenues	$ 60,855	$ 68,948	(12) %	100 %	100 %

	Three Months Ended June 30,			Six Months Ended June 30,		
	2020	2019	% Change	2020	2019	% Change
OraQuick® Revenues						
Domestic HIV	$ 3,197	$ 4,460	(28) %	$ 7,414	$ 8,765	(15) %
International HIV	3,883	5,422	(28)	10,832	9,423	15
Net HIV revenues	7,080	9,882	(28)	18,246	18,188	—
Domestic HCV	757	2,102	(64)	2,251	3,930	(43)
International HCV	641	983	(35)	1,738	2,440	(29)
Net HCV revenues	1,398	3,085	(55)	3,989	6,370	(37)
Net product revenues	$ 8,478	$ 12,967	(35) %	$ 22,235	$ 24,558	(9) %

	Three Months Ended June 30,			Six Months Ended June 30,		
	2020	2019	% Change	2020	2019	% Change
Molecular Collection Systems Revenues						
Genomics	$ 6,471	$ 13,943	(54) %	$ 14,863	$ 21,791	(32) %
Microbiome	853	2,057	(59)	2,430	3,446	(29)
COVID-19	8,472	—	N/A	8,866	—	N/A
Laboratory services	2,222	1,196	86	5,053	2,332	117
Other product revenues	49	108	(55)	78	317	(75)
Net molecular product and service revenues	18,067	17,304	4	31,290	27,886	12
Other	765	1,150	(33)	1,346	2,457	(45)
Net molecular product and service revenues	$ 18,832	$ 18,454	2 %	$ 32,636	$ 30,343	8 %

Condensed Consolidated Balance Sheets (Unaudited)

	June 30, 2020	December 31, 2019
Assets		
Cash and cash equivalents	$ 173,874	$ 75,715
Short-term investments	82,666	80,623
Accounts receivable, net	25,918	36,948
Inventories	27,707	23,155
Other current assets	7,799	8,109
Property, plant and equipment, net	33,763	30,339
Intangible assets, net	15,221	14,674
Goodwill	35,244	36,201
Long-term investments	9,222	33,420

Other non-current assets	9,413	10,111
Total assets	$ 420,827	$ 349,295
Liabilities and Stockholders' Equity		
Accounts payable	$ 9,057	$ 9,567
Deferred revenue	4,917	3,713
Contingent consideration obligation	560	3,500
Other current liabilities	16,054	15,933
Other non-current liabilities	8,482	9,437
Stockholders' equity	381,757	307,145
Total liabilities and stockholders' equity	$ 420,827	$ 349,295

Additional Financial Data (Unaudited)

	Six Months Ended June 30,	
	2020	**2019**
Capital expenditures	$ 6,037	$ 5,513
Depreciation and amortization	$ 4,600	$ 3,610
Stock-based compensation	$ 4,048	$ 1,848
Cash provided by (used in) operating activities	$ (2,184)	$ 4,661

Conference Call

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's 2020 second 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 #3276612 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, August 12, 2020, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #3276612.

Given the circumstances globally, 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, CoreBiome (now operating under the Diversigen brand), UrSure, 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 and earnings/loss per share. 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 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, 2019, Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, 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:
Sam Martin
Argot Partners
212-600-1902
orasure@argotpartners.com

Media contact:
Jeanne Mell
VP Corporate Communications
484-353-1575
media@orasure.com

OraSure Technologies, Inc.

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