



OraSure Announces 2019 Second Quarter Financial Results

August 6, 2019

BETHLEHEM, Pa., Aug. 06, 2019 (GLOBE NEWSWIRE) -- OraSure Technologies, Inc. (NASDAQ: OSUR), a leader in point-of-care diagnostic tests and specimen collection devices, today announced its financial results for the three and six months ended June 30, 2019.

"Second quarter revenues were not what we had targeted due to a three-day delayed shipment of HIV Self-Tests and ongoing softness in the consumer genomics markets. However, our earnings were strong and we continue to expect to deliver on and exceed our original profit targets for the year notwithstanding market headwinds," said Stephen S. Tang, Ph.D., OraSure President and CEO. "We are encouraged by the continued, annual double-digit growth in our Microbiome line of business, as well as growth in the Disease Risk Management sector of Consumer Genomics. On the Infectious Disease side, we continue to expect annual double-digit growth in global HIV testing revenues, driven by expanding international usage of our HIV Self-Test product."

Financial and Business Highlights

- Net revenues for the second quarter of 2019 were \$38.8 million, an 11% decrease from the second quarter of 2018. Net product revenues were \$37.3 million, representing a 4% decrease from the second quarter of 2018.
- Net revenues for the six months ended June 30, 2019 were \$68.9 million, a 19% decrease from the comparable period of 2018. Net product revenues were \$65.6 million, representing a 15% decrease from the first half of 2018.
- Molecular collection systems revenues including royalty income and other revenues were \$18.5 million during the second quarter of 2019, a decline of 4% from the second quarter of 2018. Molecular collection systems revenues including royalty income and other revenues were \$30.3 million during the first half of 2019, a decline of 23% from the same period in the prior year.
- Molecular collection systems product and service revenues were \$17.3 million and \$27.9 million during the second quarter and first half of 2019, respectively, which represents a 1% increase from the second quarter of 2018 and a 22% decrease from the first six months of 2018.
- Domestic and international sales of the Company's OraQuick® HIV products of \$9.9 million in the second quarter of 2019 decreased 21% compared to the second quarter of 2018. Domestic and international sales of the Company's OraQuick® HIV products for the six months ended June 30, 2019 of \$18.2 million decreased 22% compared to the comparable period of the prior year.
- Domestic sales of the Company's OraQuick® HCV product of \$2.1 million increased 22% over the second quarter of 2018. OraQuick® HCV domestic sales for the six months ended June 30, 2019 were \$3.9 million, a 17% increase from the comparable period of 2018.
- International sales of the Company's OraQuick® HCV product of \$1.0 million decreased 33% for the second quarter of 2019 compared to the second quarter of 2018. OraQuick® HCV international sales for the six months ended June 30, 2019 were \$2.4 million, a 14% increase from the comparable period of 2018.
- Net income for the second quarter of 2019 was \$4.4 million, or \$0.07 per share on a fully-diluted basis, which compares to net income of \$4.1 million, or \$0.07 per share on a fully-diluted basis, for the second quarter of 2018. Net income for the six months ended June 30, 2019 was \$1.1 million, or \$0.02 per share on a fully-diluted basis, which compares to net income of \$2.0 million, or \$0.03 per share on a fully-diluted basis, for the comparable period of 2018. Net income for the current three and six month periods included acquisition-related charges of \$249,000 and \$1.5 million, respectively, representing the change in fair value of contingent consideration associated with two recent acquisitions. The current six month period also included \$597,000 of transaction costs. These acquisition-related charges were negligible for the current quarter on a per share basis and approximated \$0.03 per share for the first six months of 2019. Net income for the second quarter and first six months of 2018 included \$2.2 million and \$8.6 million, respectively, of transition costs associated with executive management changes which occurred in 2018. These transition costs approximated \$0.04 and \$0.14 per share, respectively, for the second quarter and first six months of 2018, and primarily consisted of non-cash stock compensation charges.

- Cash and investments totaled \$186.6 million at June 30, 2019.

Financial Results

Net product revenues for the second quarter of 2019 decreased 4% from the comparable period of 2018, primarily as a result of lower sales of the Company's OraQuick® HIV and genomics products and lower international sales of the Company's OraQuick® HCV test, partially offset by higher sales of the Company's microbiome, cryosurgical, and domestic HCV products.

Net product revenues for the first six months of 2019 decreased 15% from the comparable period of 2018, primarily as a result of lower sales of the Company's genomics and OraQuick® HIV products, partially offset by increases in microbiome, cryosurgical systems, and OraQuick® HCV sales.

International sales of the OraQuick® HIV Self-Test for the three months ended June 30, 2019 and 2018 included \$1.1 million and \$1.7 million, respectively, of support payments under the Company's charitable support agreement with the Bill & Melinda Gates Foundation ("Gates Foundation"). International sales of the OraQuick® HIV Self-Test for the six months ended June 30, 2019 and 2018 included \$1.8 million and \$2.7 million, respectively, of support payments.

Royalty income from a litigation settlement associated with a molecular collection device was \$1.1 million and \$2.1 million for the second quarters of 2019 and 2018, respectively, and \$2.2 million and \$3.7 million for the first six months of 2019 and 2018, respectively. Other revenues, excluding royalty income, were \$445,000 and \$2.7 million for the second quarters of 2019 and 2018, respectively, and \$1.1 million and \$4.8 million for the first six months of 2019 and 2018, respectively. Other revenues in both periods decreased due to lower funding received from the U.S. Biomedical Advanced Research Development Authority (BARDA) and lower cost reimbursement from the Gates Foundation.

Gross profit percentage was 64% and 63% for the three and six months ended June 30, 2019. Gross profit percentage for the three and six months ended June 30, 2018 was 59% in both periods. Gross profit percentage in both periods of 2019 benefited from improved product mix associated with higher sales of higher gross profit products and lower royalty expense, partially offset by lower other revenues, and the lower margins generated by the Company's newly acquired subsidiaries, Novosanis and CoreBiome.

For the three months ended June 30, 2019, operating expenses were \$19.7 million, a decrease of \$604,000 from the \$20.3 million reported for the three months ended June 30, 2018. The decrease was due in part to the absence of \$2.2 million of transition costs associated with executive management changes that occurred in the second quarter of 2018, partially offset by a non-cash charge of \$249,000 in the current quarter for the change in fair value of contingent consideration associated with the recent acquisition of CoreBiome and Novosanis, as well as by the incremental operating expenses of CoreBiome and Novosanis. For the six months ended June 30, 2019, operating expenses were \$41.6 million, a decrease of \$3.7 million from the \$45.3 million reported for the six months ended June 30, 2018. This decrease was due in part to the absence of \$8.6 million of transition costs associated with executive management changes that occurred in the first half of 2018, partially offset by a non-cash charge of \$1.5 million in the first half of 2019 for the change in fair value of contingent consideration associated with the recent acquisition of CoreBiome and Novosanis as well as by the incremental operating expenses of CoreBiome and Novosanis. During the first six months of 2019, the Company also incurred \$597,000 of transaction costs associated with the recent acquisitions. There were no similar acquisition costs in either period of 2018.

The Company reported operating income of \$5.3 million and \$1.5 million in the second quarter and first six months of 2019, respectively, compared to operating income of \$5.6 million and \$5.1 million in the second quarter and first six months of 2018, respectively.

During the second quarter of 2019, the Company recorded income tax expense of \$1.4 million compared to \$2.2 million recorded in the second quarter of 2018. During the six months ended June 30, 2019, the Company recorded income tax expense of \$1.4 million compared to \$4.2 million in the six months ended June 30, 2018. The decrease in income tax expense in both periods reflects the lower pre-tax income generated by the Company's Canadian subsidiary, DNA Genotek, and includes an income tax benefit generated by Novosanis.

The Company's cash and investment balance totaled \$186.6 million at June 30, 2019, compared to \$201.3 million at December 31, 2018. For the six months ended June 30 2019, the Company generated \$4.7 million in cash from operations.

Third Quarter and Updated Full-Year 2019 Guidance

The Company expects third quarter 2019 net revenues to range from \$39.0 million to \$40.5 million and is projecting net income of approximately \$0.04 per share to \$0.05 per share. For full-year 2019, the Company is expecting net revenues to range from \$165.0 million to \$170.0 million and is projecting net income of \$0.24 to \$0.26 per share. These projections do not account for the impact of changes in the fair value of acquisition-related contingent consideration or any potential transaction costs related to future business development activity since those items cannot be fully determined at this time. The downward revision to full-year revenue expectations from \$170.0 to \$175.0 million for 2019 reflects continued softness in the consumer genomics market and lower royalties associated with that market. Nonetheless, the Company continues to expect that genomics revenues excluding the single largest customer, microbiome revenues, and global HIV testing revenues will all grow by double digits in 2019 compared to 2018.

Financial Data

Condensed Consolidated Financial Data

	Three Months Ended		Six Months Ended	
	June 30, 2019	2018	June 30, 2019	2018
Results of Operations				
Net revenues	\$ 38,826	\$ 43,625	\$ 68,948	\$ 85,612
Cost of products sold	13,808	17,730	25,850	35,250
Gross profit	25,018	25,895	43,098	50,362
Operating expenses:				
Research and development	4,535	4,261	8,906	8,336

Sales and marketing	7,687	7,429	14,982	14,928
General and administrative	7,262	8,647	16,192	22,038
Change in fair value of acquisition-related contingent consideration	249	—	1,544	—
Total operating expenses	19,733	20,337	41,624	45,302
Operating income	5,285	5,558	1,474	5,060
Other income	524	736	1,048	1,148
Income before income taxes	5,809	6,294	2,522	6,208
Income tax expense	1,411	2,173	1,382	4,206
Net income	\$ 4,398	\$ 4,121	\$ 1,140	\$ 2,002
Earnings per share:				
Basic	\$ 0.07	\$ 0.07	\$ 0.02	\$ 0.03
Diluted	\$ 0.07	\$ 0.07	\$ 0.02	\$ 0.03
Weighted average shares:				
Basic	61,709	61,100	61,621	60,983
Diluted	62,128	62,244	62,191	62,379

	Three Months Ended June 30,			Percentage of Total Net Revenues		
	Dollars					
	2019	2018	% Change	2019	2018	
Market						
Infectious disease testing	\$ 13,348	\$ 15,919	(16)%	34	36	%
Risk assessment testing	3,097	3,315	(7)	8	8	
Cryosurgical systems	3,518	2,392	47	9	6	
Molecular collection systems	17,304	17,192	1	45	39	
Net product and service revenues	37,267	38,818	(4)	96	89	
Royalty income	1,114	2,092	(47)	3	5	
Other	445	2,715	(84)	1	6	
Net revenues	\$ 38,826	\$ 43,625	(11)%	100	100	%

	Six Months Ended June 30,			Percentage of Total Net Revenues		
	Dollars					
	2019	2018	% Change	2019	2018	
Market						
Infectious disease testing	\$ 25,686	\$ 30,090	(15)%	37	35	%
Risk assessment testing	5,934	6,316	(6)	9	7	
Cryosurgical systems	6,093	5,177	18	9	6	
Molecular collection systems	27,886	35,553	(22)	40	42	
Net product revenues	65,599	77,136	(15)	95	90	
Royalty income	2,198	3,694	(40)	3	4	
Other	1,151	4,782	(76)	2	6	
Net revenues	\$ 68,948	\$ 85,612	(19)%	100	100	%

	Three Months Ended June 30,			Six Months Ended June 30,		
	2019	2018	% Change	2019	2018	% Change
OraQuick® Revenues						
Domestic HIV	\$ 4,460	\$ 5,189	(14)%	\$ 8,765	\$ 10,234	(14)%
International HIV	5,422	7,397	(27)	9,423	13,067	(28)
Net HIV revenues	9,882	12,586	(21)	18,188	23,301	(22)
Domestic HCV	2,102	1,730	22	3,930	3,358	17
International HCV	983	1,473	(33)	2,440	2,138	14
Net HCV revenues	3,085	3,203	(4)	6,370	5,496	16
Net product revenues	\$ 12,967	\$ 15,789	(18)%	\$ 24,558	\$ 28,797	(15)%

	Three Months Ended June 30,			Six Months Ended June 30,		
	2019	2018	% Change	2019	2018	% Change
Molecular Collection Systems Revenues						
Genomics	\$ 14,221	\$ 15,368	(7)%	\$ 22,269	\$ 32,456	(31)%
Microbiome	2,975	1,824	63	5,300	3,097	71
Other	108	—	100	317	—	100
Net product and service revenues	17,304	\$ 17,192	1	27,886	\$ 35,553	(22)
Royalty income	1,114	2,092	(47)	2,198	3,694	(40)
Other	36	—	100	259	—	100
Total Molecular Collection Systems Revenues	\$ 18,454	\$ 19,284	(4)%	\$ 30,343	\$ 39,247	(23)%

Condensed Consolidated Balance Sheets (Unaudited)

	June 30, 2019	December 31, 2018
Assets		
Cash and cash equivalents	\$ 72,567	\$ 88,438
Short-term investments	74,446	68,134
Accounts receivable, net	29,390	34,842
Inventories	25,670	22,888
Other current assets	7,185	5,010
Property, plant and equipment, net	27,793	24,299
Right of use assets, net	5,147	—
Intangible assets, net	12,472	5,137
Goodwill	29,280	18,521
Long-term investments	39,555	44,752
Other non-current assets	3,960	3,550
Total assets	\$ 327,465	\$ 315,571
Liabilities and Stockholders' Equity		
Accounts payable	\$ 10,956	\$ 10,598
Deferred revenue	3,914	3,521
Contingent consideration obligation	5,249	—
Other current liabilities	9,832	13,861
Long-term lease liabilities	4,196	—
Long-term contingent consideration obligation	649	—
Other non-current liabilities	4,448	4,213
Stockholders' equity	288,221	283,378
Total liabilities and stockholders' equity	\$ 327,465	\$ 315,571

	Six Months Ended June 30,	
	2019	2018
Additional Financial Data (Unaudited)		
Capital expenditures	\$ 5,513	\$ 4,484
Depreciation and amortization	\$ 3,610	\$ 3,746
Stock-based compensation	\$ 1,848	\$ 11,262
Cash provided by operating activities	\$ 4,661	\$ 13,928

Conference Call

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's 2019 second quarter results, certain business developments and updated financial guidance, 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 #9973117 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 13, 2019, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #9973117.

About OraSure Technologies

OraSure Technologies is empowering the global community to improve health and wellness by providing access to accurate essential information. OraSure is a leader in the development, manufacture and distribution of point-of-care diagnostic tests, molecular collection devices and other technologies designed to detect or diagnose critical medical conditions. Its first-to-market, innovative products include rapid tests for the detection of antibodies to HIV and Hepatitis C (HCV) on the OraQuick® platform, sample self-collection and stabilization products for molecular applications, and oral fluid laboratory tests for detecting various drugs of abuse. Together with its wholly-owned subsidiaries (DNA Genotek, CoreBiome and Novosanis), OraSure provides its customers with value-added, end-to-end solutions that encompass tools, diagnostics and services. OraSure's portfolio of products is sold globally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, research institutions, distributors, government agencies, physicians' offices, commercial and industrial entities and 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; 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; 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 increased reliance on U.S. government contracts; 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 Securities and Exchange Commission ("SEC") filings, including our registration statements, Annual Report on Form 10-K for the year ended December 31, 2018, 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. 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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Source: OraSure Technologies, Inc.