



OraSure Announces 2018 Full Year and Fourth Quarter Financial Results

February 6, 2019

BETHLEHEM, Pa., Feb. 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 full year and fourth quarter of 2018.

Financial Highlights

- Net revenues for the year ended December 31, 2018 were \$181.7 million, a 9% increase from 2017. Net product revenues were \$165.4 million, representing 2% growth over 2017.
- Net revenues for the fourth quarter of 2018 were \$50.2 million, a 3% decrease from the fourth quarter of 2017. Net product revenues were \$44.8 million, representing an 11% decrease from the fourth quarter of 2017.
- Molecular collection systems net revenues for the full year 2018, including royalty income from a litigation settlement, were \$96.1 million, up 28% from 2017. Molecular collection systems net revenues including royalty income were \$30.2 million during the fourth quarter of 2018, up 2% from the fourth quarter of 2017. Molecular collection systems net product revenues during the year ended December 31, 2018 were \$86.5 million, a 15% increase from the comparable period of 2017. Molecular collection systems net product revenues were \$25.4 million during the fourth quarter of 2018, which represents a 15% decrease from the fourth quarter of 2017.
- For the full year of 2018, international sales of the Company's OraQuick[®] HIV products were \$21.8 million, an increase of 93% compared to 2017. International sales of the Company's OraQuick[®] HIV products of \$4.4 million in the fourth quarter of 2018 increased 23% compared to the fourth quarter of 2017. The increases in both periods were primarily the result of higher sales of the Company's OraQuick[®] HIV Self-Test.
- Full year 2018 international sales of the Company's OraQuick[®] HCV product of \$4.9 million decreased 71% from 2017. International sales of the Company's OraQuick[®] HCV product of \$1.6 million increased 40% for the fourth quarter of 2018 compared to the fourth quarter of 2017. The decline for the full year was primarily the result of the non-renewal of a foreign government supply contract in support of a countrywide HCV eradication program at the end of 2017. This program contributed \$11.8 million in sales during the full year of 2017 and \$270,000 during the fourth quarter of 2017. The increase in the fourth quarter was due to continued growth in Asia and Africa.
- Net income for the year ended December 31, 2018 was \$20.4 million, or \$0.33 per share on a fully diluted basis, which compares to net income of \$30.9 million, or \$0.51 per share on a fully diluted basis, for 2017. Net income for 2018 included \$1.2 million of pre-tax transaction costs associated with two recent acquisitions that closed in early January 2019 and \$9.6 million of pre-tax transition costs associated with the retirement of the Company's former Chief Executive Officer and Chief Financial Officer and the hiring of their successors. The transaction costs were \$0.02 per share and the transition costs were \$0.15 per share for the year ended December 31, 2018. The transition costs primarily consisted of non-cash stock compensation charges. Net income for the year ended December 31, 2017 included a \$12.5 million gain related to the settlement of litigation against Ancestry.com DNA and its contract manufacturer. This gain was accounted for as a reduction of operating expenses and amounted to \$0.15 per share on a fully diluted after-tax basis in that period.
- Net income for the fourth quarter of 2018 was \$10.3 million, or \$0.16 per share on a fully diluted basis, which compares to net income of \$7.3 million, or \$0.12 per share on a fully diluted basis, for the fourth quarter of 2017. Net income for the fourth quarter of 2018 included \$1.2 million of pre-tax transaction costs related to the recent acquisitions and \$974,000 of pre-tax transition costs associated with the Company's executive management changes. The transaction and transition costs together were \$0.04 per share for the fourth quarter of 2018. The transition costs in the fourth quarter consisted of non-cash stock compensation charges.
- Cash and investments totaled \$201.3 million at December 31, 2018.

"With the highest annual revenues in our history and strong profitability, 2018 was another financially successful year for OraSure. Our OraQuick[®] international HIV business and our Molecular business continued to drive performance with double-digit growth from 2017 to 2018. Our 2018 microbiome revenues nearly doubled when compared to 2017," said OraSure President and Chief Executive Officer, Dr. Stephen S. Tang. "2018 was

also a pivotal year strategically. The acquisitions we announced in January were the first outcomes of our robust innovation-driven growth strategy. I am confident we have the right strategy and talent in place to deliver against our strategic objectives. We begin 2019 poised to leverage our strengths, grow our product portfolio and expand into new markets.”

Financial Results

Net product revenues for the year ended December 31, 2018 increased 2% over 2017, primarily as a result of higher sales of the Company's molecular collection systems products and higher international sales of the OraQuick® HIV Self-Test, partially offset by lower sales of the Company's HCV product, lower domestic sales of the professional OraQuick® HIV test and lower sales of the Company's cryosurgical systems products.

Net product revenues for the fourth quarter of 2018 decreased 11% from the comparable period of 2017, primarily as a result of lower sales of the Company's molecular collections products and lower domestic sales of the Company's HIV and HCV tests, partially offset by higher international sales of the OraQuick® HIV Self-Test and OraQuick® HCV test.

Sales of the OraQuick® HIV Self-Test for the year and three months ended December 31, 2018 included \$4.4 million and \$855,000, respectively, of support payments under the Company's charitable support agreement with the Bill & Melinda Gates Foundation (“Gates Foundation”), while the year and three months ended December 31, 2017 included \$1.0 million and \$589,000, respectively, of such payments.

Royalty income from a litigation settlement associated with a molecular collection device was \$9.7 million for the full year and \$4.8 million for the fourth quarter of 2018. There were no such royalties in 2017. Other revenues were \$6.7 million and \$5.1 million for the full year of 2018 and 2017, respectively. Other revenues were \$578,000 and \$1.8 million for the fourth quarter of 2018 and 2017, respectively. Other revenues in the full year of 2018 increased due to higher Ebola and Zika-related funding received from the U.S. Biomedical Advanced Research Development Authority (“BARDA”) and increased cost reimbursement from the Gates Foundation. Other revenues decreased in the fourth quarter of 2018 largely due to lower BARDA funding and lower cost reimbursement under the Company's charitable support agreement with the Gates Foundation.

Gross profit percentage was 63% and 69% for the year and three months ended December 31, 2018, respectively, compared to 59% and 55% and for the year and three months ended December 31, 2017, respectively. Gross profit percentage in the full year of 2018 benefited from improved product mix associated with an increase in higher gross profit percentage product sales, lower manufacturing costs associated with the Company's Oragene® product, increased royalty income and other revenues, lower scrap and spoilage costs and lower royalty expense. Gross profit percentage in the current quarter benefited from improved product mix associated with an increase in higher profit percentage product sales, increased royalty income, lower manufacturing costs associated with the Company's Oragene® product, lower scrap and spoilage costs and lower royalty expense partially offset by a decrease in other revenues.

For the year ended December 31, 2018, operating expenses were \$85.2 million, an increase of \$26.5 million from the \$58.7 million reported for the year ended December 31, 2017. The increase for the full year period was largely due to the inclusion of \$9.6 million of transition costs associated with executive management changes, \$1.2 million of transaction costs associated with the Company's recent acquisitions and higher spending on research and development and sales and marketing during the period and by the absence of the \$12.5 million litigation gain associated with the settlement of litigation against Ancestry.com DNA and its contract manufacturer that was included in 2017. There was no similar gain recorded during 2018.

Operating expenses increased to \$22.2 million during the fourth quarter of 2018 compared to \$18.4 million in the fourth quarter of 2017. The fourth quarter increase was largely due to the inclusion of \$1.2 million of transaction costs associated with the recent acquisitions, \$973,000 of additional transition costs associated with the management changes, and higher commissions, consulting costs and other staffing costs, partially offset by the absence of a cost write-off in the fourth quarter of 2017 resulting from the non-renewal of a large HCV supply contract. A similar write-off did not recur in the fourth quarter of 2018.

Operating income for the year end December 31, 2018 was \$28.4 million compared \$40.2 million for the year ended December 31, 2017. The Company reported operating income of \$12.5 million in the fourth quarter of 2018, compared to operating income of \$10.2 million in the fourth quarter of 2017.

For the year ended December 31, 2018, other income increased to \$3.3 million from \$794,000 in the comparable period of 2017. Other income increased to \$1.6 million during the fourth quarter of 2018 compared to \$118,000 in the fourth quarter of 2017. The increase in other income for the full year 2018 is largely due to increased foreign currency gains associated with the strengthening of the Canadian dollar and higher interest income, partially offset by an increase in investment losses associated with the Company's deferred compensation plan. The increase in other income in the fourth quarter of 2018 is also largely due to increased foreign currency gains and higher interest income earned on the Company's investment balances.

Income tax expense was \$11.3 million during the full year of 2018 compared to \$10.1 million during the full-year of 2017. Income tax expense was \$3.8 million during the fourth quarter of 2018 compared to \$3.0 million recorded in the fourth quarter of 2017. Income tax expense in 2018 reflects the higher pre-tax income generated by the Company's Canadian subsidiary. Income tax expense in 2017 included the additional taxes due as a result of the \$12.5 million litigation settlement gain.

The Company's cash and investment balance totaled \$201.3 million at December 31, 2018, compared to \$176.6 million at December 31, 2017. For the year ended December 31, 2018, the Company generated \$39.1 million in cash from operations.

First Quarter 2019 Outlook

The Company expects net revenues to range from \$29.0 million to \$30.5 million and is projecting a net loss of \$0.06 to \$0.07 per share for the first quarter of 2019. The foregoing guidance includes the expected revenue contribution from the two acquisitions that closed in early January 2019 and transaction costs approximating \$0.01 per share, but does not account for any additional transaction and integration costs of those or any other completed transactions, which cannot be reasonably estimated at this time.

“We believe that revenues for the second half of 2019 will be materially greater than in the first half of the year, as we have experienced in the past. Additionally, we expect that performance by our core businesses combined with additional acquisitions will support our growth in future periods,” Dr. Tang said.

Financial Data

Condensed Consolidated Financial Data (In thousands, except per-share data)

Unaudited

	Three Months Ended December 31,		Year Ended December 31,	
	2018	2017	2018	2017
Results of Operations				
Net revenues	\$ 50,246	\$ 52,028	\$ 181,743	\$ 167,064
Cost of products sold	15,540	23,503	68,130	68,108
Gross profit	34,706	28,525	113,613	98,956
Operating expenses:				
Research and development	4,059	3,829	16,250	13,365
Sales and marketing	8,377	6,991	30,609	28,532
General and administrative	9,758	7,544	38,325	29,321
Gain on litigation settlement	—	—	—	(12,500)
Total operating expenses	22,194	18,364	85,184	58,718
Operating income	12,512	10,161	28,429	40,238
Other income	1,629	118	3,287	794
Income before income taxes	14,141	10,279	31,716	41,032
Income tax expense	3,843	2,963	11,320	10,084
Net income	\$ 10,298	\$ 7,316	\$ 20,396	\$ 30,948
Earnings per share:				
Basic	\$ 0.17	\$ 0.12	\$ 0.33	\$ 0.52
Diluted	\$ 0.16	\$ 0.12	\$ 0.33	\$ 0.51
Weighted average shares:				
Basic	61,268	60,652	61,112	59,050
Diluted	62,511	62,371	62,532	61,024

Summary of Net Revenues by Market and Product Line (Unaudited)

	Three Months Ended December 31,			Percentage of Total Net Revenues		
	Dollars					
	2018	2017	% Change	2018	2017	
Market						
Infectious disease testing	\$ 13,643	\$ 14,129	(3) %	27	% 27	%
Risk assessment testing	2,898	3,141	(8)	6	6	
Cryosurgical systems	2,894	3,163	(9)	6	6	
Molecular collection systems	25,407	29,784	(15)	50	58	
Net product revenues	44,842	50,217	(11)	89	97	
Royalty income	4,826	-	N/A	10	-	
Other	578	1,811	(68)	1	3	
Net revenues	\$ 50,246	\$ 52,028	(3) %	100	% 100	%

	Year Ended December 31,			Percentage of Total Net Revenues		
	Dollars					
	2018	2017	% Change	2018	2017	
Market						
Infectious disease testing	\$ 56,148	\$ 61,951	(9) %	31	% 37	%
Risk assessment testing	12,058	12,659	(5)	7	8	
Cryosurgical systems	10,767	12,279	(12)	6	7	

Molecular collection systems	86,455	75,099	15	47	45
Net product revenues	165,428	161,988	2	91	97
Royalty income	9,653	-	N/A	5	-
Other	6,662	5,076	31	4	3
Net revenues	\$ 181,743	\$ 167,064	9	% 100	% 100

	Three Months Ended December 31,			Year Ended December 31,		
	2018	2017	% Change	2018	2017	% Change
OraQuick® Revenues						
Domestic HIV	\$ 4,974	\$ 6,494	(23) %	\$ 19,663	\$ 23,847	(18) %
International HIV	4,399	3,563	23	21,794	11,301	93
Net HIV revenues	9,373	10,057	(7)	41,457	35,148	18
Domestic HCV	2,066	2,468	(16)	7,490	8,448	(11)
International HCV	1,598	1,144	40	4,904	16,961	(71)
Net HCV revenues	3,664	3,612	1	12,394	25,409	(51)
Net product revenues	\$ 13,037	\$ 13,669	(5) %	\$ 53,851	\$ 60,557	(11) %

	Three Months Ended December 31,			Year Ended December 31,		
	2018	2017	% Change	2018	2017	% Change
Molecular Collection Systems Revenues						
Genomics	\$ 23,505	\$ 28,679	(18) %	\$ 79,765	\$ 71,611	11 %
Microbiome	1,902	1,105	72	6,690	3,488	92
Net product revenues	\$ 25,407	\$ 29,784	(15) %	\$ 86,455	\$ 75,099	15 %

Condensed Consolidated Balance Sheets (Unaudited)

	December 31, 2018	December 31, 2017
Assets		
Cash and cash equivalents	\$ 88,438	\$ 72,869
Short-term investments	68,134	83,028
Accounts receivable, net	34,842	42,521
Inventories	22,888	19,343
Other current assets	5,010	4,144
Property and equipment, net	24,299	21,372
Intangible assets, net	5,137	8,223
Goodwill	18,521	20,083
Long-term investments	44,752	20,690
Other non-current assets	3,550	3,928
Total assets	\$ 315,571	\$ 296,201
Liabilities and Stockholders' Equity		
Accounts payable	\$ 10,598	\$ 10,228
Deferred revenue	3,521	1,314
Other current liabilities	13,861	20,695
Other non-current liabilities	901	3,932
Deferred income taxes	3,312	1,951
Stockholders' equity	283,378	258,081
Total liabilities and stockholders' equity	\$ 315,571	\$ 296,201

Additional Financial Data (Unaudited)	Year Ended December 31,	
	2018	2017
Capital expenditures	\$ 6,344	\$ 4,337
Depreciation and amortization	\$ 7,222	\$ 6,402
Stock-based compensation	\$ 15,237	\$ 6,973
Cash provided by operating activities	\$ 39,090	\$ 28,156

Conference Call

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's 2018 fourth quarter and full year financial results, certain business developments and financial guidance for the first quarter of 2019, 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 either dial 844-831-3030 (Domestic) or 315-625-6887 (International) and reference Conference ID #2986827 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, February 13, 2019, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #2986827.

About OraSure Technologies

OraSure Technologies is a leader in the development, manufacture and distribution of point-of-care diagnostic and 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 HCV on the OraQuick® platform, oral fluid sample collection, stabilization and preparation products for molecular diagnostic applications, and oral fluid laboratory tests for detecting various drugs of abuse. OraSure's portfolio of products is sold globally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, research and academic institutions, distributors, government agencies, physicians' offices, commercial and industrial entities and consumers. The Company's products enable healthcare providers to deliver critical information to patients, empowering them to make decisions to improve and protect their health.

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: successfully managing and integrating 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; 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 significant customer concentration in the genomics business; impact of increased reliance on U.S. government contracts; failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our 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; impact of negative economic conditions; 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; 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 meet financial covenants in credit agreements; 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 the Company's Securities and Exchange Commission ("SEC") filings, including our registration statements, Annual Report on Form 10-K for the year ended December 31, 2017, 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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