



OraSure Announces Record 2017 Fourth Quarter and Full-Year Financial Results

February 7, 2018

BETHLEHEM, Pa., Feb. 07, 2018 (GLOBE NEWSWIRE) -- OraSure Technologies, Inc. (NASDAQ:OSUR), a leader in point-of-care diagnostic tests and specimen collection devices, today announced its consolidated financial results for the fourth quarter and full-year ended December 31, 2017.

Financial Highlights

- Consolidated net revenues for the fourth quarter of 2017 were \$52.0 million, a 47% increase from the fourth quarter of 2016. Consolidated net product revenues were \$50.2 million, representing a 75% increase over the fourth quarter of 2016.
- Consolidated net revenues for the year ended December 31, 2017 were \$167.1 million, a 30% increase from the comparable period of 2016. Consolidated net product revenues were \$162.0 million, representing a 51% improvement from 2016.
- Net molecular collection systems revenues were \$29.8 million during the fourth quarter of 2017, which represents a 248% increase over the fourth quarter of 2016. Net molecular collection systems revenues during the year ended December 31, 2017 were \$75.1 million, a 133% increase from 2016.
- International sales of the Company's OraQuick® HIV products of \$3.6 million increased 171% compared to the fourth quarter of 2016. International OraQuick® HIV sales for year ended December 31, 2017 were \$11.3 million, a 115% increase over 2016. The increase in international HIV sales for both periods was primarily the result of higher sales of the Company's HIV self-test.
- International sales of the Company's OraQuick® HCV product of \$1.1 million for the fourth quarter of 2017 decreased 61% compared to the fourth quarter of 2016 as a result of the non-renewal of a foreign government supply contract in support of a countrywide HCV eradication program. International OraQuick® HCV sales for the year ended December 31, 2017 were \$17.0 million, a 156% increase over the full year of 2016.
- Consolidated net income for the fourth quarter of 2017 was \$7.3 million, or \$0.12 per share on a fully diluted basis, which compares to consolidated net income of \$7.2 million, or \$0.13 per share on a fully diluted basis, for the fourth quarter of 2016. Consolidated net income for the year ended December 31, 2017 was \$30.9 million, or \$0.51 per share on a fully-diluted basis, which compares to consolidated net income of \$19.7 million, or \$0.35 per share, for the comparable period of 2016.
- Cash and investments totaled \$176.6 million and working capital amounted to \$189.7 million at December 31, 2017.

"Our fourth quarter and full year 2017 financial results were outstanding," said Douglas A. Michels, President and CEO of OraSure Technologies. "We reported record revenues and profitability for the year as a result of the exceptional performance of our molecular business and strong growth in our international HIV and HCV businesses. Our Company is in great shape financially and we are starting 2018 in a very solid position with significant momentum in our molecular and infectious disease businesses."

Financial Results

Consolidated net product revenues for the fourth quarter of 2017 increased 75% over the comparable period of 2016, primarily as a result of higher sales of the Company's molecular collections products and higher international sales of the OraQuick® HIV self-test, partially offset by lower international sales of the OraQuick® HCV test. Fourth quarter 2017 sales of the OraQuick® HIV self-test included \$589,000 of support payments under the Company's charitable support agreement with the Bill & Melinda Gates Foundation ("Gates Foundation").

Consolidated net product revenues for the full year of 2017 increased 51% over 2016. This increase was primarily the result of higher sales of the Company's molecular collections and OraQuick® HCV products and higher international sales of the OraQuick® HIV self-test, partially offset by lower domestic sales of the Company's professional OraQuick® HIV product and lower cryosurgical product sales. Full-year 2017 sales of the OraQuick® HIV self-test included \$1.0 million of support payments under the Gates Foundation agreement.

Consolidated other revenues for the quarter and year ended December 31, 2017 were \$1.8 million and \$5.1 million, respectively. This compares to consolidated other revenues for the fourth quarter and full year of 2016 of \$6.9 million and \$21.3 million, respectively. Other revenues in the fourth quarter of 2017 included \$1.3 million of Ebola and Zika-related funding received from the U.S. Biomedical Advanced Research Development Authority ("BARDA") and \$470,000 in cost reimbursement under the Company's charitable support agreement with the Gates Foundation. Other revenues in the fourth quarter of 2016 included \$747,000 of BARDA funding and \$6.1 million of exclusivity revenues recognized under the Company's HCV co-promotion agreement with AbbVie, which terminated on December 31, 2016. Other revenues for the full-year 2017 included \$4.4 million of BARDA

funding and \$689,000 of cost reimbursement under the Gates Foundation agreement. Other revenues in 2016 included \$2.3 million of BARDA funding and \$18.9 million of AbbVie exclusivity revenues.

Consolidated gross margin was 55% and 59% for the three months and year ended December 31, 2017, respectively. Consolidated gross margin for the three months and year ended December 31, 2016 was 67% and 69%, respectively. Gross margin for the current quarter and the full year of 2017 decreased primarily due to the absence of AbbVie exclusivity revenues during these periods, an increase in lower margin product sales, and higher scrap and spoilage costs.

Consolidated operating expenses increased to \$18.4 million during the fourth quarter of 2017 compared to \$16.9 million in the fourth quarter of 2016. This increase was largely due to higher research and development expenses resulting from increased lab supplies and staffing costs and from the inclusion in the fourth quarter of 2016 of a payment to settle a claim against one of the Company's raw material suppliers, which reduced research and development expenses by \$1.4 million. A similar payment was not received in the fourth quarter of 2017. The current quarter increase was partially offset by a decrease in general and administrative expense associated with lower legal fees and a decrease in costs caused by the absence of a corporate restructuring which occurred in the fourth quarter of 2016, partially offset by higher consulting costs and a cost write-off in the fourth quarter of 2017 resulting from the non-renewal of a foreign government supply contract in support of a country-wide HCV eradication program.

For the year ended December 31, 2017, consolidated operating expenses were \$58.7 million, a \$9.0 million decrease from the \$67.8 million reported for the year ended December 31, 2016. This decrease was primarily due to a \$12.5 million gain on a litigation settlement reported earlier this year, the absence of costs associated with the AbbVie HCV co-promotion agreement, and lower legal fees, partially offset by higher staffing costs and increased research and development expenses due to the supplier claim settlement and higher supply costs.

Operating income rose 44% to \$10.2 million in the fourth quarter of 2017 compared to \$7.1 million in the fourth quarter of 2016. Operating income for the year ended December 31, 2017 was \$40.2 million, a 99% increase over 2016.

Income tax expense was \$3.0 million during the fourth quarter of 2017 compared to a \$31,000 income tax benefit recorded in the fourth quarter of 2016. For the year ended December 31, 2017, income tax expense was \$10.1 million, a \$9.5 million increase from the \$603,000 reported for the year ended December 31, 2016. Full-year 2017 income tax expense included the additional taxes due as a result of the \$12.5 million litigation settlement gain. The increases in income tax expense in both the quarter and year ended December 31, 2017 were also a result of the higher pre-tax income generated by the Company's Canadian subsidiary during both periods.

The Company's cash and investment balance totaled \$176.6 million at December 31, 2017, compared to \$120.9 million at December 31, 2016. Working capital was \$189.7 million at December 31, 2017, compared to \$139.1 million at December 31, 2016. For the year ended December 31, 2017, the Company generated \$28.2 million in cash from operations.

First Quarter 2018 Outlook

In January 2018, the Company announced the appointment of Dr. Stephen Tang as the Company's new President and CEO, effective April 1, 2018. Dr. Tang will replace Douglas A. Michels, the Company's current President and CEO, who will be retiring on March 31, 2018. The Company has also recently announced that Ronald H. Spair, the Company's Chief Financial Officer and Chief Operating Officer, will be retiring on or before June 30, 2018.

Charges associated with these transitions are expected to total \$6.8 million in the first quarter of 2018. These charges primarily reflect non-cash charges associated with modifications to existing stock grants held by the retiring executives and expenses associated with the onboarding of the Company's new President and CEO.

The Company expects consolidated net revenues to range from \$40.0 million to \$41.0 million and is projecting a consolidated net loss of approximately \$0.06 per share for the first quarter of 2018. The projected net loss includes the transition costs noted above.

Financial Data

Unaudited

	Three months ended December 31,		Year ended December 31,	
	2017	2016	2017	2016
Results of Operations				
Net revenues	\$ 52,028	\$ 35,499	\$ 167,064	\$ 128,198
Cost of products sold	23,503	11,545	68,108	40,171
Gross profit	28,525	23,954	98,956	88,027
Operating expenses:				
Research and development	3,829	1,207	13,365	9,754
Sales and marketing	6,991	7,121	28,532	29,652
General and administrative	7,544	8,553	29,321	28,356
Gain on litigation settlement	-	-	(12,500)	-
Total operating expenses	18,364	16,881	58,718	67,762
Operating income	10,161	7,073	40,238	20,265
Other income	118	92	794	58
Income before income taxes	10,279	7,165	41,032	20,323
Income tax expense (benefit)	2,963	(31)	10,084	603
Net income	\$ 7,316	\$ 7,196	\$ 30,948	\$ 19,720
Earnings per share:				

Basic	\$ 0.12	\$ 0.13	\$ 0.52	\$ 0.35
Diluted	\$ 0.12	\$ 0.13	\$ 0.51	\$ 0.35
Weighted average shares:				
Basic	60,652	55,811	59,050	55,615
Diluted	62,371	57,232	61,024	56,513

Summary of Net Revenues by Market and Product (Unaudited)

Market	Three Months Ended December 31,			Percentage of Total Net Revenues			
	Dollars						
	2017	2016	% Change	2017	2016		
Infectious disease testing	\$ 14,129	\$ 13,679	3 %	27 %	39 %		
Risk assessment testing	3,141	3,322	(5)	6	9		
Cryosurgical systems	3,163	3,071	3	6	9		
Molecular collection systems	29,784	8,565	248	58	24		
Net product revenues	50,217	28,637	75	97	81		
Other	1,811	6,862	(74)	3	19		
Net revenues	\$ 52,028	\$ 35,499	47 %	100 %	100 %		

Market	Year Ended December 31,			Percentage of Total Net Revenues			
	Dollars						
	2017	2016	% Change	2017	2016		
Infectious disease testing	\$ 61,951	\$ 48,408	28 %	37 %	38 %		
Risk assessment testing	12,659	13,068	(3)	8	10		
Cryosurgical systems	12,279	13,234	(7)	7	10		
Molecular collection systems	75,099	32,214	133	45	25		
Net product revenues	161,988	106,924	51	97	83		
Other	5,076	21,274	(76)	3	17		
Net revenues	\$ 167,064	\$ 128,198	30 %	100 %	100 %		

HIV Revenues	Three Months Ended December 31,			Year Ended December 31,		
	2017	2016	% Change	2017	2016	% Change
Domestic	\$ 4,614	\$ 5,054	(9) %	\$ 17,015	\$ 21,499	(21) %
International	3,563	1,314	171	11,301	5,248	115
Domestic OTC	1,880	1,747	8	6,832	6,320	8
Net product revenues	\$ 10,057	\$ 8,115	24 %	\$ 35,148	\$ 33,067	6 %

HCV Revenues	Three Months Ended December 31,			Year End December 31,		
	2017	2016	% Change	2017	2016	% Change
Domestic	\$ 2,468	\$ 2,218	11 %	\$ 8,448	\$ 7,436	14 %

International	1,144	2,908	(61)	16,961	6,630	156
Net product revenues	3,612	5,126	(30)	25,409	14,066	81
Amortization of exclusivity payments	-	6,114	(100)	-	18,951	(100)
Net HCV-related revenues	\$ 3,612	\$ 11,240	(68) %	\$ 25,409	\$ 33,017	(23) %

Cryosurgical Systems Revenues	Three Months Ended December 31,			Year Ended December 31,		
	2017	2016	% Change	2017	2016	% Change
Domestic professional	\$ 1,032	\$ 1,389	(26) %	\$ 5,400	\$ 5,545	(3) %
International professional	245	165	48	797	771	3
Domestic OTC	273	288	(5)	1,230	1,350	(9)
International OTC	1,613	1,229	31	4,852	5,568	(13)
Net product revenues	\$ 3,163	\$ 3,071	3 %	\$ 12,279	\$ 13,234	(7) %

Molecular Collection Systems Revenues	Three Months Ended December 31,			Year Ended December 31,		
	2017	2016	% Change	2017	2016	% Change
Commercial Genomics	\$ 26,978	\$ 5,760	368 %	\$ 61,594	\$ 20,767	197 %
Academic Genomics	1,701	2,411	(29)	10,017	10,312	(3)
Microbiome	1,105	394	180	3,488	1,135	207
Net product revenues	\$ 29,784	\$ 8,565	248 %	\$ 75,099	\$ 32,214	133 %

Condensed Consolidated Balance Sheets (Unaudited)

	December 31, 2017	December 31, 2016
Assets		
Cash and cash equivalents	\$ 72,869	\$ 109,790
Short-term investments	83,028	11,160
Accounts receivable, net	42,521	19,827
Inventories	19,343	11,799
Other current assets	4,144	3,865
Property and equipment, net	21,372	20,033
Intangible assets, net	8,223	10,337
Goodwill	20,083	18,793
Long-term investments	20,690	-
Other non-current assets	3,928	2,331
Total assets	\$ 296,201	\$ 207,935
Liabilities and Stockholders' Equity		
Accounts payable	\$ 10,228	\$ 4,633
Deferred revenue	1,314	1,388
Other current liabilities	20,695	11,314
Other non-current liabilities	3,932	2,304
Deferred income taxes	1,951	2,446
Stockholders' equity	258,081	185,850
Total liabilities and stockholders' equity	\$ 296,201	\$ 207,935

Additional Financial Data (Unaudited)	Year Ended December 31,	
	2017	2016
Capital expenditures	\$ 4,337	\$ 4,353

Depreciation and amortization	\$ 6,402	\$ 5,640
Stock-based compensation	\$ 6,973	\$ 6,063
Cash provided by operating activities	\$ 28,156	\$ 24,598

Conference Call

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's 2017 fourth quarter and full-year financial results, certain business developments and financial guidance for the first quarter of 2018, beginning today at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). On the call will be Douglas A. Michels, President and Chief Executive Officer, and Ronald H. Spair, Chief Financial Officer and Chief Operating 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 #5872026 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 14, 2018, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #5872026.

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: 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 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 testing, collection or other products; 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, 2016, 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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OraSure Technologies, Inc.