



## OraSure Announces 2016 Third Quarter Financial Results

November 2, 2016

BETHLEHEM, Pa., Nov. 02, 2016 (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 three and nine months ended September 30, 2016.

### Financial Highlights

- Consolidated net revenues for the third quarter of 2016 were \$32.3 million, an 8% increase from the third quarter of 2015. Consolidated net revenues for the nine months ended September 30, 2016 were \$92.7 million, a 6% increase from the comparable period of 2015.
- Net revenues from international sales of the Company's OraQuick<sup>®</sup> HIV test were \$1.1 million for the third quarter of 2016, representing a 147% increase over the third quarter of 2015. Net international revenues for the OraQuick<sup>®</sup> HIV test were \$3.9 million for the nine months ended September 30, 2016, a 97% increase from the comparable period of 2015.
- Net molecular collection systems revenues were \$8.3 million during the third quarter of 2016, which represents a 14% increase over the third quarter of 2015. Net molecular collection systems revenues for the nine months ended September 30, 2016 were \$23.6 million, a 7% increase from the comparable period in 2015.
- International sales of the Company's OraQuick<sup>®</sup> rapid HCV test were \$1.3 million for the third quarter of 2016, representing a 35% increase from the third quarter of 2015. International sales of the HCV test for the nine months ended September 30, 2016 were \$3.7 million, an increase of 44% from the comparable period of 2015.
- During the third quarter, the Company was awarded a contract for up to \$16.6 million in total funding from the U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response's Biomedical Advanced Research and Development Authority ("BARDA") related to the development of a rapid Zika test.
- The Company secured a contract with a foreign government to supply \$18 million in diagnostic products, largely consisting of OraQuick<sup>®</sup> rapid HCV tests. The first shipment of this product is expected to occur in the fourth quarter of 2016 pending completion of certain ancillary documents required under the contract.
- Consolidated net income for the third quarter of 2016 was \$6.2 million, or \$0.11 per share on a fully-diluted basis, which compares to consolidated net income of \$1.5 million, or \$0.03 per share on a fully-diluted basis, for the third quarter of 2015. Consolidated net income for the nine months ended September 30, 2016 was \$12.5 million, or \$0.22 per share on a fully-diluted basis, which compares to consolidated net income of \$3.6 million, or \$0.06 per share, for the comparable period of 2015.
- Cash and short-term investments totaled \$121.2 million and working capital amounted to \$128.8 million at September 30, 2016.

"We are very pleased with the Company's financial performance for the third quarter, especially our strong bottom line results," said Douglas A. Michels, President and CEO of OraSure Technologies. "We continue to build on numerous international opportunities and have executed an \$18 million product supply agreement with a foreign government in support of a country-wide HCV elimination program. Our molecular business continues to generate impressive growth and we were successful in obtaining government funding for continued work on our rapid Zika test. We believe the progress we have made on these key objectives has positioned us well for future success."

### Financial Results

Consolidated net product revenues for the third quarter of 2016 decreased 1% from the comparable period of 2015 primarily as a result of the absence of sales of the Company's OraQuick<sup>®</sup> Ebola rapid antigen test, lower domestic sales of the Company's OraQuick<sup>®</sup> HIV and HCV products, and lower sales of the Company's cryosurgical systems and risk assessment products. These lower sales were partially offset by higher sales of the Company's molecular collection systems products and increased international OraQuick<sup>®</sup> HIV and HCV product sales.

Consolidated net product revenues for the first nine months of 2016 increased 3% over the comparable periods of 2015, primarily as a result of higher international sales of the Company's OraQuick<sup>®</sup> HCV and HIV products, and higher sales of the Company's molecular collection systems and cryosurgical systems products. These increases were partially offset by lower domestic sales of the Company's OraQuick<sup>®</sup> HIV products, lower sales of the Company's risk assessment products, and the absence of sales of the Company's OraQuick<sup>®</sup> Ebola Rapid Antigen test in the current

nine-month period.

Consolidated other revenues for the third quarter and first nine months of 2016 were \$6.8 million and \$14.4 million, respectively. This compares to consolidated other revenues for the third quarter and first nine months of 2015 of \$4.1 million and \$11.5 million, respectively. Exclusivity revenues recognized under the Company's HCV co-promotion agreement with AbbVie for the three and nine month periods ended September 30, 2016 were \$6.1 million and \$12.8 million, respectively. AbbVie exclusivity revenues for the three and nine month periods ended September 30, 2015 were \$3.4 million and \$10.0 million, respectively. Other revenues in the third quarter and first nine months of 2016 also included \$677,000 and \$1.6 million, respectively, of funding received from BARDA. Other revenues for the third quarter and first nine months of 2015 included \$750,000 and \$1.5 million, respectively, in BARDA funding.

Consolidated gross margin for the three and nine months ended September 30, 2016 was 70% and 69%, respectively. Consolidated gross margin for the three and nine months ended September 30, 2015 was 69% and 67%, respectively. Gross margin for the current quarter increased primarily due to higher other revenues partially offset by a less favorable product mix. Gross margin for the nine-month period increased largely due to lower scrap and spoilage costs and the increase in other revenues, partially offset by an unfavorable product mix.

Consolidated operating expenses decreased to \$16.5 million during the third quarter of 2016 compared to \$19.1 million in the third quarter of 2015. For the nine months ended September 30, 2016, consolidated operating expenses were \$50.9 million, a decrease from the \$54.4 million reported for the nine months ended September 30, 2015. The quarterly decrease was largely due to lower costs associated with the AbbVie HCV co-promotion agreement partially offset by increased research and development expenses. The decrease in the nine-month period was largely due to lower costs associated with the AbbVie co-promotion agreement and lower research and development expenses, partially offset by increased general and administrative expenses.

The Company's cash and short-term investment balance totaled \$121.2 million at September 30, 2016 compared to \$101.3 million at December 31, 2015. Working capital was \$128.8 million at September 30, 2016 compared to \$111.5 million at December 31, 2015. For the nine months ended September 30, 2016, the Company generated \$23.4 million in cash from operations.

#### Fourth Quarter 2016 Outlook

The Company expects consolidated net revenues to range from \$34.50 to \$35.25 million and is projecting consolidated net income of \$0.05 to \$0.06 per share for the fourth quarter of 2016. This revenue guidance includes initial contributions from the new \$18 million foreign government HCV product supply contract. However, OraSure will not commence shipment of product until certain additional ancillary documents required under the contract are completed. In addition, projected fourth quarter 2016 expenses will include \$1.4 million in restructuring charges, consisting largely of work-force reduction costs which include severance and benefit expenses. Annual cost savings resulting from this restructuring as well as the termination of the Company's HCV co-promotion agreement with AbbVie at year end are expected to be \$3.6 million, beginning in 2017.

#### Financial Data

##### Condensed Consolidated Financial Data

(In thousands, except per-share data)

##### Unaudited

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
<b>Results of Operations</b>				
Net revenues	\$ 32,251	\$ 29,861	\$ 92,699	\$ 87,337
Cost of products sold	9,576	9,192	28,626	28,974
Gross profit	22,675	20,669	64,073	58,363
Operating expenses:				
Research and development	3,196	2,525	8,547	8,961
Sales and marketing	6,428	9,677	22,531	26,465
General and administrative	6,907	6,931	19,803	18,971
Total operating expenses	16,531	19,133	50,881	54,397
Operating income	6,144	1,536	13,192	3,966
Other income (expense)	498	81	(34 )	395
Income before income taxes	6,642	1,617	13,158	4,361
Income tax expense	400	147	634	810
Net income	\$ 6,242	\$ 1,470	\$ 12,524	\$ 3,551
Earnings per share:				
Basic	\$ 0.11	\$ 0.03	\$ 0.23	\$ 0.06
Diluted	\$ 0.11	\$ 0.03	\$ 0.22	\$ 0.06
Weighted average shares:				
Basic	55,653	56,482	55,549	56,427

Diluted	56,524	56,692	56,271	56,900
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**Summary of Net Revenues by Market and Product (Unaudited)**

<b>Market</b>	<b>Three Months Ended September 30,</b>			<b>Percentage of Total Net Revenues</b>			
	<b>Dollars</b>						
	<b>2016</b>	<b>2015</b>	<b>% Change</b>	<b>2016</b>		<b>2015</b>	
Infectious disease testing	\$ 10,412	\$ 11,297	(8 ) %	32	%	38	%
Risk assessment testing	3,481	3,630	(4 )	11		12	
Cryosurgical systems	3,240	3,458	(6 )	10		11	
Molecular collection systems	8,327	7,329	14	26		25	
Net product revenues	25,460	25,714	(1 )	79		86	
Other	6,791	4,147	64	21		14	
Net revenues	\$ 32,251	\$ 29,861	8 %	100	%	100	%

<b>Market</b>	<b>Nine Months Ended September 30,</b>			<b>Percentage of Total Net Revenues</b>			
	<b>Dollars</b>						
	<b>2016</b>	<b>2015</b>	<b>% Change</b>	<b>2016</b>		<b>2015</b>	
Infectious disease testing	\$ 34,729	\$ 34,585	0 %	37	%	40	%
Risk assessment testing	9,746	10,103	(4 )	10		12	
Cryosurgical systems	10,162	8,956	13	11		10	
Molecular collection systems	23,649	22,148	7	26		25	
Net product revenues	78,286	75,792	3	84		87	
Other	14,413	11,545	25	16		13	
Net revenues	\$ 92,699	\$ 87,337	6 %	100	%	100	%

<b>HIV Revenues</b>	<b>Three Months Ended</b>			<b>Nine Months Ended</b>		
	<b>September 30,</b>			<b>September 30,</b>		
	<b>2016</b>	<b>2015</b>	<b>% Change</b>	<b>2016</b>	<b>2015</b>	<b>% Change</b>
Domestic	\$ 4,858	\$ 5,548	(12 ) %	\$ 16,446	\$ 18,147	(9 ) %
International	1,110	450	147	3,934	1,995	97
Domestic OTC	1,311	1,642	(20 )	4,574	4,923	(7 )
Net product revenues	\$ 7,279	\$ 7,640	(5 ) %	\$ 24,954	\$ 25,065	0 %

<b>HCV Revenues</b>	<b>Three Months Ended</b>			<b>Nine Months Ended</b>		
	<b>September 30,</b>			<b>September 30,</b>		
	<b>2016</b>	<b>2015</b>	<b>% Change</b>	<b>2016</b>	<b>2015</b>	<b>% Change</b>
Domestic	\$ 1,529	\$ 1,914	(20 ) %	\$ 5,218	\$ 4,803	9 %
International	1,293	957	35	3,722	2,577	44
Net product revenues	2,822	2,871	(2 )	8,940	7,380	21
Amortization of exclusivity payments	6,114	3,397	80	12,837	10,081	27
Net HCV-related revenues	\$ 8,936	\$ 6,268	43 %	\$ 21,777	\$ 17,461	25 %

<b><u>Cryosurgical Systems Revenues</u></b>	<b>Three Months Ended September 30,</b>			<b>Nine Months Ended September 30,</b>		
	<b>2016</b>	<b>2015</b>	<b>% Change</b>	<b>2016</b>	<b>2015</b>	<b>% Change</b>
Domestic professional	\$ 1,456	\$ 1,600	(9 ) %	\$ 4,155	\$ 3,268	27 %
International professional	162	258	(37 )	607	757	(20 )
Domestic OTC	339	137	147	1,062	300	254
International OTC	1,283	1,463	(12 )	4,338	4,631	(6 )
Net cryosurgical systems revenues	\$ 3,240	\$ 3,458	(6 ) %	\$ 10,162	\$ 8,956	13 %

#### **Condensed Consolidated Balance Sheets (Unaudited)**

**September 30, 2016    December 31, 2015**

##### **Assets**

Cash and cash equivalents	\$ 113,536	\$ 94,094
Short-term investments	7,618	7,225
Accounts receivable, net	15,471	19,265
Inventories	12,070	13,242
Other current assets	2,024	2,888
Property and equipment, net	20,069	20,083
Intangible assets, net	11,205	12,591
Goodwill	19,243	18,250
Other non-current assets	2,322	1,683
Total assets	\$ 203,558	\$ 189,321

##### **Liabilities and Stockholders' Equity**

Accounts payable	\$ 4,422	\$ 5,087
Deferred revenue	7,911	9,735
Other current liabilities	9,618	10,412
Other non-current liabilities	2,289	1,768
Deferred income taxes	2,836	2,883
Stockholders' equity	176,482	159,436
Total liabilities and stockholders' equity	\$ 203,558	\$ 189,321

#### **Nine months ended**

**September 30,**

#### **Additional Financial Data (Unaudited)    2016    2015**

Capital expenditures	\$ 3,512	\$ 1,885
Depreciation and amortization	\$ 4,212	\$ 4,259
Stock-based compensation	\$ 4,437	\$ 4,543
Cash provided by operating activities	\$ 23,370	\$ 15,105

#### **Conference Call**

The Company will host a conference call and audio webcast to discuss the Company's 2016 third quarter financial results, certain business developments and financial guidance for the fourth quarter of 2016, 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 #85854320 or go to OraSure Technologies' web site, [www.orasure.com](http://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 November 9, 2016, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #85854320.

## **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 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; 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 DNA Genotek to achieve its financial and strategic objectives and continue to increase its revenues; 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, high unemployment levels and poor credit 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 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; history of losses and ability to achieve sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of OraSure'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 are discussed more fully in the Company's Securities and Exchange Commission filings, including its registration statements, Annual Report on Form 10-K for the year ended December 31, 2015, 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**