



OraSure Announces 2016 Second Quarter Financial Results

August 3, 2016

BETHLEHEM, Pa., Aug. 03, 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 six months ended June 30, 2016.

Financial Highlights

- Consolidated net revenues for the second quarter of 2016 were \$31.4 million, a 3% increase from the second quarter of 2015. Consolidated net revenues for the six months ended June 30, 2016 were \$60.4 million, a 5% increase from the comparable period of 2015.
- Net revenues from sales of the Company's OraQuick[®] rapid HCV test were \$3.2 million for the second quarter of 2016, representing a 37% increase over the second quarter of 2015. Net revenues for the OraQuick[®] rapid HCV test were \$6.1 million for the six months ended June 30, 2016, a 36% increase from the comparable period of 2015.
- Net revenues from international sales of the Company's OraQuick[®] HIV test were \$2.0 million for the second quarter of 2016, representing a 230% increase over the second quarter of 2015. Net international revenues for the OraQuick[®] HIV test were \$2.8 million for the six months ended June 30, 2016, an 83% increase from the comparable period of 2015.
- The Company's molecular collection systems subsidiary, DNA Genotek ("DNAG"), contributed \$8.4 million in net revenues during the second quarter of 2016, which represents a 4% increase over the second quarter of 2015. DNAG net revenues during the six months ended June 30, 2016 were \$15.3 million, a 3% increase from the comparable period in 2015.
- Consolidated net income for the second quarter of 2016 was \$3.8 million, or \$0.07 per share on a fully-diluted basis, which compares to consolidated net income of \$2.0 million, or \$0.03 per share on a fully-diluted basis, for the second quarter of 2015. Consolidated net income for the six months ended June 30, 2016 was \$6.3 million, or \$0.11 per share on a fully-diluted basis, which compares to consolidated net income of \$2.1 million, or \$0.04 per share, for the comparable period of 2015.
- Cash and short-term investments totaled \$113.4 million and working capital amounted to \$120.3 million at June 30, 2016.

"We are pleased with the Company's financial performance for the second quarter of 2016, which exceeded expectations on both the top and bottom lines," said Douglas A. Michels, President and CEO of OraSure Technologies. "Continued growth in sales of our infectious disease and molecular collection systems products were the main drivers behind this performance. We expect long-term growth from both of these businesses and see the international marketplace as an emerging and increasingly important strategic priority for our Company."

Financial Results

Consolidated net product revenues for both the second quarter and first six months of 2016 increased 5% over the comparable periods of 2015, primarily as a result of higher sales of the Company's OraQuick[®] HCV, OraQuick[®] HIV, and molecular collection systems products. These increases were partially offset by lower sales of the Company's risk assessment products and the absence of sales of the Company's OraQuick[®] Ebola Rapid Antigen test. The increase for the six month period also included higher sales of the Company's cryosurgical systems products.

Consolidated other revenues for the second quarter and first six months of 2016 were \$3.8 million and \$7.6 million, respectively. This compares to consolidated other revenues for the second quarter and first six months of 2015 of \$4.1 million and \$7.4 million, respectively. Exclusivity revenue recognized under the Company's HCV co-promotion agreement with AbbVie for the second quarter and first six months of 2016 and 2015 was \$3.4 million and \$6.7 million, respectively. Other revenue in the second quarter of 2016 and 2015 included \$417,000 and \$714,000, respectively, of Ebola-related funding received 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"). Other revenue for the first six months of 2016 and 2015 included \$899,000 and \$714,000, respectively, in BARDA funding.

Consolidated gross margin for the three and six months ended June 30, 2016 was 67% and 68%, respectively. Consolidated gross margin for the three and six months ended June 30, 2015 was 68% and 66%, respectively. Gross margin for the current quarter decreased primarily due to an unfavorable product mix partially offset by lower scrap and spoilage costs. Gross margin for the six-month period increased largely due to lower scrap and spoilage costs, a more favorable product mix, decreased royalty expense, and an increase in Ebola-related funding from BARDA.

Consolidated operating expenses decreased to \$16.7 million during the second quarter of 2016 compared to \$17.9 million in the second quarter of 2015. For the six months ended June 30, 2016, consolidated operating expenses were \$34.4 million, a decrease from the \$35.3 million reported for the six months ended June 30, 2015. The quarterly decrease was largely due to lower costs associated with the AbbVie HCV co-promotion agreement

partially offset by higher legal costs. The decrease in the six-month period was largely due to lower research and development expenses and lower costs associated with the AbbVie co-promotion agreement, partially offset by increased legal and consulting costs.

The Company's cash and short-term investment balance totaled \$113.4 million at June 30, 2016 compared to \$101.3 million at December 31, 2015. Working capital was \$120.3 million at June 30, 2016 compared to \$111.5 million at December 31, 2015. For the six months ended June 31, 2016, the Company generated \$16.7 million in cash from operations.

Third Quarter 2016 Outlook

The Company expects consolidated net revenues to range from \$31.25 to \$31.75 million and is projecting consolidated net income of between \$0.07 and \$0.08 per share for the third quarter of 2016.

Financial Data

Condensed Consolidated Financial Data

(In thousands, except per-share data)

Unaudited

	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
Results of Operations				
Net revenues	\$ 31,359	\$ 30,388	\$ 60,448	\$ 57,476
Cost of products sold	10,274	9,692	19,050	19,782
Gross profit	21,085	20,696	41,398	37,694
Operating expenses:				
Research and development	2,985	2,996	5,351	6,436
Sales and marketing	7,397	8,904	16,103	16,788
General and administrative	6,354	6,075	12,896	12,040
Total operating expenses	16,736	17,975	34,350	35,264
Operating income	4,349	2,721	7,048	2,430
Other income (expense)	(340)	(95)	(532)	314
Income before income taxes	4,009	2,626	6,516	2,744
Income tax expense	173	658	234	663
Net income	\$ 3,836	\$ 1,968	\$ 6,282	\$ 2,081
Earnings per share:				
Basic	\$ 0.07	\$ 0.03	\$ 0.11	\$ 0.04
Diluted	\$ 0.07	\$ 0.03	\$ 0.11	\$ 0.04
Weighted average shares:				
Basic	55,543	56,453	55,497	56,398
Diluted	56,208	56,687	56,144	56,678

Summary of Net Revenues by Market and Product (Unaudited)

	Three Months Ended June 30,			Percentage of Total Net Revenues	
	Dollars				
Market	2016	2015	% Change	2016	2015
Infectious disease testing	\$ 12,949	\$ 11,792	10 %	41 %	39 %
Risk assessment testing	3,159	3,466	(9)	10	11
Cryosurgical systems	3,041	2,953	3	10	10
Molecular collection systems	8,433	8,102	4	27	27
Net product revenues	27,582	26,313	5	88	87
Other	3,777	4,075	(7)	12	13

Net revenues	\$ 31,359	\$ 30,388	3	%	100 %	100 %
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Six Months Ended June 30,

Market	Dollars			Percentage of Total Net Revenues		
	2016	2015	% Change	2016	2015	
Infectious disease testing	\$ 24,317	\$ 23,288	4 %	40 %	40 %	
Risk assessment testing	6,265	6,473	(3)	10	11	
Cryosurgical systems	6,922	5,498	26	12	10	
Molecular collection systems	15,323	14,819	3	25	26	
Net product revenues	52,827	50,078	5	87	87	
Other	7,621	7,398	3	13	13	
Net revenues	\$ 60,448	\$ 57,476	5 %	100 %	100 %	

<u>HIV Revenues</u>	Three Months Ended June 30,			Six Months Ended June 30,		
	2016	2015	% Change	2016	2015	% Change
Domestic	\$ 5,886	\$ 6,593	(11) %	\$ 11,588	\$ 12,601	(8) %
International	1,969	596	230	2,824	1,544	83
Domestic OTC	1,739	1,719	1	3,262	3,280	(1)
Net product revenues	\$ 9,594	\$ 8,908	8 %	\$ 17,674	\$ 17,425	1 %

<u>HCV Revenues</u>	Three Months Ended June 30,			Six Months Ended June 30,		
	2016	2015	% Change	2016	2015	% Change
Domestic	\$ 1,788	\$ 1,693	6 %	\$ 3,689	\$ 2,889	28 %
International	1,428	646	121	2,430	1,619	50
Net product revenues	3,216	2,339	37	6,119	4,508	36
Amortization of exclusivity payments	3,360	3,361	0	6,722	6,684	1
Net HCV-related revenues	\$ 6,576	\$ 5,700	15 %	\$ 12,841	\$ 11,192	15 %

<u>Cryosurgical Systems Revenues</u>	Three Months Ended June 30,			Six Months Ended June 30,		
	2016	2015	% Change	2016	2015	% Change
Domestic professional	\$ 1,145	\$ 1,008	14 %	\$ 2,699	\$ 1,668	62 %
International professional	211	142	49	446	498	(10)
Domestic OTC	345	108	219	723	163	344
International OTC	1,340	1,695	(21)	3,054	3,169	(4)
Net cryosurgical systems revenues	\$ 3,041	\$ 2,953	3 %	\$ 6,922	\$ 5,498	26 %

Condensed Consolidated Balance Sheets (Unaudited)**June 30, 2016 December 31, 2015****Assets**

Cash	\$ 105,701	\$ 94,094
Short-term investments	7,736	7,225
Accounts receivable, net	18,436	19,265
Inventories	11,366	13,242
Other current assets	3,136	2,888
Property and equipment, net	20,200	20,083
Intangible assets, net	12,020	12,591
Goodwill	19,541	18,250
Other non-current assets	1,784	1,683
Total assets	\$ 199,920	\$ 189,321

Liabilities and Stockholders' Equity

Accounts payable	\$ 3,956	\$ 5,087
Deferred revenue	13,822	9,735
Other current liabilities	8,293	10,412
Other non-current liabilities	2,018	1,768
Deferred income taxes	3,043	2,883
Stockholders' equity	168,788	159,436
Total liabilities and stockholders' equity	\$ 199,920	\$ 189,321

Six months ended**June 30,****Additional Financial Data (Unaudited)****2016 2015**

Capital expenditures	\$ 2,729	\$ 1,145
Depreciation and amortization	\$ 2,778	\$ 2,849
Stock-based compensation	\$ 2,942	\$ 3,008
Cash provided by (used in) operating activities	\$ 16,741	\$ (3,421)

Conference Call

The Company will host a conference call and audio webcast to discuss the Company's 2016 second quarter financial results, certain business developments and financial guidance for the third 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 #46406766 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 August 10, 2016, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #46406766.

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 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 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 CDC or other testing guidelines, algorithms or other recommendations; 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 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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