



OraSure Announces 2013 Third Quarter Financial Results

November 6, 2013

Quarterly Revenues Reach Record High

BETHLEHEM, Pa., Nov. 6, 2013 (GLOBE NEWSWIRE) -- OraSure Technologies, Inc. (Nasdaq:OSUR), a market leader in oral fluid diagnostics, today announced its consolidated financial results for the third quarter and nine months ended September 30, 2013.

Financial Highlights

- Consolidated net revenues for the third quarter of 2013 were \$24.7 million, a 12% increase from the comparable quarter of 2012. Consolidated net revenues for the nine months ended September 30, 2013 were \$70.2 million, a 7% increase from the comparable period of 2012. During the current quarter and nine month period, net product revenues increased 13% and 9%, respectively, compared to the year ago periods. These increases were primarily due to sales of the Company's OraQuick® In-Home HIV test and record revenues from the Company's molecular collection systems subsidiary, DNA Genotek ("DNAG").
- Net revenues for the third quarter and first nine months of 2013 included \$1.9 million and \$5.6 million in gross sales of the OraQuick® In-Home HIV test, respectively. These gross sales were reduced by customer allowances for cooperative advertising, cash discounts and other allowances, resulting in net revenues of \$1.8 million and \$5.2 million recorded in each respective period. There were no sales recorded for this product in the comparable 2012 periods.
- Net revenues generated by DNAG during the third quarter of 2013 were \$5.0 million, a 48% increase from the comparable period in 2012. DNAG net revenues during the nine months ended September 30, 2013 were \$13.6 million, a 36% increase from the comparable period in 2012. The increase in both periods was primarily the result of higher sales to commercial customers.
- Consolidated net loss for the third quarter of 2013 was \$1.9 million, or \$0.03 per share, which compares to a net loss of \$2.4 million, or \$0.04 per share, for the third quarter of 2012. Consolidated net loss for the nine months ended September 30, 2013 was \$17.4 million, or \$0.31 per share, which compares to a net loss of \$9.2 million, or \$0.18 per share, for the comparable period of 2012. The net loss for the third quarter and first nine months of 2013 included \$1.9 million and \$14.2 million in advertising and promotional expenses, respectively, associated with the Company's OraQuick® In-Home HIV test.

"We are pleased with the Company's record revenue performance for the third quarter," said Douglas A. Michels, President and CEO of OraSure Technologies. "Our molecular collection systems business continues to deliver strong growth and we are encouraged by the higher sales of our OraQuick® HCV test. We have also launched a new targeted promotional campaign for the OraQuick® In-Home HIV test in an effort to accelerate growth of that important product line."

Financial Results

Consolidated net product revenues for the third quarter and nine month periods of 2013 increased 13% and 9%, respectively, primarily as a result of higher sales of the Company's infectious disease testing and molecular collection systems products. These increases were partially offset by lower sales of the Company's substance abuse testing, cryosurgical systems and insurance risk assessment products.

Consolidated licensing and product development revenues for the third quarter of 2013 decreased to \$147,000 from \$386,000 for the third quarter of 2012 as a result of the expiration of certain patents licensed to a third party. Consolidated licensing and product development revenues for the nine months ended September 30, 2013 decreased to \$623,000 from \$1.9 million in the comparable period of the prior year, primarily due to the absence of a \$1.0 million milestone payment received in the first quarter of 2012 under the Company's HCV collaboration agreement with Merck. No similar payment was received during 2013 because the collaboration agreement with Merck was terminated in November 2012.

Consolidated gross margin for the three and nine months ended September 30, 2013 was 61% and 59%, respectively. Consolidated gross margin for the three and nine months ended September 30, 2012 was 63% and 64%, respectively. The current quarter gross margin was negatively impacted by higher royalties paid on sales of the Company's OraQuick® HIV products and an unfavorable change in product mix partially offset by an improvement in overhead absorption and a decline in scrap and spoilage costs. Gross margin for the current nine month period was negatively impacted by the higher royalties, the change in product mix and the absence of the \$1.0 million HCV milestone payment, partially offset by the improvement in overhead absorption.

Consolidated operating expenses remained relatively flat at \$17.0 million during the third quarter of 2013 compared to \$16.8 million in the comparable period of 2012. For the nine months ended September 30, 2013, consolidated operating expenses were \$59.7 million, an increase over the \$52.4 million reported for the nine months ended September 30, 2012. The increase for the first nine months of 2013 was primarily the result of higher promotional and advertising expenses associated with the Company's OraQuick® In-Home HIV test. The current quarter and nine month period expenses included \$1.9 million and \$14.2 million of promotional and advertising costs related to this product, compared to \$1.8 million and \$4.7 million

spent in the third quarter and first nine months of 2012, respectively.

For the three and nine months ended September 30, 2013, the Company recorded a Canadian income tax benefit of \$127,000 and \$786,000, respectively, associated with the loss before income taxes and certain Canadian research and development and investment tax credits at DNAG.

The Company's cash balance totaled \$82.6 million at September 30, 2013 compared to \$87.9 million at December 31, 2012. Working capital was \$92.1 million at September 30, 2013 compared to \$103.5 million at December 31, 2012. For the nine months ended September 30, 2013, the Company used \$3.1 million to fund operations, including the advertising and promotional activities related to the OraQuick® In-Home HIV test. Cash generated by operations in the third quarter of 2013 was \$6.1 million.

Fourth Quarter 2013 Outlook

The Company expects consolidated net revenues to range from \$27.5 to \$28.0 million and is projecting a consolidated net loss of approximately \$0.07 - \$0.08 per share for the fourth quarter of 2013.

Financial Data

Condensed Consolidated Financial Data

(In thousands, except per-share data)

Unaudited

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2013	2012	2013	2012
Results of Operations				
Net revenues	\$ 24,671	\$ 22,115	\$ 70,172	\$ 65,675
Cost of products sold	9,738	8,227	28,711	23,356
Gross profit	14,933	13,888	41,461	42,319
Operating expenses:				
Research and development	2,670	2,994	8,720	9,551
Sales and marketing	8,981	8,602	35,224	25,490
General and administrative	5,342	5,220	15,742	17,398
Total operating expenses	16,993	16,816	59,686	52,439
Operating loss	(2,060)	(2,928)	(18,225)	(10,120)
Other income (expense)	41	(34)	36	(267)
Loss before income taxes	(2,019)	(2,962)	(18,189)	(10,387)
Income tax benefit	(127)	(527)	(786)	(1,138)
Net loss	\$ (1,892)	\$ (2,435)	\$ (17,403)	\$ (9,249)
Loss per share:				
Basic and Diluted	\$ (0.03)	\$ (0.04)	\$ (0.31)	\$ (0.18)
Weighted average shares:				
Basic and Diluted	55,592	54,441	55,534	50,177

Summary of Revenues by Market and Product (Unaudited)

	Three Months Ended September 30,			Percentage of	
	Dollars			Total Net	
Market	2013	2012	% Change	2013	2012
Infectious disease testing	\$ 12,873	\$ 10,718	20%	52	48%

Substance abuse testing	2,092	2,331	(10)	8	11
Cryosurgical systems	3,649	4,199	(13)	15	19
Molecular collection systems	4,964	3,353	48	20	15
Insurance risk assessment	946	1,128	(16)	4	5
Net product revenues	24,524	21,729	13	99	98
Licensing and product development	147	386	(62)	1	2
Net revenues	\$ 24,671	\$ 22,115	12%	100%	100%

Nine Months Ended September 30,

Market	Dollars			Percentage of Total Net Revenues	
	2013	2012	% Change	2013	2012
Infectious disease testing	\$ 35,526	\$ 30,880	15%	51%	47%
Substance abuse testing	6,455	7,305	(12)	9	11
Cryosurgical systems	10,910	12,181	(10)	16	19
Molecular collection systems	13,550	9,992	36	19	15
Insurance risk assessment	3,108	3,448	(10)	4	5
Net product revenues	69,549	63,806	9	99	97
Licensing and product development	623	1,869	(67)	1	3
Net revenues	\$ 70,172	\$ 65,675	7%	100%	100%

OraQuick® Revenues	Three Months Ended September 30 ,			Nine Months Ended September 30,		
	2013	2012	% Change	2013	2012	% Change
Domestic HIV	\$ 8,093	\$ 8,527	(5)%	\$23,854	\$ 25,106	(5)%
International HIV	1,157	884	31	2,457	2,287	7
Domestic HIV OTC	1,762	--	N/A	5,196	--	N/A
Domestic HCV	653	678	(4)	1,772	1,958	(9)
International HCV	924	241	283	1,409	734	92
Net OraQuick® revenues	\$ 12,589	\$ 10,330	22%	\$34,688	\$ 30,085	15%

Intercept® Revenues	Three Months Ended September 30,			Nine Months Ended September 30,		
	2013	2012	% Change	2013	2012	% Change
Domestic	\$ 1,495	\$ 1,499	0%	\$ 4,240	\$ 4,981	(15)%
International	29	279	(90)	385	616	(38)
Net Intercept® revenues	\$ 1,524	\$ 1,778	(14)%	\$ 4,625	\$ 5,597	(17)%

Cryosurgical Systems Revenues	Three Months Ended September 30,			Nine Months Ended September 30,		
	2013	2012	% Change	2013	2012	% Change

Professional domestic	\$ 1,803	\$ 2,025	(11)%	\$ 4,192	\$ 5,342	(22)%
Professional international	435	453	(4)	1,039	1,110	(6)
Over-the-Counter	1,411	1,721	(18)	5,679	5,729	(1)
Net cryosurgical systems revenues	\$ 3,649	\$ 4,199	(13)%	\$ 10,910	\$ 12,181	(10)%

Condensed Consolidated Balance Sheets (Unaudited) September 30, 2013 December 31, 2012

Assets

	\$ 82,590	\$ 87,888
Cash		
Accounts receivable, net	14,292	17,545
Inventories	12,000	12,758
Other current assets	2,516	2,212
Property and equipment, net	17,989	18,546
Intangible assets, net	23,701	27,207
Goodwill	24,510	25,445
Other non-current assets	614	124
Total assets	\$ 178,212	\$ 191,725

Liabilities and Stockholders' Equity

Accounts payable	\$ 3,859	\$ 3,380
Deferred revenue	4,472	5,580
Accrued expenses	10,995	7,960
Other non-current liabilities	539	89
Deferred income taxes	3,456	4,401
Stockholders' equity	154,891	170,315
Total liabilities and stockholders' equity	\$ 178,212	\$ 191,725

Nine months ended

September 30,

Additional Financial Data (Unaudited) 2013 2012

Capital expenditures	\$ 1,696	\$ 1,402
Depreciation and amortization	\$ 4,846	\$ 5,455
Stock based compensation	\$ 4,187	\$ 3,845
Cash used in operating activities	\$ 3,142	\$ 4,006

Conference Call

The Company will host a conference call and audio webcast to discuss the Company's 2013 third quarter financial results, business developments and financial guidance for the fourth quarter of 2013, 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, Ronald H. Spair, Chief Financial Officer and Chief Operating Officer, and Kathleen Weber, Senior Vice President and General Manager, Consumer Products. 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 877-348-9357 (Domestic) or 970-315-0488 (International) and reference Conference ID #87563319 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 November 13, 2013, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #87563319.

About OraSure Technologies

OraSure Technologies is a leader in the development, manufacture and distribution of oral fluid diagnostic and collection devices and other technologies designed to detect or diagnose critical medical conditions. Its innovative products include rapid tests for the detection of antibodies to HIV and HCV at the point of care and testing solutions for detecting various drugs of abuse. In July 2012, the Company received approval from the U.S.

Food and Drug Administration to sell its OraQuick® In-Home HIV Test directly to consumers in the over-the-counter (OTC) market – making it the first and only rapid OTC HIV test approved in the U.S. In addition, the Company is a leading provider of oral fluid sample collection, stabilization and preparation products for molecular diagnostic applications. 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, and commercial and industrial entities. The Company's products enable healthcare providers to deliver critical information to patients, empowering them to make decisions to improve and protect their health. 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 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; 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 or minimum purchase requirements for the Company's products; impact of replacing distributors; inventory levels at distributors and other customers; ability to integrate and realize the full benefits of the Company's acquisition of DNA Genotek; 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 and high unemployment; 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, including the OraQuick® In-Home HIV test; market acceptance of oral fluid testing or other products; changes in market acceptance of products based on product performance or other factors; 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 our 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 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, 2012, 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.