

OraSure Announces 2014 First Quarter Financial Results

May 7, 2014

BETHLEHEM, Pa., May 7, 2014 (GLOBE NEWSWIRE) -- OraSure Technologies, Inc. (Nasdaq:OSUR), a market leader in oral fluid diagnostics, today announced its consolidated financial results for the first quarter of 2014.

Financial Highlights

- Consolidated net revenues for the first quarter of 2014 were \$23.5 million, an 11% increase from the comparable quarter of
 2013. Net product revenues increased 12% primarily due to higher revenues from the Company's molecular collection
 systems subsidiary, DNA Genotek ("DNAG"), and higher sales of the Company's OraQuick® HCV test, cryosurgical
 systems products, and OraQuick® In-Home HIV test.
- Net revenues generated by DNAG during the first quarter of 2014 were \$5.8 million, a 46% increase from the comparable period in 2013. This increase was the result of higher sales to both commercial and academic customers.
- Net revenues for the Company's OraQuick® rapid HCV test reached \$1.6 million for the first quarter of 2014, an increase of 133% from the comparable 2013 period. This growth reflects increasing demand for the product in both the domestic and international markets.
- Gross sales of the Company's OraQuick® In-Home HIV test were \$2.2 million for the first quarter of 2014 and \$1.5 million in the first quarter of 2013. These gross sales were reduced by customer allowances for cooperative advertising, cash discounts and other allowances, resulting in net revenues of \$2.0 million and \$1.4 million recorded in each respective period. Revenues for these periods were not recorded using the same revenue recognition policy. In December 2013, the Company changed its policy from recognizing revenue upon consummation of a purchase by the consumer to recognizing revenue upon shipment to the retailer or distributor. Based on available point-of-sale data, unit purchases by consumers increased approximately 22% in the first quarter of 2014 compared to the first quarter of 2013.
- Net cryosurgical systems revenues in the first quarter of 2014 were \$4.0 million, a 29% increase over the first quarter of 2013. This increase was primarily due to higher sales in both the U.S. professional market and the international over-thecounter ("OTC") market.
- Consolidated net loss for the first quarter of 2014 was \$5.6 million, or \$0.10 per share, which compares to a net loss of \$10.2 million, or \$0.18 per share, for the first quarter of 2013. The improvement in net loss for the quarter resulted primarily from the higher revenues and lower sales and marketing expenses.

"Solid revenue growth for the first quarter was in line with our projections and our bottom line performance was better than expected," said Douglas A. Michels, President and CEO of OraSure Technologies. "Our business growth continues to be driven primarily by the strong performance of our molecular collection systems business and by contributions from our OraQuick® HCV Test and OraQuick® In-Home HIV Test. We are pleased with our first quarter results and expect our performance to improve through the remainder of 2014."

Financial Results

Consolidated net product revenues for the first quarter of 2014 increased 12%, primarily as a result of the higher sales of the Company's molecular collection systems, infectious disease testing, and cryosurgical systems products. These increases were partially offset by lower sales of the Company's substance abuse testing products largely in the international markets and lower sales of insurance risk assessment products.

The Company had no consolidated licensing and product development revenues for the first quarter of 2014 as a result of the expiration of certain patents licensed to a third party. This compares to \$202,000 recorded for the first quarter of 2013.

Consolidated gross margin for the three months ended March 31, 2014 was 59% compared to 57% for the three months ended March 31, 2013. Gross margin for the current quarter primarily benefited from improved overhead absorption due to the absence of production issues which negatively impacted overhead absorption in the first quarter of 2013. The current quarter margin also benefitted from a more favorable product mix driven largely by increased DNAG sales.

Consolidated operating expenses decreased to \$19.5 million during the first quarter of 2014 compared to \$22.6 million in the comparable period of 2013. The decrease was primarily the result of lower promotional and advertising expenses associated with the Company's OraQuick® In-Home HIV test. These expenses totaled \$4.6 million during the current quarter, compared to \$6.9 million in the first quarter of 2013. Research and development expenses also decreased \$876,000 as a result of lower clinical trial costs and decreased staffing and supply costs. General and administrative expenses increased by \$337,000 due to higher consulting costs.

For the three months ended March 31, 2014, the Company recorded Canadian income tax expense of \$131,000. For the three months ended March 31, 2013, the Company recorded a Canadian income tax benefit of \$410,000 as a result of the loss before income taxes and certain Canadian research and development and investment tax credits at DNAG.

The Company's cash balance totaled \$84.2 million at March 31, 2014 compared to \$93.2 million at December 31, 2013. Working capital was \$96.8

million at March 31, 2014 compared to \$100.6 million at December 31, 2013. For the three months ended March 31, 2014, the Company used \$7.7 million to fund operations.

Second Quarter 2014 Outlook

The Company expects consolidated net revenues to range from \$25.2 to \$25.7 million and is projecting a consolidated net loss of approximately \$0.09 to \$0.10 per share for the second quarter of 2014.

Financial Data

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

Unaudited

	Three months ended March 31,		
	2014	2013	
Results of Operations			
Net revenues	\$ 23,537	\$ 21,164	
Cost of products sold	9,610	9,135	
Gross profit	13,927	12,029	
Operating expenses:			
Research and development	2,481	3,357	
Sales and marketing	11,340	13,874	
General and administrative	5,724	5,387	
Total operating expenses	19,545	22,618	
Operating loss	(5,618)	(10,589)	
Other income (expense)	118	(47)	
Loss before income taxes	(5,500)	(10,636)	
Income tax expense (benefit)	131	(410)	
Net loss	\$ (5,631)	\$ (10,226)	
Loss per share:			
Basic and Diluted	\$ (0.10)	\$ (0.18)	
Weighted average shares:			
Basic and Diluted	55,762	55,449	

Summary of Revenues by Market and Product (Unaudited)

Three	Months	Ended	March 31,

	Dollars			Percentage of To	tal Net Revenues
Market	2014	2013	% Change	2014	2013
Infectious disease testing	\$ 11,064	\$ 10,687	4%	47%	49%
Substance abuse testing	1,830	2,249	(19)	8	11
Cryosurgical systems	3,967	3,085	29	17	15
Molecular collection systems	5,759	3,932	46	24	19
Insurance risk assessment	917	1,009	(9)	4	5
Net product revenues	23,537	20,962	12	100	99
Licensing and product development		202	(100)		1
Net revenues	\$ 23,537	\$ 21,164	11%	100%	100%

Three Months Ended

March 31,

OraQuick [®] Revenues	2014	2013	% Change
Domestic HIV	\$ 6,618	\$ 7,672	(14)%
International HIV	558	554	1
Domestic HIV OTC	1,953	1,442	35
Net HIV revenues	9,129	9,668	(6)
Domestic HCV	663	428	55
International HCV	896	240	273
Net HCV revenues	1,559	668	133

Net OraQuick® revenues \$10,688 \$10,336 3%

Three Months Ended

March 31,

Intercept® Revenues 2014 2013 % Change

 Domestic
 \$ 1,250
 \$ 1,404
 (11)%

 International
 40
 258
 (84)

 Net Intercept® revenues
 \$ 1,290
 \$ 1,662
 (22)%

Three Months Ended

March 31,

Cryosurgical Systems Revenues 2014 2013 % Change

Domestic professional\$ 1,542\$ 89173%International professional310348(11)International over-the-counter2,1151,84615Net cryosurgical systems revenues\$ 3,967\$ 3,08529%

Condensed Consolidated Balance Sheets (Unaudited)

March 31, 2014 December 31, 2013

Assets

Cash	\$ 84,193	\$ 93,191
Accounts receivable, net	13,287	12,957
Inventories	11,994	11,444
Other current assets	2,281	1,983
Property and equipment, net	17,826	17,933
Intangible assets, net	20,659	22,226
Goodwill	22,860	23,782
Other non-current assets	980	729
Total assets	\$ 174,080	\$ 184,245

Liabilities and Stockholders' Equity

Accounts payable \$4,114 \$4,834

Deferred revenue	954	1,119
Accrued expenses	9,902	13,032
Other non-current liabilities	961	677
Deferred income taxes	3,435	3,437
Stockholders' equity	154,714	161,146
Total liabilities and stockholders' equity	\$ 174,080	\$ 184,245

Three months ended

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Additional Financial Data (Unaudited)	2014	2013
Capital expenditures	\$ 647	\$ 480
Depreciation and amortization	\$ 1,539	\$ 1,602
Stock based compensation	\$ 1,406	\$ 1,394
Cash used in operating activities	\$ 7,668	\$ 7,674

Conference Call

The Company will host a conference call and audio webcast to discuss the Company's 2014 first quarter financial results, certain business developments and financial guidance for the second quarter of 2014, 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 #31956599 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 May 14, 2014, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #31956599.

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. The Company sells the OraQuick® In-Home HIV Test, the first and only rapid HIV test approved by the U.S. Food and Drug Administration for sale to the consumer over-the-counter market 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 the Company, 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. Forwardlooking 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 the Company's 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 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, 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 the Company's 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 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 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, 2013, 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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company logo

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