



OraSure Announces 2013 First Quarter Financial Results

May 8, 2013

BETHLEHEM, Pa., May 8, 2013 (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 2013.

Quarterly Highlights

- Consolidated net revenues were \$21.2 million for the first quarter of 2013, a 1% increase from the comparable quarter of 2012. Net product revenues increased 6% primarily due to sales of the Company's OraQuick® In-Home HIV test and higher sales from the Company's molecular collection systems subsidiary, DNA Genotek ("DNAG").
- Included in the 2013 first quarter net revenues were \$1.5 million in gross sales of the OraQuick® In-Home HIV test, which were reduced by customer allowances for cooperative advertising, cash discounts and other allowances, resulting in net revenues of \$1.4 million recorded for the period. Most revenue for this product is currently recognized upon the consummation of a sale to a retail customer either in a store or over the internet.
- Net revenues generated by DNAG during the first quarter of 2013 were \$3.9 million, a 19% increase from the comparable period in 2012. This increase was primarily the result of higher sales to commercial customers.
- Consolidated net loss for the first quarter of 2013 was \$10.2 million, or \$0.18 per share, which compares to a net loss of \$3.3 million, or \$0.07 per share, for the first quarter of 2012. The net loss for the first quarter of 2013 included \$6.9 million in advertising and promotional expenses for the Company's newly-launched OraQuick® In-Home HIV test.

"We are pleased to see the first quarter performance by our molecular collection systems business and the increasing sales of our OraQuick® In-Home HIV test," said Douglas A. Michels, President and Chief Executive Officer of OraSure Technologies, Inc. "We continue to refine our advertising and promotion strategies as we learn more about how consumers are responding to the availability of our In-Home HIV test."

Financial Results

Consolidated net product revenues for the quarter increased 6%, primarily as a result of the higher sales of the Company's molecular collection systems, infectious disease testing, and substance abuse testing products. These increases were partially offset by lower sales of the Company's cryosurgical systems and insurance risk assessment products.

Consolidated licensing and product development revenues for the first quarter of 2013 decreased to \$202,000 from \$1.2 million in the first quarter of 2012. This decrease was primarily attributed 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 in the first quarter of 2013.

Consolidated gross margin for the three months ended March 31, 2013 was 57% compared to 66% for the three months ended March 31, 2012. The current quarter gross margin was negatively impacted by a change in product mix, the absence in the current quarter of the \$1.0 milestone payment received in the first quarter of 2012, higher royalties paid on sales of the Company's OraQuick® products, and an increase in scrap, spoilage, and unabsorbed overhead costs as a result of production issues that were identified and corrected in the current quarter.

Consolidated operating expenses increased to \$22.6 million for the first quarter of 2013, from \$17.4 million in the comparable period of 2012. This increase was primarily the result of higher promotional and advertising expense associated with the Company's OraQuick® In-Home HIV test. The current quarter expenses included \$6.9 million of promotional and advertising costs related to this product compared to \$1.0 million spent on launch preparation costs in the first quarter of 2012.

For the three months ended March 31, 2013 and 2012, the Company recorded an income tax benefit of \$410,000 and \$521,000, respectively, associated with the loss before income taxes and certain Canadian research and development and investment tax credits at DNAG.

Cash totaled \$79.3 million at March 31, 2013 compared to \$87.9 million at December 31, 2012. Working capital was \$94.9 million at March 31, 2013 compared to \$103.5 million at December 31, 2012. For the three months ended March 31, 2013, the Company used \$7.7 million to fund operations, including the advertising and promotional activities related to the OraQuick® In-Home HIV test.

Second Quarter 2013 Outlook

The Company expects consolidated net revenues to range from \$23.5 to \$24.0 million and is projecting a consolidated net loss of approximately \$0.15 - \$0.16 per share for the second quarter of 2013.

Financial Data

Condensed Consolidated Financial Data

(In thousands, except per-share data)

Unaudited

	Three months ended	
	March 31,	
	2013	2012
Results of Operations		
Net revenues	\$ 21,164	\$ 20,944
Cost of products sold	9,135	7,212
Gross profit	12,029	13,732
Operating expenses:		
Research and development	3,357	3,444
Sales and marketing	13,874	7,874
General and administrative	5,387	6,066
Total operating expenses	22,618	17,384
Operating loss	(10,589)	(3,652)
Other expense	(47)	(121)
Loss before income taxes	(10,636)	(3,773)
Income tax benefit	(410)	(521)
Net loss	\$ (10,226)	\$ (3,252)
Loss per share:		
Basic and Diluted	\$ (0.18)	\$ (0.07)
Weighted average shares:		
Basic and Diluted	55,449	47,807

Summary of Revenues by Market and Product (Unaudited)

	Three Months Ended March 31,			Percentage of	
				Total Net	
				Revenues	
	Dollars				
Market	2013	2012	% Change	2013	2012
Infectious disease testing	\$ 10,687	\$ 9,776	9%	49%	47%
Substance abuse testing	2,249	2,087	8	11	10
Cryosurgical systems	3,085	3,478	(11)	15	16
Molecular collection systems	3,932	3,298	19	19	16
Insurance risk assessment	1,009	1,099	(8)	5	5
Net product revenues	20,962	19,738	6	99	94
Licensing and product development	202	1,206	(83)	1	6
Net revenues	\$ 21,164	\$ 20,944	1%	100%	100%

	Three Months Ended		
	March 31,		
	2013	2012	% Change
OraQuick® Revenues			

Domestic HIV	\$ 7,672	\$ 8,148	(6)%
International HIV	554	660	(16)
Domestic HIV OTC	1,442	--	N/A
Domestic HCV	428	536	(20)
International HCV	240	282	(15)
Net OraQuick® revenues	\$ 10,336	\$ 9,626	7%

Three Months Ended

March 31,

Intercept® Revenues	2013	2012	% Change
Domestic	\$ 1,274	\$ 1,523	(16)%
International	388	46	743
Net Intercept® revenues	\$ 1,662	\$ 1,569	6%

Three Months Ended

March 31,

Cryosurgical Systems Revenues	2013	2012	% Change
Professional domestic	\$ 891	\$ 1,371	(35)%
Professional international	348	287	21
Over-the-Counter	1,846	1,820	1
Net cryosurgical systems revenues	\$ 3,085	\$ 3,478	(11)%

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

Assets

Cash	\$ 79,276	\$ 87,888
Accounts receivable, net	16,955	17,545
Inventories	13,056	12,758
Other current assets	3,599	2,212
Property and equipment, net	18,297	18,546
Intangible assets, net	25,749	27,207
Goodwill	24,823	25,445
Other non-current assets	281	124
Total assets	\$ 182,036	\$ 191,725

Liabilities and Stockholders' Equity

Accounts payable	\$ 5,622	\$ 3,380
Deferred revenue	5,611	5,580
Accrued expenses	6,756	7,960
Other non-current liabilities	249	89
Deferred income taxes	3,881	4,401
Stockholders' equity	159,917	170,315
Total liabilities and stockholders' equity	\$ 182,036	\$ 191,725

Three months ended

March 31,

Additional Financial Data (Unaudited) 2013 2012

Capital expenditures	\$ 480	\$ 306
Depreciation and amortization	\$ 1,602	\$ 1,809
Stock based compensation	\$ 1,394	\$ 1,192
Cash used in operating activities	\$ 7,674	\$ 1,356

Conference Call

The Company will host a conference call and audio webcast to discuss the Company's 2013 first quarter financial results, business developments and financial guidance for the second 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 #42321505 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 15, 2013, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #42321505.

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 for the Company's OraQuick® In-Home HIV Test for sale 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 an 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; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; impact of the economic downturn, 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, extended shelf life 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.

CONTACT: Company Contact:

Ronald H. Spair
Chief Financial Officer
610-882-1820
Investorinfo@orasure.com
www.orasure.com

[company logo](#)

OraSure Technologies, Inc.