

OraSure Announces 2015 First Quarter Financial Results

May 6, 2015

BETHLEHEM, Pa., May 6, 2015 (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 first quarter ended March 31, 2015.

Financial Highlights

- Consolidated net revenues for the first quarter of 2015 were \$27.1 million, a 15% increase from the comparable period of 2014.
- Net product revenues for the Company's OraQuick[®] rapid HCV test were \$2.2 million for the first quarter of 2015, representing a 39% increase over the first quarter of 2014. Total HCV-related revenues, including exclusivity payments recognized under the HCV co-promotion agreement with AbbVie, were \$5.5 million for the first quarter of 2015, \$3.9 million higher than the same period last year.
- Net revenues generated by the Company's molecular collection systems subsidiary, DNA Genotek ("DNAG"), were \$6.7 million during the first quarter of 2015, representing a 17% increase over the first quarter of 2014.
- Consolidated net income for the first quarter of 2015 was \$113,000, or \$0.00 per share, which compares to a net loss of \$5.6 million, or \$0.10 per share, for the first quarter of 2014. This improvement was primarily the result of the AbbVie exclusivity revenues of \$3.3 million and lower sales and marketing expenses.
- Cash and short term investments totaled \$89.5 million and working capital amounted to \$105.6 million at March 31, 2015.

"We are pleased with our financial performance for the first quarter," said Douglas A. Michels, President and CEO of OraSure Technologies, Inc. "Increased HCV-related revenues and higher sales from our molecular collections systems business were the primary reasons for this performance and will set the stage for a successful year."

Financial Results

Consolidated net product revenues for the first quarter of 2015 increased 1% from the comparable period of 2014, primarily as a result of higher sales of the Company's molecular collection systems, OraQuick[®] HCV and Intercept[®] products. These increases were partially offset by lower sales of the Company's cryosurgical systems, OraQuick[®] professional HIV and OraQuick[®] In-Home HIV products.

Consolidated net revenues for the first quarter of 2015 also included \$3.3 million of exclusivity payments recognized under the Company's HCV co-promotion agreement with AbbVie.

Consolidated gross margin for the three months ended March 31, 2015 was 63% compared to 59% for the three months ended March 31, 2014. Gross margin for the current quarter improved largely as a result of the \$3.3 million in AbbVie revenues.

Consolidated operating expenses decreased to \$17.3 million during the first quarter of 2015 compared to \$19.5 million in the comparable period of 2014. This decrease was primarily due to lower promotional expenses associated with the Company's OraQuick[®] In-Home HIV test, partially offset by higher research and development costs and legal fees. Promotional expenses for the OraQuick[®] In-Home HIV test were \$432,000 and \$4.6 million for the first quarters of 2015 and 2014, respectively.

The Company's cash and short-term investment balance totaled \$89.5 million at March 31, 2015 compared to \$97.9 million at December 31, 2014. Working capital was \$105.6 million at March 31, 2015 compared to \$104.8 million at December 31, 2014. For the three months ended March 31, 2015, the Company used \$6.6 million to fund operations.

Second Quarter 2015 Outlook

The Company expects consolidated net revenues to range from \$29.0 to \$29.5 million and is projecting consolidated net income of approximately \$0.00 to \$0.01 per share for the second quarter of 2015.

Financial Data

Condensed Consolidated Financial Data

(In thousands, except per-share data)

Unaudited

	Three months ended		
	March 31,		
	2015	2014	
Results of Operations			
Net revenues	\$ 27,088	\$ 23,537	
Cost of products sold	10,090	9,610	
Gross profit	16,998	13,927	
Operating expenses:			
Research and development	3,440	2,481	
Sales and marketing	7,884	11,340	
General and administrative	5,965	5,724	
Total operating expenses	17,289	19,545	
Operating loss	(291)	(5,618)	
Other income	409	118	
Income (loss) before income taxes	118	(5,500)	
Income tax expense	5	131	
Net income (loss)	\$ 113	\$ (5,631)	
Earnings (loss) per share:			
Basic and Diluted	\$ 0.00	\$ (0.10)	
Weighted average shares:			
Basic	56,343	55,762	
Diluted	57,173	55,762	

Summary of Net Revenues by Market and Product (Unaudited)

Three Months Ended March 31,

	Dollars			Percer Total N Reven	
Market	2015	2014	% Change	2015	2014
Infectious disease testing	\$ 11,495	\$ 11,064	4%	43%	47%
Substance abuse testing	2,102	1,830	15	8	8
Cryosurgical systems	2,545	3,967	(36)	9	17
Molecular collection systems	6,717	5,759	17	25	24
Insurance risk assessment	906	917	(1)	3	4
Net product revenues	23,765	23,537	1	88	100
Other	3,323		100	12	
Net revenues	\$ 27,088	\$ 23,537	15%	100%	100%

	Three Months Ended March 31,		
HIV Revenues	2015	2014	% Change
Domestic	\$ 6,007	\$ 6,618	(9)%
International	948	558	70

Domestic OTC	1,561	1,953	(20)
Net product revenues	\$ 8,516	\$ 9,129	(7)%

	Three Months Ended March 31,		
HCV Revenues	2015	2014	% Change
Domestic	\$ 1,197	\$ 663	81%
International	972	896	8
Net product revenues	2,169	1,559	39
Amortization of exclusivity payments	3,323		100
Net HCV-related revenues	\$ 5,492	\$ 1,559	252%

Three Months Ended

	March 31,		
Intercept [®] Revenues	2015	2014	% Change

Net Intercept® revenues \$1,575 \$1,290 22

	Three Months Ended March 31,		
Cryosurgical Systems Revenues	2015	2014	% Change
Domestic professional	\$ 661	\$ 1,542	(57)%
International professional	357	310	15
Domestic over-the-counter	55		100
International over-the-counter	1,472	2,115	(30)
Net cryosurgical systems revenues	\$ 2,545	\$ 3,967	(36)%

Condensed Consolidated Balance Sheets (Unaudited)

	March 31, 2015	December 31, 2014
Assets		
	\$ 85,547	\$ 92,867
Cash		
Short-term investments	3,942	5,000
Accounts receivable, net	16,367	16,138
Inventories	15,619	15,763
Other current assets	1,708	1,446
Property and equipment, net	17,645	17,934
Intangible assets, net	15,581	17,505
Goodwill	19,913	21,734
Other non-current assets	1,320	1,246
Total assets	\$ 177,642	\$ 189,633

Liabilities and Stockholders' Equity

Accounts payable	\$ 5,037	\$ 7,148
Deferred revenue	5,492	8,043
Accrued expenses	7,005	11,271
Other non-current liabilities	1,311	1,234
Deferred income taxes	2,970	3,236
Stockholders' equity	155,827	158,701
Total liabilities and stockholders' equity	\$ 177,642	\$ 189,633

Additional Financial Data (Unaudited)	March 31,	nths ended 2014
Capital expenditures	\$ 437	\$ 647
Depreciation and amortization	\$ 1,409	\$ 1,539
Stock based compensation	\$ 1,475	\$ 1,406
Cash used in operating activities	\$ 6,591	\$ 7,668

Conference Call

The Company will host a conference call and audio webcast to discuss the Company's 2015 first quarter financial results, certain business developments and financial guidance for the second quarter of 2015, 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 #19423338 or go to OraSure Technologies' web site, <u>www.orasure.com</u>, 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 13, 2015, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #19423338.

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. 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; our ability to achieve financial and performance objectives under the HCV co-promotion agreement with AbbVie; 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 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, 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, 2014, 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

OraSure Technologies, Inc.