



OraSure Announces Full-Year and Fourth Quarter 2014 Financial Results

February 4, 2015

--2014 Revenues Exceed \$100 million--

BETHLEHEM, Pa., Feb. 4, 2015 (GLOBE NEWSWIRE) -- OraSure Technologies, Inc. (Nasdaq:OSUR), a market leader in oral fluid diagnostics, today announced its consolidated financial results for the full-year and fourth quarter ended December 31, 2014.

Financial Highlights

- The Company exceeded \$100 million in annual revenues for the first time in its history. Consolidated net revenues for the year ended December 31, 2014 were \$106.5 million, an 8% increase from the comparable period of 2013.
- Consolidated net revenues for the fourth quarter of 2014 were \$28.7 million, which approximated the level of revenues reported in the fourth quarter of 2013.
- Licensing and product development revenues were \$3.4 million and \$7.6 million for the quarter and year ended December 31, 2014, respectively, and represent the recognition of payments under the Company's HCV collaboration with AbbVie.
- Net revenues generated by the Company's molecular collection systems subsidiary, DNA Genotek ("DNAG"), were \$6.3 million and \$23.8 million for the fourth quarter and full-year of 2014, respectively, representing an 8% decrease and a 17% increase over the fourth quarter and full-year of 2013, respectively. DNAG accounted for 22% of the Company's aggregate 2014 consolidated net revenues.
- Net revenues for the Company's OraQuick® rapid HCV test were \$1.7 million and \$7.3 million for the fourth quarter and full-year of 2014, respectively, representing a 10% decrease and a 42% increase over the fourth quarter and full-year of 2013, respectively.
- Consolidated net loss for the fourth quarter of 2014 was \$2.7 million, or \$0.05 per share, which compares to net income of \$6.2 million, or \$0.11 per share, for the fourth quarter of 2013. This change in the current quarter bottom line performance was primarily the result of the absence of an \$8.3 million contract termination payment received in the prior year period. Consolidated net loss for the year ended December 31, 2014 was \$4.6 million, or \$0.08 per share, which compares to a net loss of \$11.2 million, or \$0.20 per share, for the comparable period of 2013.
- Cash and short term investments totaled \$97.9 million and working capital amounted to \$104.8 million at December 31, 2014.

"Crossing the \$100 million threshold in annual revenues has been a long-term goal and is a significant milestone for our Company," said Douglas A. Michels, President and CEO of OraSure Technologies. "The molecular collection systems segment continues to deliver strong results and our HCV business continues to grow. Our immediate focus is on increasing usage of our OraQuick® HCV test under our HCV collaboration with AbbVie, continuing the strong performance at DNA Genotek, and pursuing a potential rapid Ebola test, including securing development funding and purchase commitments for this proposed new product."

Financial Results

Consolidated net product revenues for the fourth quarter of 2014 decreased 12% from the comparable period of 2013, primarily as a result of the change in revenue recognition policy related to the Company's OraQuick® In-Home HIV test which increased fourth quarter 2013 net revenues by \$2.5 million. Consolidated net product revenues for the year ended December 31, 2014 increased 1% over the prior year period, primarily as a result of higher sales of the Company's molecular collection systems, OraQuick® HCV and cryosurgical systems products. These increases were partially offset by lower sales of the OraQuick® professional HIV product line and OraQuick® In-Home HIV test. OraQuick® HIV In-Home revenues in 2013 included the \$2.5 million non-recurring favorable adjustment resulting from the accounting policy change.

Consolidated licensing and product development revenues for the fourth quarter and full-year of 2014 were \$3.4 million and \$7.6 million, respectively. Consolidated licensing and product development revenues for the fourth quarter and full-year of 2013 were \$0 and \$623,000, respectively. Licensing and product development revenues in 2014 represent the recognition of exclusivity payments under the Company's HCV collaboration agreement with AbbVie. Licensing and product development revenues in 2013 represent royalties paid on domestic outsales of a licensee's OTC cryosurgical wart removal product, pursuant to a license agreement that expired in that same year.

Consolidated gross margin for both the three months and year ended December 31, 2014 was 63%. Consolidated gross margin for the three months and year ended December 31, 2013 was 60% and 59%, respectively. Gross margin for the current quarter improved largely as a result of the increased licensing and product development revenues and a more favorable product mix resulting from higher margin DNAG sales, partially offset by a decline in overhead absorption as a result of facility equipment replacements. Gross margin for the full-year 2014 also improved largely due to the increased licensing and product development revenues and higher margin DNAG sales.

Consolidated operating expenses increased to \$20.5 million during the fourth quarter of 2014 compared to \$11.1 million in the comparable period of 2013. This increase was primarily due to the absence of an \$8.3 million contract termination payment from Roche Diagnostics which was received in the fourth quarter of 2013. This payment, coupled with lower promotional expenses associated with the Company's OraQuick® In-Home HIV test,

were partially offset by increased expenses incurred under the HCV collaboration with AbbVie, higher research and development costs and higher staffing expenses. Promotional expenses for the OraQuick® In-Home HIV test were \$614,000 and \$4.6 million for the fourth quarters of 2014 and 2013, respectively.

For the year ended December 31, 2014, consolidated operating expenses increased to \$71.4 million from the \$70.8 million reported for the prior year. This increase was primarily due to a \$2.8 million reduction in contract termination payments received from Roche Diagnostics during 2014, increased expenses incurred under the HCV collaboration with AbbVie, higher research and development costs, and higher legal, staffing and consulting costs, partially offset by lower promotional expenses associated with the Company's OraQuick® In-Home HIV test. Full-year promotional expenses for the OraQuick® In-Home HIV test were \$8.5 million and \$18.8 million for 2014 and 2013, respectively.

For the three months and year ended December 31, 2014, the Company recorded Canadian income tax expense of \$376,000 and \$343,000, respectively. For the three months and year ended December 31, 2013, the Company recorded Canadian income tax expense of \$14,000 and a Canadian income tax benefit of \$772,000 respectively. The 2013 full-year tax benefit was the result of certain Canadian research and development and investment tax credits and DNAG's loss before income taxes in that period.

The Company's cash and short-term investment balance totaled \$97.9 million at December 31, 2014 compared to \$93.2 million in cash at December 31, 2013. Working capital was \$104.8 million at December 31, 2014 compared to \$100.6 million at December 31, 2013. For the year ended December 31, 2014, the Company's consolidated operations generated \$7.5 million of cash.

First Quarter 2015 Outlook

The Company expects consolidated net revenues to range from \$26.5 to \$27.0 million and is projecting a consolidated net loss of approximately \$0.01 to \$0.02 per share for the first quarter of 2015.

Financial Data

Condensed Consolidated Financial Data

(In thousands, except per-share data)

Unaudited

	Three months ended		Year ended	
	December 31,		December 31,	
	2014	2013	2014	2013
Results of Operations				
Net revenues ¹	\$ 28,681	\$ 28,768	\$ 106,464	\$ 98,940
Cost of products sold	10,704	11,640	39,840	40,351
Gross profit	17,977	17,128	66,624	58,589
Operating expenses:				
Research and development	3,817	2,212	12,058	10,932
Sales and marketing	10,290	11,241	41,118	46,465
General and administrative	6,433	5,912	23,750	21,654
Gain on contract termination settlement	--	(8,300)	(5,500)	(8,300)
Total operating expenses	20,540	11,065	71,426	70,751
Operating income (loss)	(2,563)	6,063	(4,802)	(12,162)
Other income (expense)	287	164	531	200
Income (loss) before income taxes	(2,276)	6,227	(4,271)	(11,962)
Income tax expense (benefit)	376	14	343	(772)
Net income (loss)	\$ (2,652)	\$ 6,213	\$ (4,614)	\$ (11,190)
Earnings (loss) per share:				
Basic and Diluted	\$ (0.05)	\$ 0.11	\$ (0.08)	\$ (0.20)
Weighted average shares:				
Basic	56,105	55,616	55,949	55,555
Diluted	56,105	56,176	55,949	55,555

¹Net revenues for the three months and year ended December 31, 2013 include a non-recurring net favorable \$2.5 million adjustment to reflect a

change in the Company's revenue recognition policy related to its OraQuick® In-Home HIV test.

Summary of Net Revenues by Market and Product (Unaudited)

Market	Three Months Ended December 31,			Percentage of	
	Dollars			Total Net	
				Revenues	
	%				
	2014	2013	Change	2014	2013
Infectious disease testing	\$ 12,602	\$ 15,436	(18)%	44%	54%
Substance abuse testing	2,250	2,116	6	8	7
Cryosurgical systems	3,377	3,558	(5)	11	12
Molecular collection systems	6,255	6,831	(8)	22	24
Insurance risk assessment	800	827	(3)	3	3
Net product revenues	25,284	28,768	(12)	88	100
Licensing and product development	3,397	--	NM*	12	--
Net revenues	\$ 28,681	\$ 28,768	(0)%	100%	100%

Market	Year Ended December 31,			Percentage of	
	Dollars			Total Net	
				Revenues	
	%				
	2014	2013	Change	2014	2013
Infectious disease testing	\$ 47,515	\$ 50,961	(7)%	45%	51%
Substance abuse testing	8,437	8,571	(2)	8	9
Cryosurgical systems	15,505	14,468	7	15	14
Molecular collection systems	23,778	20,381	17	22	21
Insurance risk assessment	3,659	3,936	(7)	3	4
Net product revenues	98,894	98,317	1	93	99
Licensing and product development	7,570	623	NM*	7	1
Net revenues	\$ 106,464	\$ 98,940	8%	100%	100%

* Calculation is not considered meaningful

OraQuick® Revenues	Three Months Ended			Year Ended		
	December 31,			December 31,		
	%			%		
	2014	2013	Change	2014	2013	Change
Domestic HIV	\$ 8,363	\$ 8,447	(1)%	\$ 29,933	\$ 32,301	(7)%
International HIV	587	907	(35)	2,483	3,365	(26)
Domestic HIV OTC ¹	1,502	3,909	(62)	6,493	9,106	(29)
Net HIV revenues	10,452	13,263	(21)	38,909	44,772	(13)
Domestic HCV	1,036	1,073	(3)	4,220	2,847	48

International HCV	707	860	(18)	3,048	2,268	34
Net HCV revenues	1,743	1,933	(10)	7,268	5,115	42

Net OraQuick® revenues \$ 12,195 \$ 15,196 (20)% \$ 46,177 \$ 49,887 (7)%

	Three Months Ended			Year Ended		
	December 31,			December 31,		
			%			%
Intercept® Revenues	2014	2013	Change	2014	2013	Change
Domestic	\$ 1,629	\$ 1,453	12%	\$ 6,101	\$ 5,693	7%
International	73	115	(37)	149	500	(70)
Net Intercept® revenues	\$ 1,702	\$ 1,568	9%	\$ 6,250	\$ 6,193	1%

	Three Months Ended			Year Ended		
	December 31,			December 31,		
			%			%
Cryosurgical Systems Revenues	2014	2013	Change	2014	2013	Change
Domestic professional	\$ 2,149	\$ 1,828	18%	\$ 6,750	\$ 6,020	12%
International professional	111	402	(72)	693	1,441	(52)
Domestic over-the-counter	108	--	100	108	--	100
International over-the-counter	1,009	1,328	(24)	7,954	7,007	14
Net cryosurgical systems revenues	\$ 3,377	\$ 3,558	(5)%	\$ 15,505	\$ 14,468	7%

¹Net revenues for the three months and year ended December 31, 2013 include a non-recurring net favorable \$2.5 million adjustment to reflect a change in the Company's revenue recognition policy related to its OraQuick® In-Home HIV test.

Condensed Consolidated Balance Sheets (Unaudited)

	December 31, 2014	December 31, 2013
Assets		
Cash	\$ 92,867	\$ 93,191
Short-term investments	5,000	--
Accounts receivable, net	16,138	12,957
Inventories	15,763	11,444
Other current assets	1,446	1,983
Property and equipment, net	17,934	17,933
Intangible assets, net	17,505	22,226
Goodwill	21,734	23,782
Other non-current assets	1,246	729
Total assets	\$ 189,633	\$ 184,245
Liabilities and Stockholders' Equity		
Accounts payable	\$ 7,148	\$ 4,834
Deferred revenue	8,043	1,119
Accrued expenses	11,271	13,032
Other non-current liabilities	1,234	677
Deferred income taxes	3,236	3,437

Stockholders' equity	158,701	161,146
Total liabilities and stockholders' equity	\$ 189,633	\$ 184,245

Year ended

December 31,

Additional Financial Data (Unaudited) 2014 2013

Capital expenditures	\$ 3,005	\$ 2,462
Depreciation and amortization	\$ 6,307	\$ 6,552
Stock based compensation	\$ 5,744	\$ 5,572
Cash provided by operating activities	\$ 7,526	\$ 8,385

Conference Call

The Company will host a conference call and audio webcast to discuss the Company's 2014 full-year and fourth quarter financial results, certain business developments and financial guidance for the first 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 #63824420 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 February 11, 2015, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #63824420.

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. 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; our ability to achieve financial and performance objectives under the HCV collaboration 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, 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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OraSure Technologies, Inc.