



OraSure Announces 2017 First Quarter Financial Results

May 3, 2017

BETHLEHEM, Pa., May 03, 2017 (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, 2017.

Financial Highlights

- Consolidated net revenues for the first quarter of 2017 were \$32.5 million, a 12% increase from the first quarter of 2016. Net product revenues were \$31.5 million, representing a 25% increase over the first quarter of 2016.
- Net molecular collection systems revenues were \$10.7 million during the first quarter of 2017, which represents a 55% increase over the first quarter of 2016.
- Total OraQuick® HCV sales of \$6.1 million for the first quarter of 2017 increased 111% compared to the first quarter of 2016 and included a 340% increase in international sales of the product from the prior year quarter.
- Net revenues from international sales of the Company's OraQuick® HIV products were \$2.6 million in the first quarter of 2017, representing a 210% increase over the first quarter of 2016.
- First quarter 2017 results include a \$12.5 million pre-tax gain related to the settlement of litigation against Ancestry.com DNA LLC and its contract manufacturer, which was accounted for as a reduction of operating expenses.
- The Company entered into a contract to supply more than \$20 million of its saliva DNA collection devices, which represents the largest supply contract in the history of the Company's molecular business.
- Consolidated net income for the first quarter of 2017 was \$12.4 million, or \$0.21 per share on a fully diluted basis, which compares to consolidated net income of \$2.4 million, or \$0.04 per share on a fully diluted basis, for the first quarter of 2016.
- Cash and short-term investments totaled \$141.5 million and working capital amounted to \$162.2 million at March 31, 2017.

"We are extremely pleased with our financial performance and the progress made on our growth objectives during the first quarter," said Douglas A. Michels, President and Chief Executive Officer of OraSure Technologies, Inc. "Product sales increased 25% over the prior year, led by strong results from our molecular business. International sales of our OraQuick® HIV self-test and OraQuick® HCV product were also significant contributors in the quarter. Our business momentum remains strong and we are well positioned to further capitalize on the exciting market opportunities we are pursuing."

Financial Results

Consolidated net product revenues for the first quarter of 2017 increased 25% over the comparable period of 2016, primarily as a result of higher sales of the Company's molecular products and higher international sales of the OraQuick® HIV self-test and OraQuick® HCV product, partially offset by lower domestic sales of the Company's professional OraQuick® HIV product and lower cryosurgical systems sales.

Consolidated other revenues were \$1.1 million and \$3.8 million for the first quarter of 2017 and 2016, respectively. Other revenues in the first quarter of 2017 included \$1.1 million of funding received from the U.S. Biomedical Advanced Research Development Authority ("BARDA"). Other revenues in the first quarter of 2016 included \$482,000 of funding received from BARDA and \$3.4 million of exclusivity revenues recognized under the Company's HCV co-promotion agreement with AbbVie, which terminated effective December 31, 2016.

Consolidated gross margin for the three months ended March 31, 2017 was 62% compared to 70% for the three months ended March 31, 2016. Gross margin for the current quarter decreased due to the absence of exclusivity revenues, increased scrap and spoilage costs, and a less favorable product mix.

Consolidated operating expenses decreased to \$4.4 million during the first quarter of 2017 compared to \$17.6 million in the first quarter of 2016. The decrease was primarily due to the \$12.5 million gain on the litigation settlement, the absence of costs associated with the AbbVie HCV co-promotion agreement and lower legal fees. These decreases were partially offset by higher research and development expenses and increased general and administrative costs.

The Company's cash and short-term investment balance totaled \$141.5 million at March 31, 2017, compared to \$120.9 million at December 31, 2016. Working capital was \$162.2 million at March 31, 2017, compared to \$139.1 million at December 31, 2016. For the three months ended March 31,

2017, the Company generated \$12.6 million in cash from operations.

Second Quarter 2017 Outlook

The Company expects consolidated net revenues to range from \$36.5 to \$37.0 million and is projecting consolidated net income of \$0.07 to \$0.08 per share for the second quarter of 2017.

Financial Data

Condensed Consolidated Financial Data

(In thousands, except per-share data)

Unaudited

	Three months ended	
	March 31,	
	2017	2016
Results of Operations		
Net revenues	\$ 32,546	\$ 29,089
Cost of products sold	12,236	8,776
Gross profit	20,310	20,313
Operating expenses:		
Research and development	2,970	2,366
Sales and marketing	6,877	8,706
General and administrative	7,092	6,542
Gain on litigation settlement	(12,500)	-
Total operating expenses	4,439	17,614
Operating income	15,871	2,699
Other income (expense)	467	(192)
Income before income taxes	16,338	2,507
Income tax expense	3,897	61
Net income	\$ 12,441	\$ 2,446
Earnings per share:		
Basic	\$ 0.22	\$ 0.04
Diluted	\$ 0.21	\$ 0.04
Weighted average shares:		
Basic	56,929	55,451
Diluted	58,772	56,079

Summary of Net Revenues by Market and Product (Unaudited)

	Three Months Ended March 31,			Percentage of			
	Dollars			Total Net Revenues			
<u>Market</u>	2017	2016	% Change	2017	2016		
Infectious disease testing	\$ 14,583	\$ 11,368	28 %	45 %	39 %		
Risk assessment testing	3,130	3,105	1	10	11		
Cryosurgical systems	3,063	3,882	(21)	9	13		
Molecular collection systems	10,706	6,890	55	33	24		
Net product revenues	31,482	25,245	25	97	87		
Other	1,064	3,844	(72)	3	13		
Net revenues	\$ 32,546	\$ 29,089	12 %	100 %	100 %		

HIV Revenues	Three Months Ended March 31,			
	2017	2016	% Change	
Domestic	\$ 3,812	\$ 5,703	(33)	%
International	2,644	854	210	
Domestic OTC	1,542	1,523	1	
Net product revenues	\$ 7,998	\$ 8,080	(1)	%

HCV Revenues	Three Months Ended March 31,			
	2017	2016	%Change	
Domestic	\$ 1,709	\$ 1,900	(10)	%
International	4,402	1,001	340	
Net product revenues	6,111	2,901	111	
Amortization of exclusivity payments	-	3,362	(100)	
Net HCV-related revenues	\$ 6,111	\$ 6,263	(2)	%

<u>Cryosurgical Systems Revenues</u>	Three Months Ended March 31,			
	2017	2016	% Change	
Domestic professional	\$ 1,496	\$ 1,554	(4)	%
International professional	130	235	(45)	
Domestic OTC	285	378	(25)	
International OTC	1,152	1,715	(33)	
Net product revenues	\$ 3,063	\$ 3,882	(21)	%

Condensed Consolidated Balance Sheets (Unaudited)

	March 31, 2017	December 31, 2016
Assets		
Cash and cash equivalents	\$ 122,682	\$ 109,790
Short-term investments	18,776	11,160
Accounts receivable, net	24,005	19,827
Inventories	12,707	11,799
Other current assets	2,365	3,865
Property and equipment, net	20,134	20,033
Intangible assets, net	9,779	10,337
Goodwill	18,971	18,793
Other non-current assets	3,173	2,331
Total assets	\$ 232,592	\$ 207,935

Liabilities and Stockholders' Equity

Accounts payable	\$	7,286	\$	4,633
Deferred revenue		1,306		1,388
Other current liabilities		9,685		11,314
Other non-current liabilities		3,160		2,304
Deferred income taxes		2,330		2,446
Stockholders' equity		208,825		185,850
Total liabilities and stockholders' equity	\$	232,592	\$	207,935

**Three months ended
March 31,****Additional Financial Data (Unaudited) 2017 2016**

Capital expenditures	\$	878	\$	1,593
Depreciation and amortization	\$	1,408	\$	1,354
Stock-based compensation	\$	1,518	\$	1,452
Cash provided by operating activities	\$	12,619	\$	4,744

Conference Call

The Company will host a conference call and audio webcast to discuss the Company's 2017 first quarter financial results, certain business developments and financial guidance for the second quarter of 2017, 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 #3133897 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 10, 2017, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #3133897.

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. 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; impact of increased reliance on U.S. government contracts; 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 the Company to achieve its financial and strategic objectives and continue to increase its revenues, including the ability to expand international sales; 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 levels 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; 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 testing guidelines, algorithms or other recommendations by the Centers for Disease Control and Prevention ("CDC") or other agencies; 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 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 meet financial covenants in credit agreements; 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 ("SEC") filings, including our registration statements, Annual Report on Form 10-K for the year ended December 31, 2016, 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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