



## OraSure Announces 2009 First Quarter Financial Results

May 6, 2009

BETHLEHEM, Pa.--(BUSINESS WIRE)--May. 6, 2009-- OraSure Technologies, Inc. (NASDAQ:OSUR), a market leader in oral fluid diagnostics, today announced revenues of \$17.3 million for the three months ended March 31, 2009, compared to \$18.1 million recorded for the three months ended March 31, 2008. Increased sales of the Company's OraQuick *ADVANCE*<sup>®</sup> rapid HIV-1/2 antibody test and insurance risk assessment products during the first quarter 2009 were offset by decreased sales of the Company's cryosurgical systems and substance abuse testing products and lower licensing and product development revenue.

The Company recorded a net loss of \$1.6 million, or \$0.04 per share, for the first quarter of 2009, compared to net income of \$2.0 million, or \$0.04 per share on a fully-diluted basis, for the first quarter of 2008, on a GAAP<sup>1</sup> basis. The first quarter 2008 results include a \$4.9 million pre-tax gain related to a settlement and licensing agreement entered into during that quarter. On a non-GAAP basis, the Company would have reported a \$2.1 million pre-tax loss in 2008 excluding the gain, compared to a pre-tax loss for the first quarter of 2009 of \$1.6 million, an improvement of approximately \$532,000 which is largely attributable to a higher gross margin and an overall decrease in operating expenses.

During the fourth quarter of 2008, the Company established a full valuation allowance against its net deferred tax asset. As a result, the Company will not record Federal income tax expense or benefit in 2009. The Company incurred income tax expense of \$732,000 for the three months ended March 31, 2008.

Gross margin in the first quarter of 2009 was 64% compared with 59% in the first quarter of 2008, due to improved margins derived from implementing a direct sales model for the OraQuick *ADVANCE*<sup>®</sup> HIV-1/2 test in the U.S. hospital market beginning in January 2009 and a decrease in scrap and spoilage levels.

Operating expenses for the first quarter of 2009 decreased \$823,000 to \$12.8 million, from \$13.7 million in the comparable period in 2008. This decrease was primarily attributable to a decrease in research and development costs associated with the Company's OraQuick<sup>®</sup> HCV and OraQuick<sup>®</sup> HIV over-the-counter ("OTC") clinical development programs and lower staffing costs. Sales and marketing expenses were also down in the first quarter of 2009 due to cost-cutting measures in many categories, partially offset by an increase in staffing costs required to implement the direct sales model for the hospital market. General and administrative expenses were higher in the current quarter due to an increase in legal fees related to pending patent litigation.

"We are pleased with our performance during the first quarter of 2009, as we exceeded expectations on both the top and bottom lines," said Douglas A. Michels, President and Chief Executive Officer of OraSure Technologies. "Sales of our OraQuick *ADVANCE*<sup>®</sup> HIV-1/2 test remained strong, in part because of the successful transition of the hospital market to a direct sales model. At the same time, we continued advancing our two most critical clinical programs for an OraQuick<sup>®</sup> HCV test and OraQuick<sup>®</sup> HIV OTC test. Our first quarter performance is a great start to what we expect will be a very successful 2009."

Cash, cash equivalents and short-term investments totaled \$78.6 million and working capital was \$90.1 million at March 31, 2009, compared to \$82.5 million and \$90.9 million, respectively, at December 31, 2008.

### Second Quarter 2009 Outlook

The Company expects total revenues for the second quarter of 2009 to range from approximately \$18.5 to \$19.0 million. The Company is currently projecting a loss per share for the second quarter of 2009 of approximately \$0.06 to \$0.07.

### Pending Litigation

The Company also announced today that the United States District Court for the District of New Jersey issued an order denying, without prejudice, the motion for summary judgment on infringement filed by Inverness Medical and Church & Dwight against the Company in a pending patent lawsuit. The plaintiffs were granted leave to reinstate their motion upon completion of the Markman hearing where the Court will define certain claims in the asserted patent. A Markman hearing has been scheduled for August 12, 2009. The Company continues to believe that none of its products, including the OraQuick *ADVANCE*<sup>®</sup> HIV-1/2 test, infringe the patent or other intellectual property rights of any party.

### Financial Data

**Condensed Financial Data**  
(In thousands, except per-share  
data and percentages)  
(Unaudited)

	<b>Three months ended March 31,</b>	
	<b>2009</b>	<b>2008</b>
<b>Results of Operations</b>		
Revenues	\$ 17,256	\$ 18,089

Cost of products sold	6,284	7,446
Gross profit	10,972	10,643
Operating expenses:		
Research and development	3,352	4,598
Sales and marketing	5,023	5,216
General and administrative	4,457	3,841
Total operating expenses	12,832	13,655
Operating loss	(1,860)	(3,012)
Other income, net	242	5,746
Pre-tax income (loss)	(1,618)	2,734
Income tax provision	-	732
Net income (loss)	<u>\$ (1,618)</u>	<u>\$ 2,002</u>
Earnings (loss) per share		
Basic and diluted	<u>\$ (0.04)</u>	<u>\$ 0.04</u>
Weighted average shares:		
Basic	45,838	46,784
Diluted	<u>45,838</u>	<u>47,268</u>

### Non-GAAP Financial Measures

The Company's management considers the use of non-GAAP financial measures helpful in assessing the Company's current period's financial performance, especially in comparison to the same period of the prior year. As such, the Company has presented non-GAAP income (loss) before income taxes in the table below. While the Company believes that disclosing the following non-GAAP financial measures allows for greater transparency in the review of its underlying financial performance, it does not consider such measures to be substitutes for, or superior to, income (loss) before income taxes as determined in accordance with GAAP. For purposes of calculating the non-GAAP loss before income taxes, the Company excluded the \$4.9 million pre-tax gain related to a settlement and license agreement entered into during the first quarter of 2008, since such a significant or comparable transaction did not occur during the first quarter of 2009.

The following table reconciles the GAAP income (loss) before income taxes to the non-GAAP income (loss) before income taxes for the periods indicated, as well as the period-to-period change.

	Three months ended March 31,		Change
	2009	2008	
Income (loss) before income taxes, as reported under GAAP	\$ (1,618)	\$ 2,734	\$(4,352)
Pre-tax gain adjustment	-	(4,884)	4,884
Income (loss) before income taxes, non-GAAP	<u>\$ (1,618)</u>	<u>\$ (2,150)</u>	<u>\$ 532</u>

Market Revenues	Three months ended March 31,				
	Dollars		%	Percentage of Total Revenues	
	2009	2008		2009	2008
Infectious disease testing	\$10,451	\$ 9,480	10%	61%	52%
Substance abuse testing	2,690	3,277	(18)	16	18
Cryosurgical systems	2,145	3,336	(36)	12	18
Insurance risk assessment	1,635	1,543	6	9	9
Product revenues	16,921	17,636	(4)	98	97
Licensing and product development	335	453	(26)	2	3
Total revenues	<u>\$17,256</u>	<u>\$18,089</u>	<u>(5)%</u>	<u>100%</u>	<u>100%</u>

OraQuick® Revenues	Three months ended March 31,		%
	2009	2008	
Direct to U.S. Public Health	\$ 6,577	\$ 6,282	5%
Hospital Market	2,722	1,925	41

International	<u>459</u>	<u>646</u>	<u>(29)</u>
Total OraQuick® revenues	<u>\$ 9,758</u>	<u>\$ 8,853</u>	<u>10%</u>

Intercept® Revenues	Three months ended		
	March 31,		%
	2009	2008	Change
Workplace testing	\$ 857	\$ 1,016	(16)%
Criminal justice	552	619	(11)
International	523	525	–
Direct	<u>168</u>	<u>271</u>	<u>(38)</u>
Total Intercept® revenues	<u>\$ 2,100</u>	<u>\$ 2,431</u>	<u>(14)%</u>

Cryosurgical Systems Revenues	Three months ended		
	March 31,		%
	2009	2008	Change
Professional domestic	\$ 942	\$ 1,034	(9)%
Professional international	629	737	(15)
OTC domestic	57	–	–
OTC international	<u>517</u>	<u>1,565</u>	<u>(67)</u>
Total cryosurgical systems revenues	<u>\$ 2,145</u>	<u>\$ 3,336</u>	<u>(36)%</u>

Balance Sheets	March 31, 2009	December 31, 2008
Assets		
Cash, cash equivalents and short-term investments	\$ 78,620	\$ 82,523
Accounts receivable, net	11,237	11,571
Inventories	9,917	10,704
Other current assets	1,642	1,418
Property and equipment, net	21,078	21,235
Other non-current assets	4,266	4,467
Total assets	<u>\$ 126,760</u>	<u>\$ 131,918</u>
Liabilities and Stockholders' Equity		
Current portion of long-term debt	\$ 553	\$ 558
Accounts payable	2,545	3,926
Accrued expenses	8,202	10,796
Long-term debt	8,167	8,301
Other liabilities	5	12
Stockholders' equity	107,288	108,325
Total liabilities and stockholders' equity	<u>\$ 126,760</u>	<u>\$ 131,918</u>

Additional Financial Data	Three months ended March 31,	
	2009	2008
Capital expenditures	\$ 453	\$ 755
Depreciation and amortization	\$ 848	\$ 691
Purchase and retirement of common stock	\$ 309	–
Cash flows used in operating activities	\$ 2,650	\$ 3,709
Accounts receivable – days sales outstanding	59 days	69 days

## Conference Call

The Company will host a conference call and audio webcast to discuss the Company's 2009 first quarter financial results, business developments and second quarter 2009 financial guidance, 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 888-742-2024 (Domestic) or 706-643-0033 (International) and reference Conference ID #96095225, or go to OraSure Technologies' web site, [www.orasure.com](http://www.orasure.com), and click on the Investor Info link. 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, 2009, by dialing 800-642-1687 (Domestic) or 706-645-9291 (International) and entering the Conference ID #96095225.

### **About OraSure Technologies**

OraSure Technologies develops, manufactures and markets oral fluid specimen collection devices and tests and other diagnostic products using proprietary technologies, including immunoassays and other in vitro diagnostic tests and other medical devices. These products are sold in the United States and certain foreign countries to clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, distributors, government agencies, physicians' offices, and commercial and industrial entities. For more information on the Company, please visit [www.orasure.com](http://www.orasure.com).

### **Important Information**

This press release contains certain forward-looking statements, including with respect to revenues, expenses, net income, earnings/loss per share and products. Actual results could be significantly different. Factors that could affect results include the 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; changes in relationships, including disputes or disagreements, with strategic partners 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 and success of direct sales efforts; inventory levels at distributors and other customers; impact of competitors, competing products and technology changes; 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 and extended shelf life; continued bulk purchases by customers, including governmental agencies, and the ability to fully deploy those purchases in a timely manner; 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 product components; availability of related products produced by third parties or products required for use of our products; 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; history of losses and ability to achieve sustained profitability and ability to utilize net operating loss carryforwards 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 changes in international funding sources; loss or impairment of sources of capital; ability to meet financial covenants in agreements with financial institutions; ability to retain qualified personnel; exposure to patent infringement, 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; ability to identify, complete and realize the full benefits of potential acquisitions; and general political, business and economic conditions. These and other factors are discussed more fully in the Securities and Exchange Commission ("SEC") filings of OraSure Technologies, including its registration statements, its Annual Report on Form 10-K for the year ended December 31, 2008, its Quarterly Reports on Form 10-Q, and its other filings with the SEC. Although forward-looking statements help to provide complete 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.

<sup>1</sup> GAAP is defined as U.S. Generally Accepted Accounting Principles.

Source: OraSure Technologies, Inc.

OraSure Technologies, Inc.  
Ronald H. Spair  
Chief Financial Officer  
610-882-1820  
[Investorinfo@orasure.com](mailto:Investorinfo@orasure.com)  
[www.orasure.com](http://www.orasure.com)