# **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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**CURRENT REPORT PURSUANT TO SECTION 13 OR 15(d)** OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): November 5, 2008

# OraSure Technologies, Inc. (Exact Name of Registrant as Specified in Charter)

Delaware (State or Other Jurisdiction of Incorporation)

001-16537 (Commission File Number)

36-4370966 (I.R.S. Employer Identification No.)

220 East First Street Bethlehem, Pennsylvania (Address of Principal Executive Offices)

18015-1360 (Zip Code)

Registrant's telephone number, including area code: 610-882-1820

ck the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the Registrant under any of the following isions:
Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 1.01 - Entry Into a Material Agreement.

#### **SSL Distribution Agreement**

OraSure Technologies, Inc. (the "Company") and SSL International plc ("SSL") are parties to a Distribution Agreement, dated as of June 1, 2005, as amended (the "Original Distribution Agreement"), pursuant to which the Company supplies to SSL, and SSL distributes in certain foreign countries, an over-the-counter product for the cryosurgical removal of common and plantar warts.

The Company and SSL entered into Amendment No. 2 to Distribution Agreement, dated as of November 30, 2007 ("Amendment No.2"), for the purpose of amending the Original Distribution Agreement to, among other things, establish a process for modifying the terms of the Original Distribution Agreement for years beyond 2008. The Company and SSL have executed a letter agreement, dated October 31, 2008 (the "Letter Agreement), in order to extend the deadline for completing negotiations on such modifications to the Distribution Agreement from November 30, 2008 to December 19, 2008. A copy of the Letter Agreement is attached as Exhibit 10 to this Form 8-K and is incorporated herein by reference.

#### **Abbott Distribution Agreement**

The Company and Abbott Laboratories ("Abbott") previously entered into a Supply and Distribution Agreement, dated as of February 11, 2005, as amended (the "Supply and Distribution Agreement"), pursuant to which the Company agreed to supply, and Abbott agreed to distribute, the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test ("OraQuick *ADVANCE*® Test") on an exclusive basis to hospitals and reference laboratories and on a non-exclusive basis to physicians' offices in the U.S. On October 31, 2008, the parties entered into a Termination and Transition Agreement (the "Transition Agreement"), pursuant to which the parties have mutually agreed to terminate the Supply and Distribution Agreement on December 31, 2008. As a result, beginning in 2009, the Company will directly sell the OraQuick *ADVANCE*® Test to hospitals and reference laboratories and continue to sell to physicians' offices through distributors. Pursuant to the Transition Agreement, the Company will pay Abbott a termination fee and Abbott will assist in transitioning its OraQuick® business to the Company. A copy of a press release announcing the transition is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

#### Item 2.02 – Results of Operations and Financial Condition.

On November 5, 2008, OraSure Technologies, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2008 and providing an update on financial guidance for the fourth quarter of 2008. A copy of the press release is attached as Exhibit 99.2 to this Form 8-K and is incorporated herein by reference.

## $Item\ 9.01-Financial\ Statements\ and\ Exhibits.$

# (d) Exhibits

Exhibit Number 10	<u>Description</u> Letter Agreement, dated October 31, 2008, between OraSure Technologies, Inc. and SSL International plc.
99.1	Press Release, dated November 5, 2008, announcing the termination of the Supply and Distribution Agreement between OraSure Technologies, Inc. and Abbott Laboratories.
99.2	Press Release, dated November 5, 2008, announcing financial results of OraSure Technologies, Inc. for the quarter ended September 30, 2008 and providing an update on financial guidance for the fourth quarter 2008.

#### **Signatures**

Pursuant to the requirements of the Securities and Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

ORASURE TECHNOLOGIES, INC.

Date: November 5, 2008

By: /s/ Jack E. Jerrett

Jack E. Jerrett

Senior Vice President, General Counsel and Secretary

## **Index to Exhibits**

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October 31, 2008

#### Via Federal Express

Mr. Robert Kaiser SSL Americas, Inc. 3585 Engineering Drive, Suite 200 Norcross, GA 30092

Re: Distribution Agreement, dated as of June 1, 2005, as

amended (the "Agreement"), between OraSure Technologies,

Inc. ("OraSure") and SSL International plc ("SSL")

#### Dear Mr. Kaiser:

Reference is made to Amendment No. 2 to Distribution Agreement, dated as of November 30, 2007 ("Amendment No. 2"), between OraSure and SSL. The purpose of this letter is to acknowledge the parties' agreement that the reference to November 30, 2008 in Section 10 of Amendment No. 2 is hereby changed to December 19, 2008. Except as amended by this letter, the above-referenced Distribution Agreement (including Amendment No.2 thereto) shall remain in full force and effect.

If the foregoing correctly sets forth our agreement, please indicate that by signing the duplicate copy of this letter in the space provided below and returning it to the undersigned. Thank you.

Sincerely,

OraSure Technologies, Inc.

/s/ Douglas A. Michels

By: Douglas A. Michels Title: President and CEO

Agreed to and accepted:

SSL International plc

/s/ Robert Kaiser

By: Robert Kaiser Title: Attorney

> 220 East First Street, Bethlehem, PA 18015-1360 Phone: 610.882.1820 www.orasure.com



Investor Contact: Ronald H. Spair Chief Financial Officer 610-882-1820 investorinfo@orasure.com Media Contact: Jennifer Moritz Zer0 to 5ive for OraSure Technologies 917-748-4006 jmoritz@0to5.com

# OraSure Technologies to Sell OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test Directly to U.S. Hospitals

- OraSure Sales Force Expansion will Support Hospital Customers -

**BETHLEHEM, PA** – November 5, 2008 – (BW HealthWire) – OraSure Technologies, Inc. (NASDAQ: OSUR), a market leader in oral fluid diagnostics, today announced that it will begin to sell its OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test directly into the U.S. hospital market beginning in 2009. In recent years, the U.S. hospital market has received this product through an exclusive distribution arrangement with Abbott.

In early 2005, OraSure and Abbott entered into an agreement under which Abbott has distributed OraQuick *ADVANCE*® on an exclusive basis to U.S. hospitals and reference laboratories and on a non-exclusive basis to the U.S. physician office market. Pursuant to a transition agreement recently executed by the parties, the distribution agreement will terminate effective as of the end of 2008. Abbott and OraSure will work to implement a transition of this business directly to OraSure.

In anticipation of the transition, OraSure has started to increase the size of its hospital sales force along with inside sales, customer service and sales support resources. The direct sales force will be responsible for selling OraQuick *ADVANCE*® to U.S. hospital customers along with other future products, including the OraQuick® Hepatitis C test recently submitted to the FDA for pre-market approval. The U.S. physician office market will continue to be served through distributors.

"We have enjoyed a successful relationship with Abbott and appreciate all of Abbott's efforts to successfully build our OraQuick *ADVANCE*® business in the U.S. hospital market," said Douglas A. Michels, President and CEO of OraSure Technologies. "Beginning in 2009, OraSure will sell OraQuick *ADVANCE*® directly to the U.S. hospital and reference laboratory markets. Our hospital business is extremely important and we anticipate continued growth in this market with both current and future products. We are eager to continue the development of even closer relationships with our hospital customers."

The transition will result in incremental expense related to sales force recruitment, infrastructure expansion and payment of a termination fee to Abbott pursuant to the transition agreement. In addition, OraSure sales to Abbott in the fourth quarter of 2008 are expected to be somewhat lower than normal as Abbott reduces its inventory level of OraQuick *ADVANCE*® as part of the transition. Additional information regarding the transition will be provided during the Company's third quarter earnings call scheduled for 5:00 p.m. EST (2:00 p.m. PST) today.

OraQuick *ADVANCE*<sup>®</sup> is the only rapid, point-of-care test for the detection of antibodies to both HIV-1 and HIV-2 within twenty minutes that is approved by the U.S. Food and Drug Administration (FDA) for use on oral fluid, finger-stick or venipuncture whole blood, and plasma specimens. The test is also CLIA (Clinical Laboratory Improvements Amendments Act of 1988) waived for all specimen types except plasma. OraSure commercially launched the OraQuick *ADVANCE*<sup>®</sup> test in October 2004.

#### **About OraSure Technologies**

OraSure Technologies develops, manufactures and markets oral fluid specimen collection devices using proprietary oral fluid technologies, diagnostic products including immunoassays and other in vitro diagnostic tests, and other medical devices. These products are sold in the United States as well as internationally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, distributors, government agencies, physicians' offices, and commercial and industrial entities.

OraSure Technologies is the leading supplier of oral-fluid collection devices and assays to the life insurance industry and public health markets for the detection of antibodies to HIV. In addition, the Company supplies oral-fluid testing solutions for drugs of abuse testing. For more information on the Company, please go to www.orasure.com.

#### **Important Information**

This press release contains certain forward-looking statements, including with respect to markets, product sales and distribution, sales personnel, expenses and revenues. Actual results could be significantly different. Factors that could affect results include the ability to market and sell products; 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; inventory levels at distributors and other customers; impact of replacing distributors; 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; 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; 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, 2007, 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.



Company Contact:

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

#### **OraSure Technologies Announces 2008 Third Quarter Results**

**BETHLEHEM, PA** – November 5, 2008 – (BW HealthWire) – OraSure Technologies, Inc. (NASDAQ:OSUR), a market leader in oral fluid diagnostics, today announced quarterly revenues of \$16.9 million for the three months ended September 30, 2008, compared to \$21.4 million in revenues for the three months ended September 30, 2007. Sales of the Company's OraQuick *ADVANCE®* rapid HIV-1/2 antibody test increased 18% for the third quarter 2008. This increase was offset primarily by an expected decrease in sales of the Company's over-the-counter ("OTC") cryosurgical products.

The Company's net loss was \$1.8 million, or \$0.04 per share for the third quarter of 2008, compared to net income of \$4,000 and break-even earnings per share for the third quarter of 2007. This decrease was primarily caused by reduced sales in the current quarter.

"Sales of our OraQuick *ADVANCE*® rapid HIV test were strong during the current quarter, and we have taken steps to drive stronger sales performance in our other product lines," said Douglas A. Michels, President and CEO of OraSure Technologies. "As previously announced, we are terminating our distribution agreement with Abbott Laboratories and will begin selling OraQuick *ADVANCE*® directly to U.S. hospitals in 2009. We expect our OraQuick® business will continue to grow with the transition to this direct sales model. We also continue to make great progress against our strategic objectives, the most significant of which was the recent submission of a pre-market approval application to the FDA for our OraQuick® HCV test."

For the nine months ended September 30, 2008, the Company recorded revenues of \$53.9 million, a decrease of 14% when compared to revenues of \$62.9 million for the nine months ended September 30, 2007. The Company recorded a net loss of \$2.0 million or \$0.04 per share, for the nine months ended September 30, 2008, compared to net income of \$2.4 million, or \$0.05 per share on a fully-diluted basis, for the nine months ended September 30, 2007.

Gross margin in both the third quarter and the nine months ended September 30, 2008 was 58% compared with 60% in the third quarter of 2007 and 62% in the nine months ended September 30, 2007. Margins in the current periods were primarily impacted by an unfavorable product mix.

Operating expenses for the third quarter of 2008 decreased \$670,000 to \$13.1 million, from \$13.7 million in the comparable period in 2007 primarily due to lower legal costs in the current three-month period. Operating expenses for the nine months ended September 30, 2008 were \$41.7 million, compared to \$38.5 million for the comparable period in 2007. The increase in year-to-date operating expenses is attributable to higher research and development costs associated with the Company's OraQuick® HIV OTC and OraQuick® HCV clinical development programs, partially offset by a decline in general and administrative expenses largely due to decreased legal costs.

Cash, cash equivalents and short-term investments were \$85.4 million and working capital was \$99.5 million at September 30, 2008, compared to \$95.6 million and \$105.6 million, respectively, at December 31, 2007. Cash flow used in operating activities for the nine months ended September 30, 2008 was \$3.7 million compared to \$7.8 million provided by operations for the comparable period in 2007. During the third quarter of 2008, the Company purchased \$3.1 million of stock under its previously announced stock repurchase plan.

#### Fourth Quarter and Full Year 2008 Outlook

The Company expects revenues of \$16.0 to \$16.5 million in the fourth quarter of 2008 with a loss per share of approximately \$0.10. Included in the loss per share are charges associated with the transition of hospital and other business under the agreement with Abbott Laboratories and a \$1.0 million charge associated with a milestone payment related to the filing of a pre-market approval application with the FDA for the Company's OraQuick® HCV test.

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

Unaudited

		nths ended	Nine months ended September 30,		
		nber 30, 2007	2008	2007	
Results of Operations					
Revenues	\$16,860	\$21,415	\$ 53,895	\$62,877	
Cost of products sold	7,145	8,647	22,393	24,122	
Gross profit	9,715	12,768	31,502	38,755	
Operating expenses:					
Research and development	4,167	3,672	14,864	9,896	
Sales and marketing	5,327	4,979	15,505	14,999	
General and administrative	3,562	5,074	11,293	13,637	
Total operating expenses	13,056	13,725	41,662	38,532	
Operating income (loss)	(3,341)	(957)	(10,160)	223	
Other income, net	588	1,085	7,078	4,443	
Income tax provision (benefit)	(991)	124	(1,079)	2,221	
Net income (loss)	\$ (1,762)	\$ 4	\$ (2,003)	\$ 2,445	
Earnings (loss) per share:		<del></del>	<del></del>		
Basic and Diluted	\$ (0.04)	\$ —	\$ (0.04)	\$ 0.05	
Weighted average shares:		<del></del>	<del></del>		
Basic	46,692	46,341	46,774	46,393	
Diluted	46,692	46,988	46,774	46,893	

		Three months ended September 30,			
	Dol	Dollars		Percenta Total Rev	
	2008	2007	% <u>Change</u>	2008	2007
Market Revenues					
Infectious disease testing	\$ 9,743	\$ 8,233	18%	58%	38%
Substance abuse testing	3,581	4,070	(12)	21	19
Cryosurgical systems	1,671	6,738	(75)	10	31
Insurance risk assessment	1,163	1,620	(28)	7	8
Product revenues	16,158	20,661	(22)	96	96
Licensing and product development	702	754	(7)	4	4
Total revenues	\$16,860	\$21,415	(21)%	100%	100%

		Nine months ended September 30,						
	Dolla	Dollars			Percentage of Total Revenues			
	2008	2007	% <u>Change</u>	2008	2007			
Market Revenues								
Infectious disease testing	\$29,260	\$26,350	11%	54%	42%			
Substance abuse testing	10,554	12,396	(15)	20	20			
Cryosurgical systems	7,726	18,190	(58)	14	29			
Insurance risk assessment	4,395	3,859	14	8	6			
Product revenues	51,935	60,795	(15)	96	97			
Licensing and product development	1,960	2,082	(6)	4	3			
Total revenues	\$53,895	\$62,877	(14)%	100%	100%			
		onths ended mber 30, %		Nine months ended September 30,		%		
	2008	2007	<u>Change</u>	2008	2007	Change		
OraQuick® Revenues								
Direct to U.S. Public Health	\$ 6,147	\$ 4,492	37%	\$19,263	\$14,339	34%		
Abbott	1,799	2,159	(17)	5,489	6,087	(10)		
SAMHSA/CDC	10	30	(67)	10	1,464	(99)		
International	957	850	13	2,303	2,110	9		
Total OraQuick® revenues	<u>\$ 8,913</u>	\$ 7,531	18%	\$27,065	\$24,000	13%		
		Three months ended September 30,		%         September 30,           Change         2008         2007		%		
Intercept® Revenues		2007	Change	2000	2007	Change		
Workplace testing	\$ 1,193	\$ 1,845	(35)%	\$ 3,480	\$ 5,368	(35)%		
Criminal Justice	637	641	(1)	1,965	1,948	1		
International	481	525	(8)	1,570	1,757	(11)		
Direct	303	273	11	904	739	22		
Total Intercept® revenues	\$ 2,614	\$ 3,284	(20)%	\$ 7,919	\$ 9,812	(19)%		
		Three months ended September 30,				Nine months ended September 30,		%
	2008	2007	Change	2008	2007	Change		
Cryosurgical Systems Revenues								
Professional domestic	\$ 903	\$ 1,028	(12)%	\$ 2,942	\$ 3,441	(15)%		
Professional international	401	574	(30)	1,802	1,551	16		
OTC domestic	_	2,453	(100)	_	5,587	(100)		
OTC international	367	2,683	(86)	2,982	7,611	(61)		
Total cryosurgical systems revenues	\$ 1,671	\$ 6,738	(75)%	\$ 7,726	\$18,190	(58)%		

		Unaudited		
	Septe	September 30, 2008		nber 31, 2007
Balance Sheets				
<u>Assets</u>				
Cash, cash equivalents and short-term investments	\$	85,382	\$	95,566
Accounts receivable, net		12,381		11,296
Inventories		10,238		9,410
Current portion of deferred income taxes		2,676		5,061
Other current assets		1,193		2,456
Property and equipment, net		21,373		20,911
Deferred income taxes		21,108		17,266
Other non-current assets		4,668		5,387
Total assets	\$	159,019	\$	167,353
<u>Liabilities and Stockholders' Equity</u>				
Current portion of long-term debt	\$	558	\$	557
Accounts payable		2,534		5,616
Accrued expenses		9,228		11,995
Long-term debt		8,441		8,818
Other liabilities		11		312
Stockholders' equity		138,247		140,055
Total liabilities and stockholders' equity	\$	159,019	\$	167,353
	As of September 30,			
	2008 2007			

	 As of September 30,		
	2008		2007
Additional Financial Data			
Capital expenditures	\$ 1,949	\$	4,281
Depreciation and amortization	\$ 2,122	\$	1,997
Purchase and retirement of common stock	\$ 3,052		_
Accounts receivable – days sales outstanding	63 days		52 days

#### **Conference Call**

The Company will host a conference call and audio webcast today to discuss the Company's 2008 third quarter financial results, business developments and the Company's 2008 fourth quarter outlook, beginning 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 Operating Officer and Chief Financial Officer. The call will include remarks by management and a question and answer session.

In order to listen to the conference call, please dial 888-742-2024 (Domestic) or 706-643-0033 (International) and reference 69750537 or go to OraSure Technologies' web site, <a href="www.orasure.com">www.orasure.com</a>, 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 November 11, 2008, by dialing 800-642-1687 (Domestic) or 706-645-9291 (International) and entering the Conference ID #69750537.

#### **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.

#### **Important Information**

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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.