

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

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 9, 2005

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

Check 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 provisions:

- 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))
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Item 2.02 – Results of Operations and Financial Condition

On November 9, 2005, OraSure Technologies, Inc. issued a press release announcing its financial results for the quarter and nine months ended September 30, 2005. A copy of the press release is attached as Exhibit 99 to this Form 8-K and is incorporated herein by reference.

Item 9.01 – Financial Statements and Exhibits**(c) Exhibits**

<u>Exhibit Number</u>	<u>Description</u>
99	Press Release dated November 9, 2005, announcing financial results of OraSure Technologies, Inc. for the quarter and nine months ended September 30, 2005.

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 9, 2005

By: _____ /s/ *JACK E. JERRETT*
Jack E. Jerrett
Senior Vice President, General Counsel and Secretary

Index to Exhibits

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OraSure Technologies, Inc.

diagnostic solutions for the new millennium

Company Contact:

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Chief Financial Officer
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www.orasure.com

OraSure Announces Record Third Quarter Financial Results

- Increases Full-Year Earnings Guidance -

BETHLEHEM, PA – November 9, 2005 – (BW HealthWire) – OraSure Technologies, Inc. (Nasdaq NM:OSUR), a market leader in oral fluid diagnostics, today announced record revenues of \$18.1 million for the quarter ended September 30, 2005, representing a 28% increase over the \$14.2 million in revenues recorded for the comparable period in 2004.

The Company's net income was \$3.8 million, or \$0.08 per share on a basic and fully-diluted basis, for the third quarter of 2005. These results compare to a net loss of \$294,000, or \$(0.01) per share on a basic and fully-diluted basis, reported for the third quarter of 2004.

For the nine months ended September 30, 2005, the Company had revenues of \$51.3 million, a 29% increase over revenues of \$39.8 million for the nine months ended September 30, 2004. The Company recorded net income of \$6.8 million, or \$0.15 per share on a basic and fully-diluted basis, for the nine months ended September 30, 2005, compared to a net loss of \$314,000, or \$(0.01) per share on a basic and fully-diluted basis, for the comparable period in 2004.

"We are certainly very pleased with the Company's financial results for the third quarter," said Douglas A. Michels, President and Chief Executive Officer of OraSure Technologies. "Our performance this quarter was driven primarily by continued increases in sales to the infectious disease and substance abuse testing markets. As a result of our continued earnings growth, we are increasing full-year earnings per share guidance to \$0.20 per share on a basic and fully-diluted basis, without giving effect to the impact of the potential recognition of a portion of a deferred tax asset."

The revenue increase for the third quarter was primarily attributable to increased sales of the Company's OraQuick® ADVANCE™ rapid HIV-1/2 antibody test and Intercept® oral fluid drug test.

Gross margin in the third quarter was 64% compared to 60% in the third quarter of 2004. Gross margin was positively affected by more efficient utilization of the Company's manufacturing facilities and lower inventory scrap expense.

Operating expenses for the third quarter of 2005 decreased to approximately \$8.4 million from approximately \$8.9 million in the comparable period in 2004. This decrease was primarily attributable to a reduction in research and development expenses and a reduction in consulting expenses, partially offset by increased charges for non-cash stock-based compensation. Operating expenses for the nine months ended September 30, 2005 were \$25.2 million, compared to \$24.2 million for the comparable period in 2004.

The Company's results for the nine months ended September 30, 2005 reflect a \$1.5 million charge for a reserve related to the value of inventory and certain fixed assets for the UPlink® rapid point-of-care oral fluid drug detection system. Excluding this charge, the Company's net income for the nine months ended September 30, 2005 would have been approximately \$8.3 million, or \$0.18 per share on a basic and fully-diluted basis, and gross margin would have been 63%.

Cash, cash equivalents and short-term investments totaled approximately \$75.3 million and working capital was approximately \$80.0 million at September 30, 2005, compared to approximately \$66.7 million and \$68.9 million, respectively, at December 31, 2004.

Cash flow from operations was approximately \$3.6 million for the third quarter of 2005, up substantially from the \$342,000 reported for the third quarter of 2004. Cash flow from operations for the nine months ended September 30, 2005 was \$8.5 million, compared to \$2.2 million for the comparable period in 2004.

OraSure expects total revenues for 2006 to increase by 25% over 2005 levels. In addition, OraSure expects to achieve fully-taxed full-year net income for 2006 in the range of \$0.18 to \$0.20 per share, before giving effect to stock option expensing which will become effective in 2006 and will reduce GAAP earnings per share. The magnitude of the charge for stock option expensing will not be known or disclosed until the Company reports its full year 2005 financial results in February 2006.

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

	Three months ended September 30,		Nine months ended September 30,	
	2005	2004	2005	2004
Results of Operations				
Revenues	\$18,077	\$14,176	\$51,335	\$39,799
Cost of products sold	6,432	5,722	20,773	16,437
Gross profit	11,645	8,454	30,562	23,362
Operating expenses:				
Research and development	1,298	1,465	3,750	4,745
Sales and marketing	3,965	3,956	12,289	11,388
General and administrative	3,168	3,514	9,132	8,086
Total operating expenses	8,431	8,935	25,171	24,219
Operating income (loss)	3,214	(481)	5,391	(857)
Other income, net	594	187	1,421	543
Net income (loss)	\$ 3,808	\$ (294)	\$ 6,812	\$ (314)
Basic and diluted earnings (loss) per share	\$ 0.08	\$ (0.01)	\$ 0.15	\$ (0.01)
Weighted average shares:				
Basic	45,372	44,539	44,936	44,426
Diluted	46,676	44,539	45,850	44,426

	Nine months ended September 30,	
	2005	2004
Reconciliation of Non-GAAP Financial Measures		
Net income (loss) – before UPlink® charge	\$8,299	\$ (314)
UPlink® charge	1,487	—
Net income (loss) – GAAP basis	\$6,812	\$ (314)
Basic and diluted earnings (loss) per share – before UPlink® charge	\$ 0.18	\$(0.01)
UPlink® charge	0.03	—
Basic and diluted earnings (loss) per share – GAAP basis	\$ 0.15	\$(0.01)
Gross margin – before UPlink® charge	63%	59%
UPlink® charge	3%	—
Gross margin – GAAP basis	60%	59%

Three months ended September 30,

	Dollars		% Change	Percentage of Total Revenues	
	2005	2004		2005	2004
Market Revenues					
Infectious disease testing	\$ 7,037	\$ 3,702	90%	39%	26%
Substance abuse testing	3,595	2,745	31	20	19
Cryosurgical systems	6,143	5,831	5	34	41
Insurance risk assessment	1,275	1,808	(29)	7	13
Product revenues	18,050	14,086	28	100	99
Licensing and product development	27	90	(70)	—	1
Total revenues	\$18,077	\$14,176	28%	100%	100%

Nine months ended September 30,

	Dollars		% Change	Percentage of Total Revenues	
	2005	2004		2005	2004
Market Revenues					
Infectious disease testing	\$19,672	\$11,009	79%	38%	28%
Substance abuse testing	10,060	7,329	37	20	18
Cryosurgical systems	16,002	15,162	6	31	38
Insurance risk assessment	5,364	5,997	(11)	11	15
Product revenues	51,098	39,497	29	100	99
Licensing and product development	237	302	(22)	—	1
Total revenues	\$51,335	\$39,799	29%	100%	100%

	September 30, 2005	December 31, 2004
Balance Sheets		
Assets		
Cash, cash equivalents and short-term investments	\$ 75,297	\$ 66,723
Accounts receivable, net	10,233	7,074
Inventories	4,666	4,952
Other current assets	1,188	1,195
Property and equipment, net	5,536	5,551
Other non-current assets	3,519	2,569
Total assets	\$ 100,439	\$ 88,064
Liabilities and Stockholders' Equity		
Current portion of long-term debt	\$ 686	\$ 1,123
Accounts payable	1,974	2,360
Accrued expenses	8,726	7,552
Long-term debt, less current portion	933	1,334
Other liabilities	228	118
Stockholders' equity	87,892	75,577
Total liabilities and stockholders' equity	\$ 100,439	\$ 88,064

Non-GAAP Financial Measures

Net income (loss) - before UPlink[®] charge, earnings (loss) per share - before UPlink[®] charge, and gross margin - before UPlink[®] charge, each exclude the impact of the \$1.5 million UPlink[®] charge. These financial measures should not be considered an alternative to net income (loss), earnings (loss) per share, or gross margin, respectively, which are indicators of operating performance determined in accordance with generally accepted accounting principles (GAAP). OraSure Technologies believes that net income (loss) - before UPlink[®] charge, earnings (loss) per share - before UPlink[®] charge, and gross margin - before UPlink[®] charge, although non-GAAP financial measures, are also useful and meaningful to investors because they provide investors with the Company's underlying earnings performance as another criterion in making their investment decisions. OraSure's management also uses these calculations in measuring certain corporate performance goals. Other companies may use different measures to present financial information.

Conference Call

The Company will host a conference call and audio webcast today to discuss the Company's third quarter 2005 financial results and to provide an update on major business objectives, 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 Financial Officer. The call will include 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), or go to OraSure Technologies' Web site, 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 November 14, 2005, by dialing 800-642-1687 (Domestic) or 706-645-9291 (International) and entering the Conference ID #1701906.

About OraSure Technologies

OraSure Technologies develops, manufactures and markets oral fluid specimen collection devices and tests and other diagnostic products using its 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.

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Important Information

This press release contains certain forward-looking statements, including with respect to revenues, net income, expenses and products. Actual results could be significantly different. Factors that could affect results include the ability to market products; impact of competitors, competing products and technology changes; ability to develop, commercialize and market new products; market acceptance of oral fluid testing products and other new products or technology; ability to fund research and development and other projects 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; ability to obtain, and timing of obtaining, necessary regulatory approvals; ability to comply with applicable regulatory requirements; history of losses and ability to achieve sustained profitability; volatility of our 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; loss or impairment of sources of capital; ability to meet financial covenants in agreements with financial institutions; ability to retain qualified personnel; exposure to product liability, patent infringement, and other types of litigation; changes in international, federal or state laws and regulations; changes in relationships with strategic partners and reliance on strategic partners for the performance of critical activities under collaborative arrangements; 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 complete consolidation or restructuring activities; 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, 2004, 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.

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