

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

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**FORM 8-K**

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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): August 2, 2005

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**OraSure Technologies, Inc.**

(Exact Name of Registrant as Specified in Charter)

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**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**

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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 August 2, 2005, OraSure Technologies, Inc. issued a press release announcing its financial results for the quarter and six months ended June 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 August 2, 2005, announcing financial results of OraSure Technologies, Inc. for the quarter and six months ended June 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: August 2, 2005

By: */s/ Jack E. Jerrett*

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Jack E. Jerrett  
Senior Vice President, General Counsel  
and Secretary

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**Index to Exhibits**

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99	Press Release dated August 2, 2005, announcing financial results of OraSure Technologies, Inc. for the quarter and six months ended June 30, 2005.

**OraSure Technologies, Inc.**

diagnostic solutions for the new millennium

Company Contact:

Ronald H. Spair  
Chief Financial Officer  
610-882-1820

[Investorinfo@orasure.com](mailto:Investorinfo@orasure.com)

[www.orasure.com](http://www.orasure.com)

**OraSure Announces Record Second Quarter Financial Results**

*- Increases Full-Year Earnings Guidance -*

**BETHLEHEM, PA** – August 2, 2005 – (BW HealthWire) – OraSure Technologies, Inc. (Nasdaq NM:OSUR), a market leader in oral fluid diagnostics, today announced record revenues of \$17.4 million for the quarter ended June 30, 2005, representing a 32% increase over the \$13.2 million in revenues recorded for the comparable period in 2004.

The Company's net income was \$1.4 million, or \$0.03 per share on a basic and fully-diluted basis, for the second quarter of 2005. These results compare to net income of \$142,000, or \$0.00 per share on a basic and fully-diluted basis, reported in the second quarter of 2004.

For the six months ended June 30, 2005, the Company had revenues of \$33.3 million, a 30% increase over revenues of \$25.6 million for the six months ended June 30, 2004. The Company recorded net income of \$3.0 million, or \$0.07 per share on a basic and fully-diluted basis, for the six months ended June 30, 2005, compared to a net loss of \$20,000, or \$(0.00) per share on a basic and fully-diluted basis, for the comparable period in 2004.

"We are extremely pleased with the Company's financial results for the second quarter of 2005," said Douglas A. Michels, President and Chief Executive Officer of OraSure Technologies. "Our strong performance this quarter was driven primarily by increased sales to the infectious disease and substance abuse testing markets. I believe we are well positioned to achieve our financial goals for the full year. As a result of the earnings growth experienced, we are increasing our full-year earnings per share guidance to \$0.14 to \$0.16 per share on a basic and fully-diluted basis."

The revenue increase for the second 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. These increases were partially offset by lower sales to the cryosurgical systems market.

The Company's second quarter results 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. During the first half of 2005, the Company explored the possible transition of UPlink® manufacturing to Dräger Safety, the Company's distributor in the roadside testing market. The Company was not able to reach an agreement with Dräger Safety or determine an alternative outlet for this product and, therefore, has recorded a reserve against the carrying value of the related assets.

Excluding this charge, the Company's net income was approximately \$3.0 million, or \$0.06 per share on a basic and fully-diluted basis, in the second quarter of 2005, and, for the six months ended June 30, 2005, the Company's net income was approximately \$4.5 million, or \$0.10 per share on a basic and fully-diluted basis.

Gross margin in the second quarter was 54% compared to 58% in the second quarter of 2004. Excluding the UPlink® charge, gross margin was 63% for the quarter. The adjusted gross margin was positively affected by more efficient utilization of the Company's manufacturing capacity.

Operating expenses for the second quarter of 2005 increased to approximately \$8.5 million from approximately \$7.7 million in the comparable period in 2004. This increase was primarily attributable to increased charges for non-cash stock-based compensation and higher staffing related charges in both the sales and marketing and general and administrative areas, partially offset by a reduction in research and development expenses. Operating expenses for the six months ended June 30, 2005 were \$16.7 million, compared to \$15.3 million for the comparable period in 2004.

Cash, cash equivalents and short-term investments totaled approximately \$71.5 million and working capital equaled approximately \$74.8 million at June 30, 2005, compared to approximately \$66.7 million and \$68.9 million, respectively, at December 31, 2004.

Cash flow from operations was approximately \$4.3 million for the second quarter of 2005, up substantially from the \$1.7 million reported for the second quarter of 2004. Cash flow from operations for the six months ended June 30, 2005 was \$4.8 million, compared to \$1.9 million for the comparable period in 2004.

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

**Results of Operations**

	Three months ended June 30,		Six months ended June 30,	
	2005	2004	2005	2004
Revenues	\$17,430	\$13,215	\$33,258	\$25,623
Cost of products sold	7,970	5,525	14,340	10,715
Gross profit	9,460	7,690	18,918	14,908
Operating expenses:				
Research and development	1,254	1,514	2,453	3,281
Sales and marketing	4,456	3,781	8,324	7,431
General and administrative	2,788	2,446	5,964	4,572
Total operating expenses	8,498	7,741	16,741	15,284
Operating income (loss)	962	(51)	2,177	(376)
Other income, net	481	193	827	356
Net income (loss)	\$ 1,443	\$ 142	\$ 3,004	\$ (20)
Basic and diluted earnings (loss) per share	\$ 0.03	\$ 0.00	\$ 0.07	\$ (0.00)
Weighted average shares:				
Basic	44,784	44,465	44,715	44,368
Diluted	45,872	45,334	45,475	44,368

**Reconciliation of Non-GAAP Financial Measures**

	Three months ended June 30,		Six months ended June 30,	
	2005	2004	2005	2004
Net income (loss) – before UPlink® charge	\$2,956	\$ 142	\$4,517	\$ (20)
UPlink® charge	1,513	—	1,513	—
Net income (loss) – GAAP basis	\$1,443	\$ 142	\$3,004	\$ (20)
Basic and diluted earnings (loss) per share – before UPlink® charge	\$ 0.06	\$0.00	\$ 0.10	\$(0.00)
UPlink® charge	0.03	—	0.03	—
Basic and diluted earnings (loss) per share – GAAP basis	\$ 0.03	\$0.00	\$ 0.07	\$(0.00)
Gross margin – before UPlink® charge	63%	58%	61%	58%
UPlink® charge	9%	—	4%	—
Gross margin – GAAP basis	54%	58%	57%	58%

## Market Revenues

	Three months ended June 30,				
	Dollars		% Change	Percentage of Total Revenues	
	2005	2004		2005	2004
Insurance risk assessment	\$ 1,974	\$ 1,905	4%	11%	14%
Infectious disease testing	7,509	3,970	89	43	30
Substance abuse testing	3,540	2,389	48	20	18
Cryosurgical systems	4,281	4,858	(12)	25	37
Product revenues	17,304	13,122	32	99	99
Licensing and product development	126	93	35	1	1
Total revenues	\$17,430	\$13,215	32%	100%	100%

## Market Revenues

	Six months ended June 30,				
	Dollars		% Change	Percentage of Total Revenues	
	2005	2004		2005	2004
Insurance risk assessment	\$ 4,089	\$ 4,190	(2)%	12%	16%
Infectious disease testing	12,635	7,307	73	38	29
Substance abuse testing	6,465	4,583	41	19	18
Cryosurgical systems	9,859	9,331	6	30	36
Product revenues	33,048	25,411	30	99	99
Licensing and product development	210	212	(1)	1	1
Total revenues	\$33,258	\$25,623	30%	100%	100%

## Balance Sheets

	June 30, 2005	December 31, 2004
<b>Assets</b>		
Cash, cash equivalents and short-term investments	\$71,463	\$ 66,723
Accounts receivable, net	8,753	7,074
Inventories	4,127	4,952
Other current assets	1,193	1,195
Property and equipment, net	5,144	5,551
Other non-current assets	2,172	2,569
Total assets	\$92,852	\$ 88,064
<b>Liabilities and Stockholders' Equity</b>		
Current portion of long-term debt	\$ 905	\$ 1,123
Accounts payable	2,009	2,360
Accrued expenses	7,800	7,552
Long-term debt, less current portion	993	1,334
Other liabilities	250	118
Stockholders' equity	80,895	75,577
Total liabilities and stockholders' equity	\$92,852	\$ 88,064



## **Non-GAAP Financial Measures**

Net income - 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 second 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](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 August 5, 2005, by dialing 800-642-1687 (Domestic) or 706-645-9291 (International) and entering the Conference ID #7819208.

## **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](http://www.orasure.com).

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**Important Information**

This press release contains certain forward-looking statements, including with respect to revenues, net income 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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