

---

# 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 2, 2004

---

## 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 Securities 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 2.02 – Results of Operations and Financial Condition**

On November 2, 2004, OraSure Technologies, Inc. issued a press release announcing its financial results for the quarter and nine months ended September 30, 2004. 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 2, 2004, announcing financial results of OraSure Technologies, Inc. for the quarter and nine months ended September 30, 2004.

## 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 2, 2004

By: /s/ Jack E. Jerrett

---

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

---

**Index to Exhibits**

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
99	Press Release dated November 2, 2004, announcing financial results of OraSure Technologies, Inc. for the quarter and nine months ended September 30, 2004.



**OraSure Technologies, Inc.**

diagnostic solutions for the new millennium

Investor Contact:

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

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

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

Media Contacts:

Ron Ticho or Jennifer Moritz  
Zero to Five  
610-360-0205 or 718-623-0355  
[rticho@orasure.com](mailto:rticho@orasure.com) or [jmoritz@0to5.com](mailto:jmoritz@0to5.com)

**OraSure Announces 2004 Third Quarter Results**

*- Company Reports Record Quarterly Revenues -*

*- Increases Full Year Revenue Estimate-*

**BETHLEHEM, PA** – November 2, 2004 – (BW HealthWire) – OraSure Technologies, Inc. (Nasdaq NM:OSUR), a market leader in oral fluid diagnostics, today announced its financial results for the quarter and nine months ended September 30, 2004.

Total revenues for the third quarter of 2004 increased 37% to \$14.2 million, compared to \$10.3 million for the quarter ended September 30, 2003. Product revenues for the third quarter increased 38% to \$14.1 million, compared to \$10.2 million in 2003. Both amounts represent record quarterly revenues for the Company. The Company recorded a net loss for the quarter of \$294,000, or \$(0.01) per share, compared to a net profit of \$53,000, or \$0.00 per share, in the third quarter of 2003.

For the nine months ended September 30, 2004, the Company had total revenues of \$39.8 million, a 39% increase over revenues of \$28.6 million for the nine months ended September 30, 2003. Product revenues for the nine months ended September 30, 2004 were \$39.5 million, or 41% higher than the \$28.0 million in product revenues recorded during the comparable period in 2003. The Company recorded a net loss of \$314,000, or \$(0.01) per share, for the nine months ended September 30, 2004, compared to a net loss of \$1.6 million, or \$(0.04) per share, for the comparable period in 2003.

“We are certainly very pleased with the Company’s performance during the third quarter of 2004,” said Douglas A. Michels, President and CEO of OraSure Technologies. “This is the seventh consecutive quarter of record revenues and our growth continues to be well balanced across our Infectious Disease, Substance Abuse and Cryosurgical product lines. We believe we are on track to achieve 2004 full year revenues of approximately \$54.0 million, and we now expect a loss for the year of approximately \$(0.03) per share.”

Gross margin in the third quarter of 2004 was approximately 60%, a decrease from the gross margin of approximately 61% recorded in the third quarter of 2003. Gross margin was positively affected by both the favorable resolution of an outstanding royalty obligation and more efficient utilization of the Company's manufacturing capacity, offset by a less favorable product sales mix and higher production costs associated with the Company's *UPlink*<sup>®</sup> oral fluid drug detection system, which was recently launched in Europe.

Operating expenses for the third quarter of 2004 increased to approximately \$8.9 million from approximately \$6.3 million in the comparable period in 2003. This increase was primarily attributable to higher advertising expenditures, staffing expenses, including CEO transition-related expenses, legal fees associated with the Schering-Plough patent litigation, and consulting fees, partially offset by a reduction in research and development expenses. Operating expenses for the nine months ended September 30, 2004 were \$24.2 million, compared to \$18.8 million for the comparable period in 2003.

Cash, cash equivalents and short-term investments totaled approximately \$65.5 million and working capital equaled approximately \$68.2 million at September 30, 2004, compared to approximately \$64.0 million and \$67.2 million, respectively, at December 31, 2003.

Cash flow from operations was approximately \$342,000 for the third quarter of 2004. This is the tenth consecutive quarter of positive cash flow from operations. Cash flow from operations for the nine months ended September 30, 2004 was approximately \$2.2 million.

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

	Three months ended September 30,		Nine months ended September 30,	
	2004	2003	2004	2003
<b>Results of Operations</b>				
Revenues	\$14,176	\$10,331	\$39,799	\$28,571
Cost of products sold	5,722	4,002	16,437	11,403
Gross profit	8,454	6,329	23,362	17,168
Operating expenses:				
Research and development	1,465	2,202	4,745	6,222
Sales and marketing	3,956	2,513	11,388	7,485
General and administrative	3,514	1,602	8,086	5,125
Total operating expenses	8,935	6,317	24,219	18,832
Operating income (loss)	(481)	12	(857)	(1,664)
Other income, net	187	41	543	94
Net income (loss)	\$ (294)	\$ 53	\$ (314)	\$ (1,570)
Basic and diluted net income (loss) per share	\$ (0.01)	\$ 0.00	\$ (0.01)	\$ (0.04)
Weighted average shares:				
Basic	44,539	38,666	44,426	38,444
Diluted	44,539	39,777	44,426	38,444

Three months ended September 30,

	Dollars		% Change	Percentage of Total Revenues	
	2004	2003		2004	2003
<b>Market Revenues</b>					
Insurance risk assessment	\$ 1,808	\$ 2,827	(36)%	13%	27%
Infectious disease testing	3,702	2,295	61	26	22
Substance abuse testing	2,745	1,801	52	19	18
Cryosurgical systems	5,831	3,298	77	41	32
Product revenues	14,086	10,221	38	99	99
Licensing and product development	90	110	(18)	1	1
Total revenues	\$14,176	\$10,331	37%	100%	100%

Nine months ended September 30,

	Nine months ended September 30,				
	Dollars			Percentage of Total Revenues	
	2004	2003	% Change	2004	2003
<b>Market Revenues</b>					
Insurance risk assessment	\$ 5,997	\$ 8,285	(28)%	15%	29%
Infectious disease testing	11,009	7,766	42	28	27
Substance abuse testing	7,329	5,234	40	18	18
Cryosurgical systems	15,162	6,717	126	38	24
	<u>39,497</u>	<u>28,002</u>	41	99	98
Product revenues	39,497	28,002	41	99	98
Licensing and product development	302	569	(47)	1	2
	<u>39,799</u>	<u>28,571</u>	39%	100%	100%
<b>Total revenues</b>	<b>\$39,799</b>	<b>\$28,571</b>	<b>39%</b>	<b>100%</b>	<b>100%</b>

**Balance Sheets**

	September 30, 2004	December 31, 2003
<u>Assets</u>		
Cash, cash equivalents and short-term investments	\$ 65,456	\$ 64,024
Accounts receivable, net	7,098	8,234
Inventories	4,664	4,003
Other current assets	726	923
Property and equipment, net	5,941	6,471
Other non-current assets	2,845	2,496
	<u>86,730</u>	<u>86,151</u>
<b>Total assets</b>	<b>\$ 86,730</b>	<b>\$ 86,151</b>
<u>Liabilities and Stockholders' Equity</u>		
Current portion of long-term debt	\$ 1,126	\$ 1,126
Accounts payable	1,625	3,511
Accrued expenses	6,976	5,376
Long-term debt, less current portion	1,612	2,457
Other liabilities	220	172
Stockholders' equity	75,171	73,509
	<u>86,730</u>	<u>86,151</u>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 86,730</b>	<b>\$ 86,151</b>

**Conference Call**

The Company will host a conference call with analysts and simultaneous audio webcast to discuss the Company's third quarter 2004 financial results beginning at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time) today. On the call will be Douglas A. Michels, President and Chief Executive Officer, and Ronald H. Spair, Chief Financial Officer. The call will include brief 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 Information 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 5, 2004, by dialing 800-642-1687 (Domestic) or 706-645-9291 (International) and entering the Conference ID #211244.



## **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).

## **Important Information**

This press release contains certain forward-looking statements, including with respect to revenues and net loss. 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 up-converting phosphor technology products; ability to fund research and development and other projects and operations; ability to 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; 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 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; changes in accounting practices or interpretation of accounting requirements; 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, 2003, 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.

###