## 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): July 26, 2004

# **ORASURE TECHNOLOGIES, INC.**

(Exact name of issuer as specified in charter)

DELAWARE

(State or Other Jurisdiction of Incorporation or Organization)

001-16537

(Commission file number)

36-4370966 (I.R.S. Employer Identification Number)

220 East First Street
Bethlehem, Pennsylvania 18015-1360
(Address of principal executive offices)

## Item 5 - Other Events and Regulation FD Disclosure.

OraSure Technologies, Inc. (the "Company") issued a press release on July 26, 2004, announcing that it has filed a lawsuit against Schering-Plough Healthcare Products, Inc. for infringement of several of the Company's patents relating to the technology for the cryosurgical removal (i.e., freezing) of warts and other benign skin lesions. The information contained in the press release, dated July 26, 2004, is incorporated herein by reference and attached to this Current Report on Form 8-K as Exhibit 99.1.

## Item 7. Financial Statements, Pro Forma Financial Information and Exhibits.

## (c) Exhibits

Exhibit Number	Description
99.1	Press Release dated July 26, 2004, announcing that the Company has filed a lawsuit against Schering-Plough
55.1	Healthcare Products, Inc. for infringement of several of the Company's patents relating to the technology for the
	cryosurgical removal (i.e., freezing) of warts and other benign skin lesions.

## **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: July 27, 2004 By: /s/ Jack E. Jerrett

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

## **Index to Exhibits**

## Exhibit No.

Description

99.1

Press Release dated July 26, 2004, announcing that OraSure Technologies, Inc. has filed a lawsuit against Schering-Plough Healthcare Products, Inc. for infringement of several of the Company's patents relating to the technology for the cryosurgical removal (i.e., freezing) of warts and other benign skin lesions.



Company contact:

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#### ORASURE TECHNOLOGIES SUES SCHERING-PLOUGH FOR PATENT INFRINGEMENT

Bethlehem, PA. (July 26, 2004) – OraSure Technologies, Inc. (Nasdaq NM: OSUR) today announced that it has filed a lawsuit against Schering-Plough Healthcare Products, Inc. (NYSE:SGP) for infringement of several OraSure patents relating to the technology for the cryosurgical removal (i.e., freezing) of warts and other benign skin lesions.

The suit was commenced in the United States District Court for the Eastern District of Pennsylvania, and alleges that Schering-Plough's manufacture and sale of its Dr. Scholl's® Freeze Away™ cryosurgical wart removal product in the over-the-counter market infringes the following OraSure United States patents: Nos. 5,738,682; 6,092,527 and 4,865,028. OraSure intends to file an application for a preliminary injunction in order to stop the further sale of the Freeze Away™ product by Schering-Plough in the United States.

"This litigation involves several patents that cover our Histofreezer® and Freeze OFF™ cryosurgical wart removal products," said Jack Jerrett, Senior Vice President and General Counsel of OraSure Technologies. "We view the protection of our patents and other intellectual property very seriously and intend to defend our patent rights vigorously."

#### About OraSure Technologies, Inc.

OraSure Technologies sells the Histofreezer® wart removal system to professional markets in the United States and many foreign countries, for the treatment of warts and other benign skin lesions, and the Freeze OFF™ wart removal product in the U.S. over-the-counter market through its distributor, Medtech Holdings.

OraSure Technologies also 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. In addition, the Company supplies oral-fluid testing solutions for drugs of abuse testing. For more information on OraSure, please go to <a href="https://www.orasure.com">www.orasure.com</a>.

#### **Important Information**

This press release contains certain forward-looking statements, including with respect to litigation, patent and other intellectual property rights 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 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 (including our ability to successfully implement a direct sales effort or other alternative distribution for OraQuick®); 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.