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# 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): September 28, 2004

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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 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))
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**Item 1.01 – Entry Into a Material Definitive Agreement**

OraSure Technologies, Inc. (the “Company”) and Comerica Bank (“Comerica”) are parties to a Loan and Security Agreement, dated as of September 10, 2002, as amended (the “Loan Agreement”), pursuant to which Comerica has provided the Company with \$10.9 million in credit facilities, including a \$4.0 million revolving working capital line of credit (the “Revolving Line”) which had a maturity date of November 9, 2004. On September 27, 2004, the Company executed a letter agreement with Comerica (the “Letter Agreement”) extending the maturity date of the Revolving Line to April 30, 2005. A copy of the Letter Agreement is attached as Exhibit 10 to this Form 8-K.

**Item 7.01 – Regulation FD Disclosure**

On September 28, 2004, the Company issued a press release announcing that an expedited trial has been ordered in the Company’s patent infringement lawsuit against Schering-Plough Healthcare Products, Inc. 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>
10	Letter Agreement, executed September 27, 2004, between OraSure Technologies, Inc. and Comerica Bank.
99	Press release, dated September 28, 2004, announcing that an expedited trial has been ordered in the Company’s patent infringement lawsuit against Schering-Plough Healthcare Products, Inc.

**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: September 28, 2004

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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September 21, 2004

Richard Hooper  
OraSure Technologies, Inc.  
220 East First Street  
Bethlehem, Pennsylvania 18015

Re: LOAN EXTENSION  
Borrower Name: OraSure Technologies, Inc.  
Customer Number/Obligor Number: 5793834584  
Loan Number/Note Number: 18/26

Dear Rich:

Comerica Bank, successor by merger to Comerica Bank- California, has approved an extension of the Revolving Maturity Date to April 30, 2005, under that certain Loan and Security Agreement dated September 10, 2002, as may be or have been modified from time to time (the "Loan Agreement").

Except as modified and extended hereby, the Loan Agreement remains in full force and effect.

Very truly yours,

*/s/ Peter Gibson*

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Peter Gibson

Acknowledged and accepted on September 27, 2004

OraSure Technologies, Inc.

By: */s/ Richard D. Hooper*

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**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)

**EARLY TRIAL SET IN ORASURE  
PATENT INFRINGEMENT LAWSUIT AGAINST SCHERING-PLOUGH**

Bethlehem, PA. (September 28, 2004) – OraSure Technologies, Inc. (Nasdaq NM: OSUR) today announced that an early trial has been set in the Company’s patent infringement lawsuit filed against Schering-Plough Healthcare Products, Inc. (NYSE:SGP). As a result, a final trial on the merits in this matter is expected to occur in February 2005.

The trial will include an early final determination of the Company’s request for permanent injunctive relief, in lieu of its prior request for a preliminary injunction. The Company supported the Court’s action because it believes an early trial on the merits will offer the most efficient and cost effective method for resolution of this lawsuit.

The lawsuit was originally commenced by the Company in late July 2004 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 several OraSure patents relating to the Company’s technology for the cryosurgical removal (i.e., freezing) of warts and other benign skin lesions.

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

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**Important Information**

This press release contains certain forward-looking statements concerning litigation with respect to patent and other intellectual property rights and products, among other things. Results could be significantly different. Additional 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<sup>®</sup>); 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 actual 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.

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