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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): June 21, 2004

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**ORASURE TECHNOLOGIES, INC.**

(Exact name of issuer as specified in charter)

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**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)

**(610) 882-1820**  
(Registrant's telephone number, including area code)

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**Item 5 – Other Events and Regulation FD Disclosure.**

OraSure Technologies, Inc. (the “Company”) issued a press release on June 21, 2004, announcing that it has received a worldwide, non-exclusive sublicense from Bio-Rad Laboratories under certain patents relating to the Human Immunodeficiency Virus, Type 2, or HIV-2. The information contained in the press release dated June 21, 2004 is incorporated herein by reference and attached to this Current Report on Form 8-K as Exhibit 99.1.

The Company issued a press release on June 23, 2004, announcing that Douglas A. Michels has been named President and Chief Executive Officer and appointed to the Company’s Board of Directors. The information contained in the press release is incorporated herein by reference and attached to this Current Report on Form 8-K as Exhibit 99.2.

The Company issued a press release on June 23, 2004, announcing that it has received U.S. Food and Drug Administration approval of its OraQuick® Rapid HIV-1/2 Antibody Test for use in detecting antibodies to HIV-2 in oral fluid samples. The information contained in the press release is incorporated herein by reference and attached to this Current Report on Form 8-K as Exhibit 99.3.

**Item 7. Financial Statements, Pro Forma Financial Information and Exhibits.****(c) Exhibits**

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated June 21, 2004, announcing that OraSure Technologies, Inc. (the “Company”) has received a worldwide, non-exclusive sublicense from Bio-Rad Laboratories under certain patents relating to the Human Immunodeficiency Virus, Type 2, or HIV-2.
99.2	Press Release dated June 23, 2004, announcing that Douglas A. Michels has been named President and Chief Executive Officer and appointed to the Company’s Board of Directors.
99.3	Press Release dated June 23, 2004, announcing that the Company has received U.S. Food and Drug Administration approval of its OraQuick® Rapid HIV-1/2 Antibody Test for use in detecting antibodies to HIV-2 in oral fluid samples.

**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: June 24, 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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**OraSure Technologies, Inc.**

diagnostic solutions for the new millennium

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Chief Financial Officer  
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**ORASURE RECEIVES RAPID TEST HIV-2 PATENT SUBLICENSE FROM BIO-RAD**

*- Sublicense Enables OraSure To Market OraQuick® Rapid HIV-1/2 Antibody Test -*

**BETHLEHEM, PA– June 21, 2004** – OraSure Technologies, Inc. (NASDAQ NM:OSUR) announced today that it has received a worldwide, non-exclusive sublicense from Bio-Rad Laboratories (AMEX: BIO and BIOb) under patents relating to the Human Immunodeficiency Virus, Type 2, or HIV-2. Bio-Rad is the exclusive licensee of Institut Pasteur of Paris, France, under the HIV-2 patents.

“Securing this HIV-2 sublicense will allow us to fully develop a global strategy for our OraQuick® HIV-1/2 test,” said Mike Gausling, president and chief executive officer of OraSure Technologies. “Our goal has always been to create the most versatile and comprehensive point-of-care rapid HIV test in the world. We believe that a combination OraQuick® rapid antibody test for both HIV-1 and HIV-2, which can be used on a variety of specimen types, such as oral fluid, blood and plasma, will be a critical tool in fighting the pandemic of HIV/AIDS.”

“HIV is a critical health care issue. Bio-Rad continues to work with global partners to expand the range of available HIV diagnostic products,” said Norman Schwartz, Bio-Rad’s president and chief executive officer. “Granting a sublicense to OraSure for the HIV-2 patents provides a new diagnostic option to the public health community.”

Under the terms of the sublicense, OraSure has obtained non-exclusive rights to certain HIV-2 patents from Bio-Rad, which will permit OraSure to sell a rapid test for both HIV-1 and HIV-2 using its OraQuick® technology platform on a worldwide basis. Bio-Rad maintains rights to patents claiming the HIV-2 virus and various means to detect its presence in infected patients. Other companies have also received HIV-2 diagnostic sublicenses from Bio-Rad and France’s Institut Pasteur.

*- more -*

OraSure recently announced FDA approval of its new OraQuick® Rapid HIV-1/2 Antibody Test, the first and only rapid, point-of-care test approved by the U.S. Food and Drug Administration (“FDA”) for use with oral fluid, fingerstick and venipuncture whole blood, and plasma samples. Specifically, the FDA approved the use of this test in detecting antibodies to HIV-1 in oral fluid and antibodies to both HIV-1 and HIV-2 in finger stick whole blood, venous whole blood and plasma samples. OraSure intends to seek FDA approval for use of the test to detect HIV-2 in oral fluid and a CLIA (Clinical Laboratory Improvements Amendments of 1988) waiver before obtaining FDA approval of final labeling of the complete OraQuick® HIV-1/2 test with all claims.

There are an estimated 40 million people in the world currently living with the HIV virus. Although the number of reported cases of HIV-2 infection in the United States is still relatively low, the incidence of HIV-2 infection is much higher in certain other countries, and many foreign countries require testing for both HIV-1 and HIV-2.

#### **About OraSure Technologies**

OraSure Technologies 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. OraSure Technologies is the leading supplier of oral-fluid collection devices and assays to the life insurance industry and public health markets for the detection of antibodies to HIV-1. In addition, the Company supplies oral-fluid testing solutions for drugs of abuse testing. For more information on the Company, please go to [www.orasure.com](http://www.orasure.com).

#### **About Bio-Rad Laboratories**

Bio-Rad Laboratories, Inc. ([www.bio-rad.com](http://www.bio-rad.com)) is a multinational manufacturer and distributor of life science research products and clinical diagnostics. It is based in Hercules, California, and serves more than 70,000 research and industry customers worldwide through a network of more than 30 wholly owned subsidiary offices.

#### **Important Information**

This press release contains certain forward-looking statements, including with respect to products, markets, regulatory submissions and approvals. 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 OraSure’s ability to 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; ability to obtain 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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**OraSure Technologies Appoints New President and Chief Executive Officer**

*- Conference Call/Webcast Scheduled For 1:00 PM Eastern Time Today -*

**BETHLEHEM, PA** – June 23, 2004 – (BW HealthWire) – OraSure Technologies, Inc. (NASDAQ NM:OSUR), a market leader in oral fluid diagnostics, today announced that Douglas A. Michels has been named President and Chief Executive Officer and appointed to the Company's Board of Directors. Mr. Michels will replace Mike Gausling, who has been OraSure's President and Chief Executive Officer since January 2002 and a member of the Company's Board since September 2000. Mr. Gausling had previously announced that he would retire this year.

Mr. Michels has had more than twenty-three years of experience in the medical device, diagnostics and managed care industries, primarily with the Johnson & Johnson family of companies ("J&J"). He has served as Group Vice President, Global Marketing of Ortho-Clinical Diagnostics, President of Ortho-Clinical Diagnostics International, President of Johnson & Johnson Healthcare Systems, Inc. and Vice President Sales & Marketing of Johnson & Johnson Healthcare Systems, Inc. Earlier in his J&J career, Mr. Michels held various positions of increasing responsibility, including Vice President, Sales & Marketing, Vice President/General Manager – Immunocytometry Business, Executive Director Sales & Marketing, Director of Marketing, Director of Sales and Regional Sales Manager for Ortho Diagnostic Systems, Inc. Prior to joining J&J, Mr. Michels worked for the Diagnostics Division of Abbott Laboratories in various sales and product management positions.

Mr. Michels received a B.S. degree in Public Health Administration from the University of Illinois in 1978 and an M.B.A. from Rutgers University in 1990.

"We are very pleased that Doug has decided to join OraSure," said Douglas G. Watson, OraSure's Chairman of the Board. "Doug's extensive experience in the medical device and diagnostics field, and in particular his proven track record in achieving substantial revenue growth and increased market penetration, is exactly what we need to take OraSure to the next level. We believe his strong leadership experience will help OraSure attain its aggressive financial and business goals."

*- more -*



“I am very excited to be joining the OraSure team,” said Doug Michels. “I believe OraSure has a great business model and a very strong and talented management team. With the recent regulatory approvals obtained for the Company’s OraQuick® Rapid Antibody HIV-1/2 Test and its strong balance sheet, I believe OraSure is well positioned to further penetrate the infectious disease testing market with this important product and to pursue other strategic opportunities to help achieve its growth objectives.”

#### **Conference Call/Audio Webcast**

OraSure Technologies will host a conference call with analysts and an audio webcast to introduce Mr. Michels and discuss his appointment as President and Chief Executive Officer, beginning at 1:00 p.m. Eastern Time (10:00 a.m. Pacific Time) today. On the call will be Mike Gausling, Ronald H. Spair, Chief Financial Officer, and Doug Michels.

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 at the top of the page, at least ten minutes prior to the start of the call, to register and download and install any necessary audio software. 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 June 30, 2004, by dialing 800-642-1687 (Domestic) or 706-645-9291 (International) and entering the Conference ID #8354353.

The webcast will also be distributed over the CCBN (Corporate Communications Broadcast Network) Investor Distribution Network. Institutional investors can access the call via CCBN’s password protected event management site, StreetEvents ([www.streetevents.com](http://www.streetevents.com)).

#### **About OraSure Technologies**

OraSure Technologies 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.

OraSure Technologies is the leading supplier of oral-fluid collection devices and assays to the life insurance industry and public health markets for the detection of antibodies to HIV-1. In addition, the Company supplies oral-fluid testing solutions for drugs of abuse testing. For more information on the Company, please go to [www.orasure.com](http://www.orasure.com).

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**FDA APPROVES ORAQUICK® HIV-1/2 TEST TO DETECT HIV-2 IN ORAL FLUID**

**BETHLEHEM, PA** – June 23, 2004 – OraSure Technologies, Inc. (NASDAQ NM:OSUR), the market leader in oral fluid diagnostics, announced today that it has received U.S. Food and Drug Administration (“FDA”) approval of its OraQuick® Rapid HIV-1/2 Antibody Test for use in detecting antibodies to the Human Immunodeficiency Virus Type 2, or HIV-2, in oral fluid samples. With this approval, the OraQuick® HIV-1/2 Test is the only rapid, point-of-care test approved by the FDA for use in detecting antibodies to both HIV-1 and HIV-2 in oral fluid, finger stick and venous whole blood, and plasma samples.

“We are extremely pleased to have obtained FDA approval of an oral fluid HIV-2 claim for our OraQuick® HIV-1/2 Test,” said Ron Spair, Executive Vice President and Chief Financial Officer of OraSure Technologies. “This is another major milestone for the Company as we continue to build our leadership position in the oral fluid diagnostics market. The next step is to obtain a CLIA (Clinical Laboratory Improvements Amendment of 1988) waiver for our OraQuick® HIV-1/2 test, which will allow us to expand the availability of this product in the United States, especially in the public health market.”

Now that the oral fluid HIV-2 approval has been received, OraSure will promptly submit an application for CLIA waiver of the OraQuick® HIV-1/2 test. Upon approval of this waiver, the OraQuick® HIV-1/2 test, which provides results in just 20 minutes, can be used by more than 180,000 sites in the United States, including outreach clinics, community-based organizations and physicians’ offices.

In March 2004, OraSure announced FDA approval of the OraQuick® Rapid HIV-1/2 Antibody Test for use in detecting antibodies to HIV-1 in oral fluid and antibodies to both HIV-1 and HIV-2 in finger stick whole blood, venous whole blood and plasma samples. On June 21, 2004, OraSure announced that it had obtained a non-exclusive, worldwide sublicense to certain HIV-2 patents held by Bio-Rad Laboratories. With the receipt of an HIV-2 oral fluid approval and the HIV-2 patent sublicense, OraSure believes it is now positioned to pursue a global distribution strategy for its OraQuick® Rapid HIV-1/2 Antibody Test.

- more -

There are an estimated 40 million people in the world currently living with the HIV virus. Although the number of reported cases of HIV-2 infection in the United States is believed to be relatively low, the incidence of HIV-2 infection is much higher in certain other countries, and many foreign countries require testing for both HIV-1 and HIV-2.

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