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**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): November 18, 2009**

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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 1.01 – Entry Into a Material Definitive Agreement.**

On November 18, 2009, OraSure Technologies, Inc. (the “Company”) entered into a Settlement Agreement, a License Agreement and certain other agreements in order to settle a patent infringement lawsuit filed against the Company by Inverness Medical Innovations, Inc. (“IMI”), Inverness Medical Switzerland GmbH and Church & Dwight, Co., Inc. On November 19, 2009, the Company issued a press release announcing the settlement and describing, among other things, the principal terms of the Settlement Agreement and License Agreement. A copy of this press release is attached as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

**Item 7.01 – Regulation FD Disclosure.**

On November 18, 2009, the Company issued a press release announcing its participation in a recent Blood Products Advisory Committee (“BPAC”) meeting and its plans to continue pursuing U.S. Food and Drug Administration (“FDA”) approval of an OraQuick® HIV over-the-counter test. A copy of this press release is attached as Exhibit 99.2 to this Form 8-K and is incorporated herein by reference.

**Item 9.01 – Financial Statements and Exhibits.****(d) Exhibits**

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release, dated November 19, 2009, Announcing Settlement of Patent Infringement Litigation between the Company and Inverness Medical Innovations, Inc., Inverness Medical Switzerland GmbH and Church & Dwight, Co., Inc.
99.2	Press Release, dated November 18, 2009, announcing the Company’s participation in a recent BPAC meeting and plans to continue pursuing FDA approval of an OraQuick® HIV OTC test.



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**Index to Exhibits**

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99.2	Press Release, dated November 18, 2009, announcing the Company's participation in a recent BPAC meeting and plans to continue pursuing FDA approval of an OraQuick® HIV OTC test.



Company contact:

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Chief Financial Officer  
610-882-1820  
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**ORASURE TECHNOLOGIES ANNOUNCES SETTLEMENT OF PATENT INFRINGEMENT  
LAWUIT WITH INVERNESS AND CHURCH & DWIGHT**

Bethlehem, PA (November 19, 2009) – OraSure Technologies, Inc. (NASDAQ: OSUR) today announced the settlement of the patent infringement lawsuit filed against OraSure by Inverness Medical Innovations, Inc. (NYSE: IMA), Inverness Medical Switzerland GmbH and Church & Dwight, Co., Inc. (NYSE: CHD).

Under the settlement, OraSure has agreed to pay Inverness a sum of \$3,000,000 in cash and Inverness has agreed to grant OraSure certain licenses to its lateral flow patents. In addition, each party has received distribution rights to certain products supplied by the other party. Terms of the settlement include the following:

- The grant to OraSure of a worldwide, non-exclusive, royalty-bearing, lateral flow patent license (subject to a royalty-free period) for the OraQuick® HIV-<sup>1</sup>/<sub>2</sub> test and other visually-read HIV lateral flow products in the professional market;
- The grant to OraSure of a worldwide, non-exclusive, royalty-bearing, lateral flow patent license (subject to a royalty-free period) for the OraQuick® HCV test and other visually read HCV lateral flow products in the professional market;
- The grant to OraSure of a worldwide, non-exclusive, royalty-bearing, license to Inverness lateral flow patents for visually-read products for the detection of certain infectious diseases, metabolic disorders, cancer and autoimmune disorders;
- The grant to OraSure of non-exclusive rights to distribute in the United States as private label products certain rapid, point-of-care, flu, strep, drugs of abuse and pregnancy tests manufactured by Inverness;
- A right of first negotiation during the 120-day period following the settlement effective date for OraSure to negotiate the terms for the marketing and distribution of the OraQuick® HIV-<sup>1</sup>/<sub>2</sub> test on an exclusive basis in the over-the-counter markets worldwide with the consumer diagnostics joint venture between Proctor & Gamble (NYSE: PG) and Inverness; and
- The grant to Inverness of exclusive distribution rights to the OraQuick® HCV test in the employee health services and home healthcare markets and in acute care clinics located in pharmacies and other mass retail outlets in the United States.

## Updated Financial Guidance

As a result of the litigation settlement, the Company now expects its net loss for the fourth quarter of 2009 to be \$0.10 to \$0.11 per share.

## 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. For more information on the Company, please go to [www.orasure.com](http://www.orasure.com).

## Private Securities Litigation Reform Act of 1995 —

### A Caution Concerning Forward-Looking Statements

This press release contains certain forward-looking statements, including with respect to royalties, expenses, net loss per share and products. Actual results could be significantly different. Factors that could affect results include the ability to market and sell products, whether through an internal, direct sales force or third parties; ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements; changes in relationships, including disputes or disagreements, with strategic partners and reliance on strategic partners for the performance of critical activities under collaborative arrangements; failure of distributors or other customers to meet purchase forecasts or minimum purchase requirements for the Company's products; impact of replacing distributors and success of direct sales efforts; inventory levels at distributors and other customers; impact of competitors, competing products and technology changes; impact of the economic downturn, high unemployment and credit crisis; ability to develop, commercialize and market new products; market acceptance of oral fluid testing or other products; changes in market acceptance of products based on product performance and extended shelf life; continued bulk purchases by customers, including governmental agencies, and the ability to fully deploy those purchases in a timely manner; ability to fund research and development and other products 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 or products required for use of our products; ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; ability to comply with applicable regulatory requirements; history of losses and ability to achieve sustained profitability and ability to utilize net operating loss carryforwards or other deferred tax assets; volatility of the Company's 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, including changes in international funding sources; loss or impairment of sources of capital; ability to meet financial covenants in agreements with financial institutions; ability to retain qualified personnel; exposure to patent infringement, product liability, and other types of litigation; changes in international, federal or state laws and regulations; 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 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, 2008, 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.



OraSure Technologies, Inc.

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#### ORASURE TECHNOLOGIES PARTICIPATES IN BPAC MEETING ON HIV OVER-THE-COUNTER TEST

Bethlehem, PA (November 18, 2009) – OraSure Technologies, Inc. (NASDAQ: OSUR) today announced that it participated in a Blood Products Advisory Committee (“BPAC”) meeting held November 17, 2009 in which the BPAC considered, among other topics, the public need and performance characteristics for over-the-counter (“OTC”) home use HIV test kits. The BPAC provides advice to the U.S. Food and Drug Administration (“FDA”) on issues related to the safety and effectiveness of biological products and medical devices.

During the November 17 meeting, a number of public presentations were made including with respect to the perspectives of the Centers for Disease Control and Prevention on the role of home use HIV test kits and the risks and benefits of home use HIV test kits. In addition, OraSure participated in a closed session with the BPAC in which OraSure reviewed the results of its ongoing clinical studies related to its OraQuick® HIV OTC test and the additional clinical work required for FDA approval. Based on feedback from the meeting, the Company intends to continue its efforts to seek FDA approval of its OraQuick® HIV OTC test.

“We are very pleased to have had the opportunity to discuss our ongoing clinical efforts for an at-home HIV test with the Blood Products Advisory Committee,” said Douglas A. Michels, President and CEO of OraSure Technologies. “The meeting was productive and very informative. We are gaining greater clarity as to the additional steps for this clinical program and intend to work closely with the FDA to define and execute the remaining studies required for approval.”

#### 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. For more information on the Company, please go to [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 products, clinical programs and regulatory approvals. Actual results could be significantly different. Factors that could affect results include the ability to market and sell products, whether through an internal, direct sales force or third parties; ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements; changes in relationships, including disputes or disagreements, with strategic partners and reliance on strategic partners for the performance of critical activities under collaborative arrangements; failure of distributors or other customers to meet purchase forecasts or minimum purchase requirements for the Company's products; impact of replacing distributors and success of direct sales efforts; inventory levels at distributors and other customers; impact of competitors, competing products and technology changes; impact of the economic downturn, high unemployment and credit crisis; ability to develop, commercialize and market new products; market acceptance of oral fluid testing or other products; changes in market acceptance of products based on product performance and extended shelf life; continued bulk purchases by customers, including governmental agencies, and the ability to fully deploy those purchases in a timely manner; ability to fund research and development and other products 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 or products required for use of our products; ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; ability to comply with applicable regulatory requirements; history of losses and ability to achieve sustained profitability and ability to utilize net operating loss carryforwards or other deferred tax assets; volatility of the Company's 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, including changes in international funding sources; loss or impairment of sources of capital; ability to meet financial covenants in agreements with financial institutions; ability to retain qualified personnel; exposure to patent infringement, product liability, and other types of litigation; changes in international, federal or state laws and regulations; 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 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, 2008, 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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