ORASURE TECHNOLOGIES INC
Form 8-K
January 10, 2006

UNITED STATES

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): January 9, 2006

OraSure Technologies, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-16537**	**36-4370966**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

220 East First Street

Bethlehem, Pennsylvania	**18015-1360**
(Address of Principal Executive Offices)	**(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 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))

Item 5.02 Departure of Directors or Principal Officers; Election of Directors; Appointment of Principal Officers.

On January 9, 2006, the Company appointed Charles W. Patrick as a member of the Company s Board of Directors. Mr. Patrick has also been appointed to serve on the Compensation Committee of the Board. A press release, dated January 9, 2006, announcing Mr. Patrick s appointment to the Board, is attached as Exhibit 99.1 to this Report and is incorporated by reference herein.

Item 7.01 Regulation FD Disclosure.

OraQuick® Update

As previously announced, OraSure Technologies, Inc. (the Company) is taking several actions in response to reports that specific clinical sites have recently experienced increased levels of false positive results using the Company s OraQuick® *ADVANCE* Rapid HIV-1/2 Antibody Test with oral fluid. It should be noted that all of these sites continue to use the OraQuick® *ADVANCE* test with either oral fluid or fingerstick whole blood.

Immediately after receiving the reports, the Company commenced a scientific and systematic evaluation of each situation. The Company is closely working with the affected customers, healthcare officials and government agencies, including The Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) and is providing information and updates regarding its evaluation on a regular basis to all such parties. The evaluation includes the collection of test data, an assessment of test procedures, specimen collection and other clinical variables that could affect test results at the sites. The Company is also conducting a thorough review of its manufacturing processes and all related variables that may affect product performance and quality, and has been contacting its customers throughout the country to determine if they are experiencing any unexpected results or issues with regard to the performance and procedures associated with the test.

The Company continues to make good progress with its evaluation, and the following is an update on some of the information generated to date.

First, the Company has contacted certain state and city health departments, HIV/AIDS service organizations and other public health agencies in 35 states. Of this total, agencies in eight states, which include the specific sites that have recently reported the unexpected test results, have provided aggregate test data to the Company. The data indicates that approximately 112,000 oral fluid tests were performed in these states during 2005, with a calculated aggregate specificity of 99.8%. It must be emphasized that these figures reflect only data reported to the Company by the agencies contacted in these states and are based on estimates of the total number of oral fluid tests performed. This data has not been audited and may not reflect the results of all oral fluid HIV testing in each of these states. Agencies in many of the other 27 states contacted, from which the Company has not received quantitative performance data, have generally indicated that they are satisfied with the overall performance of the test and have not experienced an unusual level of false positive results. Based on the data and information collected to date, the Company believes that the

OraQuick® *ADVANCE* test, when used with oral fluid, continues to perform overall as expected and in a manner consistent with its FDA-approved label claims.

Second, the Company has conducted an analysis into the possible relationship between product performance and particular lots of product used at the customer sites that reported unexpected results. So far, the Company has found no correlation between the reported false positive issues at these sites and particular lots of the OraQuick® *ADVANCE* test. For example, within two regions that had certain sites experiencing higher false positive rates, the same lot of product was used over the same time period by other sites within that region and in other parts of the country and demonstrated performance consistent with its FDA-approved label claims.

Third, the Company has obtained monthly test data from sites within the regions that reported higher levels of false positive results. After reviewing the data for the testing period of September through November 2005, the Company found that only a few sites within those regions experienced specificity that was significantly lower than that observed at the other sites in those regions. Excluding the monthly test results from these few sites, the aggregate specificity for the remaining sites in these regions was consistent with the product s expected performance and FDA-approved labeling. These findings are suggestive that a site-dependent factor may be playing a role in the lower specificity observed at these sites and the Company is continuing to evaluate this possibility as part of its evaluation. These factors could include potential interfering factors, sample collection and testing procedures, or patient specific variables.

Finally, the Company is performing several experimental field studies involving the use of the OraQuick® *ADVANCE* test in oral fluid. These studies will focus on a number of variables that could affect test performance, including lot variation, shelf life, specimen collection and various site-specific factors observed by the Company during its data collection process. These studies are expected to take several weeks to complete.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release, dated January 9, 2006, announcing the appointment of Charles W. Patrick to the Board of Directors of OraSure Technologies, 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: January 10, 2006

By: /s/ JACK E. JERRETT
Jack E. Jerrett
Senior Vice President, General Counsel and Secretary

Index to Exhibits

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