

ORASURE TECHNOLOGIES INC

Form 8-K

March 29, 2004

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): March 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)

(610) 882-1820

(Registrant's telephone number, including area code)

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

(c) Exhibits

| <u>Exhibit Number</u> | <u>Description</u> |
|-----------------------|---|
| 99.1 | Press Release dated March 26, 2004, announcing that OraSure Technologies, Inc. (the Company) will need to submit additional performance data to the U.S. Food and Drug Administration (FDA) in order to obtain 510(k) clearance of its <i>UPLink</i> [®] Oral Fluid Drug Detection System. |
| 99.2 | Press Release dated March 26, 2004, announcing that the FDA has approved oral fluid and plasma claims for the Company's OraQuick [®] Rapid HIV-1/2 Antibody Test. |

Item 9. Regulation FD Disclosure.

The Company issued a press release on March 26, 2004, announcing that it will need to submit additional performance data to the FDA in order to obtain 510(k) clearance of its *UPLink*[®] Oral Fluid Drug Detection System. The information contained in the press release is incorporated herein by reference and attached to this Current Report on Form 8-K as Exhibit 99.1.

The Company also issued a press release on March 26, 2004, announcing that the FDA has approved oral fluid and plasma claims for its OraQuick[®] Rapid HIV-1/2 Antibody Test. 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.

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: March 29, 2004

By: /s/ Jack E. Jerrett

Jack E. Jerrett
Senior Vice President, General Counsel

and Secretary

Index to Exhibits

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