

December 13, 2005

OraSure ain't a sure thing.

OraSure Technologies Inc. (NASDAQ: OSUR, \$12.26) claims to be taking steps towards applying for approval to sell its OraQuick ADVANCE Rapid HIV 1/2 Antibody Test ("OraQuick") over-the-counter ("OTC") for at home use. OSUR's stock price has risen sharply on analysts' reports of this development. The price of the stock has risen close to 43% from \$8.77 on February, 10, 2005, one of OSUR's most serious mentions of its intent to seek OTC approval for OraQuick, as of the close yesterday December 12, 2005.

Recent press accounts have helped fuel the stock's rise. Serious questions remain as to whether OSUR will get Federal Drug Administration ("FDA") approval to sell OraQuick over-the-counter. Even if OraQuick is approved for OTC use there are questions as to whether an OTC HIV test's potential sales can be as great as what is already fully discounted into OSUR's stock. The number of people getting tested for HIV, not in conjunction with other incidental medical testing, is declining very rapidly. Meanwhile the number of people who are incidentally tested as part of a medical routine has increased sharply.

According to a study referenced by a participant in the FDA's review of OSUR's concept to apply to sell its HIV test in the OTC market for at-home use titled "Shift in Reasons Why Adults Seek HIV Testing in the United States: Policy Implications," the number of people who got tested "to find out if infected or not" declined 65% from 1998 to 2002, but during this time the number of people tested as "part of a routine medical checkup or surgical procedure" increased over 100%.

Investors may be well served to focus on the adverse impact of next week's Center for Disease Control's advisory that individuals who test positive with OraQuick follow-up the test with a blood rapid retest and Western blot laboratory test, due to the recent high instances of false-positive results. The lack luster sales growth of OSUR's OraQuick test, which has been on the market since November 2002, and its production cost in an extremely cost sensitive and competitive market overshadow the promise of an OTC HIV test that appears to have been grossly over hyped.

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