

GEN PROBE INC
Form 8-K
July 25, 2006

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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): July 19, 2006
Gen-Probe Incorporated
(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-31279
(Commission File Number)

33-0044608
(I.R.S. Employer
Identification No.)

10210 Genetic Center Drive
San Diego, CA 92121
(Address of Principal Executive Offices)

(858) 410-8000
(Registrant's telephone number, including area code)

N/A

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

- 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 8.01. Other Events

On July 25, 2006, Gen-Probe Incorporated (Gen-Probe or the Company) issued a press release providing an update on the regulatory status of its investigational blood screening products based on recent communications with the U.S. Food and Drug Administration (FDA).

In April 2006, Gen-Probe submitted to the FDA a post-approval supplement to its Biologics License Application (BLA) for its West Nile virus assay, adding the TIGRIS[®] instrument. On July 19, 2006, the Company received a complete review letter from the FDA setting forth questions regarding the post-approval supplement to the BLA adding the TIGRIS[®] instrument. The West Nile virus assay is approved for commercial blood screening use in the United States on the eSAS instrument system.

Gen-Probe's press release with respect to this matter is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits.* The following exhibit is furnished with this current report.

| Exhibit No. | Description |
|-------------|---|
| 99.1 | Press release of Gen-Probe Incorporated dated July 25, 2006 concerning regulatory matters |

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Gen-Probe Incorporated

Date: July 25, 2006

By: /s/ R. William Bowen

R. William Bowen
Vice President and General Counsel

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EXHIBITS

**Exhibit
Number**

Description

99.1 Press release of Gen-Probe Incorporated dated July 25, 2006 concerning regulatory matters