GEN PROBE INC
Form 8-K
October 06, 2005

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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): **October 5, 2005**

Gen-Probe Incorporated
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-31279**	**33-0044608**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

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

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

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 October 5, 2005, Gen-Probe Incorporated (Gen-Probe) issued a news 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).

The FDA notified Gen-Probe that it considers the PROCLEIX® TIGRIS® system not substantially equivalent to the PROCLEIX enhanced semi-automated system (eSAS) for screening donated human blood with the PROCLEIX ULTRIO™ assay. The FDA made this determination in response to Gen-Probe s 510(k) application for the TIGRIS system. Gen-Probe has discussed the determination with the FDA and is scheduling a series of meetings to resolve the outstanding issues.

Gen-Probe previously received 510(k) marketing clearance for the eSAS system used to screen donated human blood using the ULTRIO assay. Gen-Probe also continues to expect approval of its Biologics License Application for the ULTRIO assay this year. This approval, if granted, would enable U.S. customers to run the ULTRIO assay on the eSAS system on a commercial basis.

A copy of the news release is furnished with this Current Report as Exhibit 99.1.

Forward-Looking Statements

Any statements in this Current Report about Gen-Probe s expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and are forward-looking statements. These statements are often, but not always, made through the use of words or phrases such as believe, will, expect, anticipate, estimate, int plan, and would. For example, statements concerning Gen-Probe s financial condition, possible or expected future results of operations, growth opportunities, and plans and objectives of management are all forward-looking statements. They involve known and unknown risks, uncertainties and assumptions that may cause actual results, levels of activity, performance or achievements to differ materially from those expressed or implied by any forward-looking statement. Some of the risks, uncertainties and assumptions that could cause actual results to differ materially from estimates or projections in the forward-looking statement include, but are not limited to: (i) the risk that new products, including the PROCLEIX ULTRIO and PROCLEIX West Nile virus assays and the PROCLEIX TIGRIS system, will not be cleared for marketing in the timeframes we expect, if at all, (ii) the risk that we may not earn or receive milestone payments from our collaborators, including Chiron (iii) the possibility that the market for the sale of our new products, such as our ULTRIO and West Nile virus assays and the TIGRIS system, may not develop as expected, (iv) we may not be able to compete effectively, (v) we may not be able to maintain our current corporate collaborations and enter into new corporate collaborations or customer contracts, and (vi) we are dependent on Chiron and other third parties for the distribution of some of our products. For additional information about risks and uncertainties Gen-Probe faces and a discussion of Gen-Probe s financial statements, see documents filed with the SEC, including our Quarterly Report on Form 10-Q for the quarter ended June 30, 2005 and all periodic filings made with the SEC. Gen-Probe assumes no obligation and expressly disclaims any duty to update any forward-looking statement to reflect events or circumstances after the date of this current report or to reflect the occurrence of subsequent events.

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Item 9.01. Financial Statements and Exhibits.

(c) The following exhibit is furnished with this Current Report:

99.1 News release dated October 5, 2005.(1)

(1) This Exhibit is being furnished by the Registrant and shall not be deemed filed by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, or deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934.

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SIGNATURE

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.

Date: October 5, 2005

GEN-PROBE INCORPORATED

By: /S/ R. William Bowen
R. William Bowen
Vice President, General Counsel and
Corporate Secretary

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EXHIBITS

Exhibit Number	Description
99.1	News Release dated October 5, 2005.