GEN PROBE INC
Form 8-K
October 05, 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): October 3, 2006
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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 4, 2006, Gen-Probe Incorporated (the Company) issued a press release announcing that the U.S. Food and Drug Administration (FDA) has granted marketing approval for the PROCLEIX® ULTRIO® Assay to run on the enhanced Semi-Automated PROCLEIX® System. The PROCLEIX ULTRIO Assay was approved to screen donated blood, plasma, organs and tissue for HIV-1 and hepatitis C virus (HCV) in individual blood donations or in pools of up to 16 blood samples, and to detect the presence of hepatitis B virus (HBV). However, the initial pivotal study for the PROCLEIX ULTRIO Assay was not designed to, and did not, demonstrate yield, defined as HBV-infected blood donations that are negative based on serology tests for HBV surface antigen and core antibody. Based on discussions with the FDA, Gen-Probe and Chiron, Gen-Probe s blood screening partner, will initiate a post-marketing study to demonstrate HBV yield and gain a donor-screening claim. The companies expect this study to begin in early 2007 as the commercial Assay becomes available.

The Company 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) The following exhibit is furnished with this Current Report:

99.1 Press Release of Gen-Probe Incorporated dated October 4, 2006

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, intend, plan and would. For example, statements concerning new products, potential regulatory approvals, customer adoption, and results of future R&D studies are all forward-looking statements. Forward-looking statements are not guarantees of performance. 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 contained in the forward-looking statements include but are not limited to: (i) the risk that new products will not be cleared for marketing in the timeframes we expect, if at all, (ii) the possibility that the market for the sale of our new products, such as our PROCLEIX ULTRIO assay and TIGRIS system, may not develop as expected, (iii) the risk that additional studies will not demonstrate HBV yield or otherwise achieve the desired results, (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 third parties for the distribution of some of our products. The foregoing describes some, but not all, of the factors that could affect our ability to achieve results described in any forward-looking statements. For additional information about risks and uncertainties we face and a discussion of our financial statements and footnotes, see documents we file with the SEC, including our most recent annual report on Form 10-K and all subsequent periodic reports. We assume no obligation and expressly disclaim any duty to update any forward-looking statement to reflect events or circumstances after the date of this news release or to reflect the occurrence of subsequent events.

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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, 2006

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	Press Release of Gen-Probe Incorporated dated October 4, 2006