GEN PROBE INC
Form 8-K
November 07, 2011

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): November 4, 2011

Gen-Probe Incorporated

(Exact Name of Registrant as Specified in Charter)

Delaware	**000-49834**	**33-0044608**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

10210 Genetic Center Drive

San Diego, CA	**92121**
(Address of Principal Executive Offices)	**(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))

Item 8.01. Other Events.

In August 2010, Gen-Probe Incorporated (the Company) submitted a Premarket Approval Application (PMA) for the Company s PROGENSA PCA3 assay to the U.S. Food and Drug Administration (FDA). The Company was subsequently notified by FDA that the PROGENSA PCA3 assay would be submitted for review by the Immunology Panel of FDA s Medical Devices Advisory Committee (the Panel).

On November 4, 2011, the Company received notice from the FDA that FDA has concluded Panel review is no longer necessary in connection with the PMA for the PROGENSA PCA3 assay, based on recent discussions between FDA and the Company with respect to product labeling and related issues. The Company expects to work interactively with FDA to address outstanding issues related to the PROGENSA PCA3 assay PMA. However, there can be no assurances as to whether the PROGENSA PCA3 assay will be approved for sale in the United States on a timeline consistent with the Company s expectations, or at all.

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: November 7, 2011

GEN-PROBE INCORPORATED

By: /s/ R. William Bowen
R. William Bowen
Senior Vice President, General Counsel and

Corporate Secretary