GEN PROBE INC
Form 8-K
August 29, 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): August 24, 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.

On August 24, 2011, Gen-Probe Incorporated (the Company) received notice from the U.S. Food and Drug Administration (FDA) that the Company s PROGENSA PCA3 Assay will not be reviewed by the Immunology Panel of FDA s Medical Devices Advisory Committee (the Panel) at the Panel s meeting in October 2011 as previously scheduled, but will be reviewed by the Panel at a later date. The Company was informed that Panel review has been postponed in order to provide FDA more time to review and respond to information and materials that have been provided by the Company in connection with the Panel meeting and the Company s Premarket Approval Application for the PROGENSA PCA3 Assay. A new date for Panel review of the PROGENSA PCA3 Assay has not yet been confirmed, but the Company currently expects that Panel review will take place in the first quarter of 2012.

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: August 29, 2011

GEN-PROBE INCORPORATED

By: /s/ R. William Bowen
R. William Bowen

Senior Vice President, General Counsel and

Corporate Secretary