

GEN PROBE INC
Form 8-K
August 18, 2008

**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 12, 2008

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**

(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))
-

Item 8.01. Other Events.

In July 2008, the Company was notified that certain blood screening assays manufactured by the Company for Novartis Vaccines & Diagnostics, Inc. (Novartis) and sold outside of the United States might have been improperly stored at a Novartis warehouse in Singapore. Following the Company's established quality system, an investigation for product performance was initiated. On August 12, 2008, the Company determined that, based on the results of its investigation to date, it could not fully assess the potential impact of these improper storage conditions on the ultimate performance of the product without conducting additional stability testing, which is expected to be completed over the course of the next 30 to 60 days. As a result, Novartis and the Company agreed that products previously delivered to customers from this warehousing facility should be replaced and the appropriate field actions were initiated with customers and the regulatory authorities in the affected countries.

The affected products include Novartis PROCLEIX and PROCLEIX ULTRIO blood screening assays. The Company believes that Novartis has sufficient inventory at other locations to prevent any significant disruption in supply to Novartis customers.

The Company does not expect to incur any charges in connection with this event and believes that Novartis may replace the majority of the affected products with replacement products that will be ordered during the remainder of 2008.

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 18, 2008

GEN-PROBE INCORPORATED

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