GEN PROBE INC
Form 8-K
May 24, 2007

Table of Contents

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): May 23, 2007
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**	**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):

- 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))

TABLE OF CONTENTS

Table of Contents

Item 8.01 Other Events.

On May 24, 2007, Gen-Probe Incorporated (the Company) issued a press release announcing that the U.S. Food and Drug Administration (FDA) has approved the Company s PROCLEIX® TIGRIS® system, the first fully automated molecular diagnostics instrument, for use with the PROCLEIX ULTRIO® assay. The PROCLEIX TIGRIS system was approved with the PROCLEIX ULTRIO assay 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. The system and assay also detect hepatitis B virus (HBV) in blood donations that are HBV-positive based on traditional serology tests for HBV surface antigen and core antibodies. As expected, the system and assay have not been approved at this time to screen donated blood for HBV, as the initial clinical studies were not designed to, and did not, demonstrate HBV yield. Yield is defined as HBV-infected blood donations that were intercepted by the PROCLEIX ULTRIO assay, but that were initially negative based on the serology tests. Gen-Probe and Chiron have initiated a post-marketing study to demonstrate HBV yield and gain the associated donor screening claim.

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 May 24, 2007.

Forward-Looking Statements

  Any statements in this Current Report 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, clinical trials, potential regulatory approvals and customer adoption 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 the post-marketing study for the PROCLEIX ULTRIO assay will not be successful, (ii) the risk that additional claims for the PROCLEIX ULTRIO assay and the PROCLEIX TIGRIS system will not be granted in the timeframes we expect, if at all, (iii) the risk that we may not earn or receive milestone payments from our collaborators, (iv) the possibility that the market for the sale of our new products, such as our PROCLEIX ULTRIO assay, PROCLEIX WNV assay and PROCLEIX TIGRIS system, may not develop as expected, (v) we may not be able to compete effectively, (vi) we may not be able to maintain our current corporate collaborations and enter into new corporate collaborations or customer contracts, and (vii) we are dependent on Chiron and other 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

Table of Contents

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 Current Report or to reflect the occurrence of subsequent events.

Table of Contents

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: May 24, 2007

GEN-PROBE INCORPORATED

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

Table of Contents

EXHIBITS

Exhibit Number	Description
99.1	Press Release of Gen-Probe Incorporated dated May 24, 2007