GEN PROBE INC
Form 8-K
June 24, 2005

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): **June 3, 2005**

Gen-Probe Incorporated

(Exact Name of Registrant as Specified in Charter)

Delaware	**0-49834**	**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)

(858) 410-8000
(Registrant s telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

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 CRF 240.13e-4(c))

TABLE OF CONTENTS

Table of Contents

Section 8 Other Events

Item 8.01. Other Events.

On June 3, 2005 (Effective Date), Gen-Probe Incorporated (Gen-Probe) entered into a Research Agreement (Agreement) with SmithKline Beecham Corporation, doing business as GlaxoSmithKline, and SmithKline Beecham (Cork) Ltd. (together GSK). Pursuant to the terms of the Agreement, Gen-Probe will provide its investigational PCA3 assay to test up to 6,800 clinical samples obtained from patients enrolled in GSK s REDUCE (REduction by DUtasteride of prostate Cancer Events) clinical trial, which is designed to determine the efficacy and safety of GSK s drug dutasteride (AVODART®) in reducing the risk of prostate cancer in men at increased risk of this disease. Collection of urine samples from selected study sites will commence pending approvals by regulatory authorities and appropriate study sites ethics committees. Gen-Probe will reimburse GSK for expenses GSK incurs for sample collection and related processes during the four-year prospective clinical trial. Gen-Probe will provide the PCA3 assay without charge and will pay third party clinical laboratory expenses for using the assay to test the samples.

Dutasteride is currently indicated for the treatment of benign prostatic hyperplasia (BPH) and for reducing the risk of acute urinary retention and BPH-related surgery. Dutasteride is not currently indicated for the reduction in risk of or treatment for prostate cancer.

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, int plan, and would. For example, statements concerning intellectual property, future development, the potential of the cancer diagnostics market, reimbursement of fees, and future growth are 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 in the forward-looking statement include, but are not limited to: (i) the risk that further development of the APTIMA PCA3 assay may not be successful or consistent with prior results, (ii) the risk that the APTIMA PCA3 assay may not receive all necessary regulatory approvals, (iii) the risk that the APTIMA PCA3 assay may not gain market acceptance, (iv) the risk that Gen-Probe may not be able to maintain its current corporate collaborations, including with GSK or DiagnoCure, or enter into new ones, and (v) the risk that third party patent rights may limit Gen-Probe s ability to develop and sell products. For additional information about risks and uncertainties Gen-Probe faces and a discussion of Gen-Probe s financial statements, see documents filed with the SEC, including the Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2005 and all periodic filings made with the SEC. Gen-Probe assumes no obligation and expressly disclaims 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

SIGNATURES

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.

Gen-Probe Incorporated

By: /s/ R. William Bowen

R. William Bowen
Vice President and General Counsel

Date: June 24, 2005