

GEN PROBE INC
Form 8-K
May 05, 2009

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**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): April 29, 2009

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))
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Item 1.01. Entry into a Material Definitive Agreement.

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Item 1.01. Entry into a Material Definitive Agreement.

On November 19, 2003, Gen-Probe Incorporated (the Company) and Diagnostics, Inc. (Diagnostics) entered into a License, Development and Cooperation Agreement (the Agreement), pursuant to which the Company acquired exclusive worldwide diagnostic rights to the PCA3 gene (the PCA3 Patent Rights) and agreed to develop in collaboration with Diagnostics, and the Company agreed to market, a test to detect the PCA3 marker for prostate cancer. On April 29, 2009, the Company and Diagnostics entered into an amendment to the Agreement (the Amendment).

Pursuant to the Amendment, the Company has agreed to use its commercially reasonable efforts to obtain U.S. Food and Drug Administration (FDA) approval of (a) the Company's current end-point Transcription-Mediated Amplification (TMA) assay for PCA3 and prostate specific antigen, and (b) a future real-time TMA PCA3 assay which will run on the Company's development-stage Panther instrument system. The Company has also agreed to file an application with the FDA for regulatory approval of a TMA PCA3 assay in the United States by a specified date.

In addition, the Company has agreed to make an annual payment to Diagnostics of US\$500,000 (the Annual Payment) until the earlier of: (i) the date which is two years after the Company's filing of an application with the FDA for approval of a TMA PCA3 assay in the United States; (ii) FDA approval of a PCA3 assay in the United States; or (iii) the date on which Diagnostics obtains co-exclusive rights in the United States to the PCA3 Patent Rights pursuant to the terms of the Amendment as described below. Half of the Annual Payment may be applied by the Company against future royalties due and payable to Diagnostics under the Agreement.

Pursuant to the terms of the Amendment, the Company's exclusive license in the United States to the PCA3 Patent Rights under the Agreement will be converted into a co-exclusive license (with Diagnostics) in the United States under certain conditions, including the Company's failure to timely file an application with the FDA for regulatory approval of a TMA PCA3 assay in the United States. If Diagnostics were to obtain a co-exclusive license in the United States to the PCA3 Patent Rights pursuant to the terms of the Amendment, Diagnostics would not have the right to grant a sublicense to any third party or serve as a foundry for any third party, nor would Diagnostics have the right to assign its co-exclusive license without the prior written consent of the Company, subject to certain conditions.

The Company has also agreed to pay US\$5 million to purchase 4.9 million shares of newly issued Diagnostics preferred stock, which shall be convertible, in whole or in part at the Company's election, into Diagnostics common stock on a one-to-one basis. The preferred stock will have a liquidation preference upon the occurrence of certain events, which will be secured by certain intellectual property collateral. Diagnostics will have the right to convert the preferred stock into common stock under certain circumstances and may redeem the preferred stock at any time prior to conversion at a specified price.

The foregoing summary is qualified in its entirety by reference to the terms of the Amendment, which will be filed by the Company as an exhibit to its Quarterly Report on Form 10-Q for the period ending June 30, 2009. The Company intends to submit a Confidential Treatment Request to the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended, requesting that it be permitted to redact certain portions of the Amendment.

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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 5, 2009

GEN-PROBE INCORPORATED

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