NEOPROBE CORP
Form 8-K
October 06, 2010

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) October 6, 2010

NEOPROBE CORPORATION
(Exact name of registrant as specified in its charter)

Delaware	0-26520	31-1080091
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

425 Metro Place North, Suite 300, Columbus, Ohio	43017
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code	(614) 793-7500

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing 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))

Item 8.01. Other Events.

On October 6, 2010, Neoprobe Corporation (the "Company") issued a press release announcing that it had completed a pre-NDA assessment for Lymphoseek® with the U.S. Food and Drug Administration (the "FDA"). As a result of the pre-NDA assessment, the FDA has requested that data from both the completed NEO3-05 study and the NEO3-09 study currently in progress be included in the Company's primary New Drug Application (NDA) for Lymphoseek rather than submitting the NEO3-09 study data as a major amendment to the ongoing NDA review. The previous plan to submit the NEO3-09 study data as a major amendment to the ongoing NDA review for Lymphoseek was the outcome of the successful March 2, 2010 meeting with the FDA. The pre-NDA meeting held earlier this week with the FDA was intended to review that plan for NDA submission with the safety and efficacy data from the NEO3-05 study and a pre-planned major amendment to submit the NEO3-09 study safety data as part of the ongoing NDA review.

NEO3-09 was originally intended as a supplement to the primary NDA for Lymphoseek for safety evaluation purposes and to support expanded product labeling claims. The pre-NDA assessment resulted in no modification to the NEO3-09 trial design or endpoints or to any of the other previously agreed-to clinical or regulatory components of the Lymphoseek NDA. As such, NEO3-09 will now be one of two adequate and well-controlled trials included in the primary NDA submission for first-cycle review. NEO3-09 is currently enrolling patients at eight study sites across the U.S. Neoprobe expects this study to be completed in the first quarter of 2011 and to submit the primary NDA for Lymphoseek soon thereafter. A copy of the complete text of the Company's October 6, 2010, press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Statements contained or incorporated by reference in this Current Report on Form 8-K which relate to other than strictly historical facts, such as statements about the Company's plans and strategies, expectations for future financial performance, new and existing products and technologies, anticipated clinical and regulatory pathways and markets for the Company's products, are forward-looking statements. The words "believe," "expect," "anticipate," "estimate," "project and similar expressions identify forward-looking statements that speak only as of the date hereof. Investors are cautioned that such statements involve risks and uncertainties that could cause actual results to differ materially from historical or anticipated results due to many factors including, but not limited to, the Company's continuing operating losses, uncertainty of market acceptance of its products, reliance on third party manufacturers, accumulated deficit, future capital needs, uncertainty of capital funding, dependence on limited product line and distribution channels, competition, limited marketing and manufacturing experience, risks of development of new products, regulatory risks and other risks detailed in the Company's most recent Annual Report on Form 10-K and other Securities and Exchange Commission filings. The Company undertakes no obligation to publicly update or revise any forward-looking statements.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Exhibit Description
99.1	Neoprobe Corporation press release dated October 6, 2010, entitled "Neoprobe Completes Lymphoseek Pre-NDA Meeting."

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.

Neoprobe Corporation

Date: October 6, 2010

By: /s/ Brent L. Larson
Brent L. Larson, Vice President, Finance and Chief Financial Officer