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NEOPROBE CORP
Form 8-K
February 28, 2005

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) February 24, 2005

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):

- ☐ 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 2.02. Results of Operations and Financial Condition.

On February 24, 2005, Neoprobe Corporation (the "Company") issued a press release regarding its consolidated financial results for the fourth quarter and for the full year ended December 31, 2004. A copy of the Company's press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

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The information contained in Item 2.02 of this Current Report on Form 8-K, including the exhibit 99.1 hereto, shall not be treated as "filed" for purposes of the Securities Exchange Act of 1934, as amended.

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, 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, 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, and other risks detailed in the Company's most recent Annual Report on Form 10-KSB and other Securities and Exchange Commission filings. The Company undertakes no obligation to publicly update or revise any forward-looking statements.

Item 8.01. Other Events.

On February 24, 2005, the Company issued a press release announcing that the U.S. Food and Drug Administration (FDA) has accepted its request to establish a corporate Investigational New Drug (IND) application for Lymphoseek(TM). A copy of the Company's press release is furnished as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference. With the establishment of the corporate IND, responsibility for the clinical and commercial development of Lymphoseek has been officially transferred from the University of California, San Diego (UCSD) to Neoprobe. Lymphoseek is intended to be used in biopsy procedures for the detection of lymph nodes in a variety of tumor types including breast, melanoma, prostate, gastric and colon cancers.

In connection with the transfer of responsibility for the Lymphoseek IND from UCSD to Neoprobe, FDA has provided guidance suggesting Lymphoseek be evaluated in a multi-center clinical study to confirm the findings observed by the UCSD researchers. This initial multi-center trial would then be followed by a confirmatory Phase III study using the final cGMP material. Neoprobe intends to commence enrollment in the first of the two multi-institutional studies as soon as the appropriate regulatory and institutional review board clearances are received. These multi-center studies are planned to be conducted at some of the leading cancer treatment institutions in the world. FDA guidelines also require Neoprobe to complete some additional preclinical activities prior to the initiation of the multi-center trials. Neoprobe has initiated this preclinical work in parallel to its other development activities and intends to submit an IND amendment prior to the initiation of the multi-center studies.

Item 9.01 Financial Statements and Exhibits.

(c) Exhibits.

Exhibit Number	Exhibit Description
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99.1	Neoprobe Corporation press release dated February 24, 2005, entitled "Neoprobe Announces 2004 Annual Results."
99.2	Neoprobe Corporation press release dated February 24, 2005, entitled "Neoprobe Establishes Corporate IND for Lymphoseek."

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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: February 28, 2005

By: /s/ Brent L. Larson

Brent L. Larson, Vice President Finance
and Chief Financial Officer