

NEOPROBE CORP
Form 8-K
November 03, 2008

**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 31, 2008

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))
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Item 8.01. Other Events.

On October 31, 2008, Neoprobe Corporation (the Company) issued a press release announcing that the centralized European Medicines Agency (EMEA) has provided positive formal responses to the Company's scientific advice submission regarding RIGScan CR and the pathway to receive a marketing authorization for the drug. The Company asked the EMEA to review its manufacturing and clinical development plan for RIGScan CR. The EMEA concurred that the Company could use updated and improved manufacturing processes to produce the antibody that is used in RIGScan CR and would be able to use all previously produced drug safety data derived from prior clinical studies to support a marketing authorization. The EMEA reviewed and agreed to the design and adequacy of a Phase 3 clinical study to be conducted in 380 patients with diagnosed primary or metastatic/recurrent colorectal cancer. The Phase 3 study would be a randomized trial with equal control and RIGScan CR treatment cohorts. The primary endpoint of the study would be improved survival for the RIGScan CR treated patients as compared to the control arm. Improved survival for the RIGScan CR treated patients was demonstrated in a retrospective survival analysis of patients in a prior RIGScan CR clinical study (NEO2-14) that was accepted by the EMEA. In addition, the EMEA agreed to the clinical need for a product like RIGScan CR to improve the treatment of patients with colorectal cancer. Finally, the EMEA provided Neoprobe the opportunity to request a conditional marketing authorization (CMA) after completion of the initial antibody production or prospective clinical activities. The opportunity for granting a CMA will be dependent upon the review of the supportive manufacturing and/or clinical information and there can be no assurance that a CMA request would receive a favorable response. A copy of the complete text of the Company's October 31, 2008, 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, 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 31 2008, entitled Neoprobe Receives Positive Response to European RIGS Submission.
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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: November 3, 2008

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