NEOPROBE CORP
Form 8-K
September 09, 2011

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) September 7, 2011

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 September 7, 2011, Neoprobe Corporation (the "Company") issued a press release announcing that that it has received positive scientific advice late last week from the European Medicines Agency (EMA) on the development of RIGScanTM CR, the Company's proprietary radiopharmaceutical for the detection of colorectal cancer. In the EMA meeting, the Company sought scientific guidance on the chemistry, manufacturing and controls (CMC) related to RIGScan and on non-clinical requirements needed to resume clinical development. EMA provided positive feedback on these development activities and on the Company's plan for manufacturing and non-clinical testing. EMA confirmed the opportunity for the Company to consider evaluating a humanized RIGScan antibody for clinical development and commercialization.

The meeting with the EMA follows a successful pre-investigational new drug (IND) meeting with the United States Food and Drug Administration (FDA) earlier this year. Potential use of a humanized antibody form instead of a mouse-based antibody is an important, positive development enabling utility of an improved technology, state-of-the art manufacturing processes and a more clinically acceptable drug. The potential shift to a humanized structure would better position the product for regulatory approval, partnering, commercialization and enhanced intellectual property protection opportunities.

The Company does not believe that the transition to a humanized antibody would delay the ongoing CMC process development activities underway since the FDA pre-IND meeting. Additionally, based on the discussion of clinical objectives for RIGScan with EMA, the Company does not envision that a change to the humanized antibody form will increase the anticipated overall number of patients required for registration. Detailed plans for clinical development must be presented to and discussed with both FDA and EMA to align, to the extent possible, the clinical studies required for approval.

A copy of the complete text of the Company's September 7, 2011, press release is attached 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 September 7, 2011, entitled “Neoprobe Receives Positive Scientific Advice From European Medicines Agency (EMA) For RIGScan CR.”

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: September 9, 2011	By:	/s/ Brent L. Larson Brent L. Larson, Senior Vice President and Chief Financial Officer