

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):

- 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 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 RIGScan™ 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.

<u>Exhibit Number</u>	<u>Exhibit Description</u>
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

IMMEDIATE RELEASE

September 7, 2011

NEOPROBE RECEIVES POSITIVE SCIENTIFIC ADVICE FROM EUROPEAN MEDICINES AGENCY (EMA) FOR RIGSCAN CR***– Guidance From EU and US Regulatory Agencies Clarifies Development Plan –***

DUBLIN, OHIO – September 7, 2011 – Neoprobe Corporation (NYSE Amex: NEOP), a diversified developer of innovative diagnostic products, today announced that it received positive scientific advice late last week from the European Medicines Agency (EMA) on the development of RIGScan™ CR, the Company's proprietary radiopharmaceutical for the detection of colorectal cancer.

In the EMA meeting, Neoprobe 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 Neoprobe's plan for manufacturing and non-clinical testing. Importantly, EMA confirmed the opportunity for Neoprobe to consider evaluating a humanized RIGScan antibody for clinical development and commercialization.

The meeting with the European regulatory body follows a successful pre-investigational new drug (IND) meeting with the 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.

"Following review of our development package, EMA provided important guidance on our RIGScan development plan which allows us to maintain our current activities in re-starting manufacturing of the RIGScan antibody," said Rodger Brown, Vice President, Regulatory Affairs and Quality Assurance of Neoprobe. "Positive guidance from both agencies enables us to begin harmonized efforts to reintroduce RIGScan back into the clinic. We are evaluating the overall implications on our clinical plans of the specific feedback received from these two agencies, but the guidance received to date from regulatory authorities is consistent with our objective of bringing the technology back into clinical development."

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.

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“Positive feedback from EMA and FDA is a critical step toward reactivating the RIGS[®] technology development effort after being out of the clinical setting for more than 14 years,” said Dr. Mark Pykett, Neoprobe President and Chief Executive Officer. “Re-initiating any program on the sidelines for an extended period requires clear, deliberate steps. The opportunity to move away from an antiquated mouse-based antibody to a state-of-the-art humanized form can potentially provide important return on our investment. We look forward to clarifying next steps in the coming months toward bringing our RIGS program back online and moving ahead with developing a novel agent aimed at improving diagnosis and treatment for colorectal cancer patients.”

About RIGScan[™] CR

Neoprobe’s RIGScan[™] CR is being developed as a diagnostic technology for the intra-operative detection of clinically occult or metastatic disease in patients with colon or rectal cancer. RIGScan is a targeting antibody consisting of a radiolabeled monoclonal antibody tagged with any of several potential radioisotopes to help detect cancer in patients having colorectal cancer. Previous clinical studies in patients with colorectal cancer demonstrated that RIGScan detected, at a significant rate, the presence of occult tumor that had been missed during surgery. In 2004, survival analyses of patients with colorectal cancer enrolled in the RIGScan clinical studies indicated that RIGScan status was potentially correlated with patient survival trends and that RIGScan may be predictive of, or possibly contribute to, a positive outcome when measuring survival of patients that participated in earlier studies. Based on these findings and the continued unmet medical need in identifying tumors in patients with colorectal cancer and potentially other cancers, Neoprobe has reinitiated development of RIGScan CR. Additional information about RIGScan CR can be found at www.neoprobe.com/RIGScan-CR.html.

About Neoprobe

Neoprobe Corporation (NYSE Amex: NEOP) is a biomedical company focused on development of precision diagnostics that enhance patient care and improve patient benefit. Neoprobe is actively developing and commercializing targeted agents aimed at the identification of occult (undetected) disease. The Company’s two lead radiopharmaceutical agent platforms – Lymphoseek[®] and RIGScan[™] – are intended to help surgeons better identify and treat certain types of cancer. In achieving its goals, our business model leverages collaborations and partnerships with world-class institutions, manufacturing concerns and distribution entities. Neoprobe’s strategy is to deliver superior growth and stockholder return by bringing to market novel radiopharmaceutical agents and advancing the Company’s pipeline programs through continued investment and selective acquisition or in-licensing of complementary technologies. For more information, please visit www.neoprobe.com.

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The Private Securities Litigation Reform Act of 1995 (the Act) provides a safe harbor for forward-looking statements made by or on behalf of the Company. Statements in this news release, 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 within the meaning of the Act. 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.

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