

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  
(State or other jurisdiction of incorporation)

0-26520  
(Commission File Number)

31-1080091  
(IRS Employer Identification No.)

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

43017  
(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 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.

<i>Exhibit Number</i>	<i>Exhibit Description</i>
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



**IMMEDIATE RELEASE**

**October 6, 2010**

**CONTACTS:**

**Brent Larson**  
Sr. VP & CFO  
(614) 822-2330

**Gene Marbach**  
Makovsky + Company  
(212) 508-9645

---

**NEOPROBE COMPLETES LYMPHOSEEK PRE-NDA MEETING**

**– FDA Requests Inclusion of NEO3-09 Data to Comply with Recently Established Agency Guidelines –**

**– Investor Conference Call Scheduled for October 7<sup>th</sup> at 9:00 AM ET –**

DUBLIN, OHIO – October 6, 2010 – Neoprobe Corporation (OTCBB: NEOP), a diversified developer of innovative oncology surgical and diagnostic products, today announced that it has completed a pre-NDA assessment for Lymphoseek<sup>®</sup> with the U.S. Food and Drug Administration (FDA). As a result of the pre-NDA assessment, 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 FDA. The pre-NDA meeting held earlier this week with 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.

David Bupp, Neoprobe's President and CEO, said, "Neoprobe has agreed to FDA's request to include safety and efficacy data for Lymphoseek from both clinical trials to ensure that the Agency has the requested information to conduct a complete first-cycle review of the NDA for Lymphoseek. We believe the earlier than originally planned inclusion of the NEO3-09 study data will support stronger product labeling as an outcome of a first-cycle review of the Lymphoseek NDA and may also positively impact market adoption. The clinical and regulatory team at Neoprobe is working diligently on this process and looks forward to a complete and expeditious review of Lymphoseek."

Dr. George Mills, consultant to the Company and former FDA Division Director of Medical Imaging and Hematology Products, said, "The request for the total data package from two clinical trials is consistent with FDA's ongoing initiative to push for more complete primary submissions and to limit major amendments made to NDAs. This ongoing initiative to shorten drug review cycle times was re-emphasized by FDA's Office of New Drug Development in late 2009 and enables more successful first-cycle reviews which ultimately shortens overall drug approval timelines. The request for the inclusion of both clinical trials in the primary NDA review should be viewed as a positive indicator for Lymphoseek's approval prospects in the first-cycle review by the Agency."

---

Neoprobe will hold a conference call Thursday, October 7<sup>th</sup> at 9:00 AM ET to review the FDA request and provide an update following the pre-NDA meeting. Mr. Bupp will be joined on the conference call by Dr. Frederick Cope, Senior Vice President, Pharmaceutical Research and Clinical Development. The conference call can be accessed as follows:

#### Conference Call Information

##### TO PARTICIPATE LIVE:

Date: October 7, 2010  
Time: 9:00 AM ET  
  
Toll-free (U.S.) Dial in #: (877) 407-8033  
International Dial in #: (201) 689-8033

##### TO LISTEN TO A REPLAY:

Available until: October 21, 2010  
Toll-free (U.S.) Dial in #: (877) 660-6853  
International Dial in #: (201) 612-7415  
  
Replay passcode:  
Account #: 286  
Conference ID #: 358364

#### About Neoprobe

Neoprobe is a biomedical company focused on enhancing patient care and improving patient outcome by meeting the critical intraoperative diagnostic information needs of physicians and therapeutic treatment needs of patients. Neoprobe currently markets the neoprobe<sup>®</sup> GDS line of gamma detection systems that are widely used by cancer surgeons. In addition, Neoprobe holds significant interests in the development of related biomedical systems and radiopharmaceutical agents including Lymphoseek<sup>®</sup> and RIGScan<sup>™</sup> CR. Neoprobe's subsidiary, Cira Biosciences, Inc., is also advancing a patient-specific cellular therapy technology platform called ACT. Neoprobe's strategy is to deliver superior growth and shareholder return by maximizing its strong position in gamma detection technologies and diversifying into new, synergistic biomedical markets through continued investment and selective acquisitions. [www.neoprobe.com](http://www.neoprobe.com)

*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. 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.*

---